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"Unnatural Deaths," Criminal Sanctions, and Medical Quality Improvement in Japan

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INTRODUCTION

A worldwide awakening to the high incidence of preventable harm resulting from medical care,[1] combined with pressure on hospitals and physicians from liability litigation, has turned international attention to the need for better structures to resolve medical disputes in a way that promotes medical safety and honesty toward patients. The civil justice system in the United States, in particular, is criticized as inefficient, arbitrary, and sometimes punitive. It is charged with undermining sound medical care by encouraging wasteful expenditures through defensive medicine; by driving information about medical mistakes underground where it escapes analysis, undercutting quality improvement efforts; and by forcing physicians in liability-prone specialties such as obstetrics out of practice.[2] Similar charges are leveled against medical injury compensation systems in the United Kingdom, Australia, and elsewhere.[3] While these criticisms have been strongly countered,[4] they have gained a foothold in the

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1. *See, e.g.*, INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 1999) [hereinafter TO ERR IS HUMAN]; PETER DAVIS ET AL., ADVERSE EVENTS IN NEW ZEALAND PUBLIC HOSPITALS: PRINCIPAL FINDINGS FROM A NATIONAL SURVEY (2001), *available at* http://www.moh.govt.nz/publications/adverseevents; WORLD HEALTH ORG., WORLD ALLIANCE FOR PATIENT SAFETY, PROGRESS REPORT 2006-2007 (2008), *available at* http://www.who.int/patientsafety/information_centre/documents/progress_report_2006_2007.pdf; G. Ross Baker et al., *The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada*, 170 CAN. MED. ASS'N J. 1678 (2004); F.D. Dastur, Editorial, *Quality and Safety in Indian Hospitals*, 56 J. ASS'N PHYSICIANS INDIA 85 (2008), *available at* http://www.japi.org/february2008/E-85.htm; T. Schioler et al., *Incidence of Adverse Events in Hospitals: A Retrospective Study of Medical Records*, 163 UGESKR FOR LAEGER 5370 (2001) (Den.); Charles Vincent, G. Neale & M. Woloshynowych, *Adverse Events in British Hospitals: Preliminary Retrospective Record Review*, 322 BRIT. MED. J. 517 (2001); R.M. Wilson et al., *The Quality in Australian Health Care Study*, 163 MED. J. AUSTL. 458 (1995).

2. *See, e.g.*, U.S. DEP'T OF HEALTH & HUMAN SERVS., ADDRESSING THE NEW HEALTH CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM TO IMPROVE THE QUALITY OF HEALTH CARE (2003), *available at* http://aspe.hhs.gov/daltcp/reports/medliab.pdf; Press Release, The White House, President Discusses Medical Liability Reform (Jan. 5, 2005), *available at* http://www.whitehouse.gov/news/releases/2005/01/20050105-4.html.

3. *See, e.g.*, COMMONWEALTH OF AUSTL., REVIEW OF THE LAW OF NEGLIGENCE FINAL REPORT (2002) (the "Ipp Report"), *available at* http://revofneg.treasury.gov.au/content/Report2/PDF/Law_Neg _Final.pdf; FRANK FUREDI, COURTING MISTRUST: THE HIDDEN GROWTH OF A CULTURE OF LITIGATION IN BRITAIN (1999).

4. *See, e.g.*, TOM BAKER, THE MEDICAL MALPRACTICE MYTH (2005); George J. Annas, *The Patient's Right to Safety – Improving the Quality of Care Through Litigation Against Hospitals*, 354 NEW ENG. J. MED. 2063 (2006); David A. Hyman & Charles Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 CORNELL L. REV. 893 (2005).

public imagination[5] sufficient to place structural reform of medical litigation on the American political agenda.[6]

One enlightened response to mounting concerns over medical error and liability has been a partial shift in focus, in the United States and other Western nations, from the blameworthiness of individual physicians to the correction of system-related deficiencies in the quality of care,[7] and from confrontational litigation between patients and health care providers to a more integrative approach emphasizing disclosure to patients and families of the underlying facts[8] and apology for harm done.[9] Drawing in considerable measure on Wagatsuma

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5. *See, e.g.*, WILLIAM HALTON & MICHAEL MCCANN, DISTORTING THE LAW: POLITICS, MEDIA, AND THE LITIGATION CRISIS (2004) (explaining the success of "tort reform" advocates in swaying public opinion); Anthony J. Sebok, *Dispatches from the Tort Wars*, 85 TEX. L. REV. 1465 (2007) (reviewing HALTON & MCCANN, *supra*; BAKER, *supra* note 4; and HERBERT M. KRITZER, RISKS, REPUTATIONS, AND REWARDS: CONTINGENCY FEE LEGAL PRACTICE IN THE UNITED STATES (2004)).

6. Barack Obama and Hillary Clinton jointly proposed a bill in 2005 to explore modifications in the existing medical malpractice litigation system. National Medical Error Disclosure and Compensation Act, S. 1784, 109th Cong. (2005) (discussed in Hillary Rodham Clinton & Barack Obama, *Making Patient Safety the Centerpiece of Medical Liability Reform*, 354 NEW ENG. J. MED. 2205 (2006)). Support for reform is found on both sides of the aisle. *See, e.g.*, Fair and Reliable Medical Justice Act, S. 1337, 109th Cong. (2005) (sponsored by Senators Enzi & Baucus). In 2005, Congress enacted the Patient Safety and Quality Improvement Act of 2005 as a step aimed at fostering hospitals' self-critical analysis by standardizing, to an extent, confidentiality protections for error reports. Pub. L. No. 109-41, 119 Stat. 424 (2005) (codified at 42 U.S.C. § 299b-24 (Supp. 2005)).

7. *E.g.*, TO ERR IS HUMAN, *supra* note 1; AUSTL. COMM'N ON SAFETY & QUALITY IN HEALTH CARE, SUBMISSION TO THE NATIONAL HEALTH AND HOSPITALS REFORM COMMISSION: INCLUDING A SAFETY AND QUALITY FRAMEWORK FOR THE FUTURE (2008), *available at* http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/1C0D0866C0742129CA2574FE00009310/$File/NHHRC-Submission.pdf; DEP'T OF HEALTH, AN ORGANISATION WITH A MEMORY (2000) (U.K.), *available at* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065083; NAT'L STEERING COMM. ON PATIENT SAFETY, BUILDING A BETTER SYSTEM: A NATIONAL INTEGRATED STRATEGY FOR IMPROVING PATIENT SAFETY IN CANADIAN HEALTH CARE (2002), *available at* http://www.rcpsc.medical.org/publications/ building_a_safer_system_e.pdf.

8. *See, e.g.*, Thomas H. Gallagher, David Studdert & Wendy Levinson, *Disclosing Harmful Medical Errors to Patients*, 356 NEW ENG. J. MED. 2713 (2007); Thomas H. Gallagher & Wendy Levinson, *Disclosing Harmful Medical Errors to Patients: A Time for Professional Action*, 165 ARCHIVES INTERNAL MED. 1819 (2005); Thomas H. Gallagher et al., *Disclosing Unanticipated Outcomes to Patients: The Art and Practice*, 3 J. PATIENT SAFETY 158 (2007); Rae M. Lamb et al., *Hospital Disclosure Practices: Results of a National Survey*, 22 HEALTH AFF. 73 (2003); Kathleen M. Mazor et al., *Communicating with Patients About Medical Errors*, 164 ARCHIVES INTERNAL MED. 1690 (2004).

9. *See, e.g.*, Jonathan R. Cohen, *Advising Clients to Apologize*, 72 S. CAL. L. REV. 1009 (1999); Douglas N. Frenkel & Carol B. Liebman, *Words That Heal*, 140 ANNALS INTERNAL MED.

and Rosett's pioneering 1986 article explaining the importance of apology (in non-medical settings) in Japan,[10] the scholarship in this area portrays honest disclosure as more than an ethical and professional duty, and sincere apology as more than a way of fulfilling the emotional needs of patients, families, and medical personnel. These scholars, and the "Sorry Works!" movement that their writing has spurred,[11] also assert that contrary to long-standing assumptions of liability insurers and hospital defense lawyers, disclosure and apology have in fact the practical benefit of diffusing some of the dissatisfaction that leads to compensation claims, thereby potentially shrinking liability burdens.[12] While its likely effects on lawsuit filings are contested,[13] the disclosure-and-apology philosophy is gaining considerable traction in medical practice.[14]

Compared with the United States, Japan (like most countries) enjoys a comparatively low rate of civil litigation over medical injury.[15] What accounts

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482 (2004); Jennifer K. Robbennolt, *Apologies and Legal Settlement: An Empirical Examination*, 102 MICH. L. REV. 460 (2003).

10. Hiroshi Wagatsuma & Arthur Rosett, *The Implications of Apology: Law and Culture in Japan and the United States*, 20 LAW & SOC'Y REV. 461 (1986); *see also* Cohen, *supra* note 9 (drawing on Wagatsuma & Rosett); Robbennolt, *supra* note 9 (same); John O. Haley, Comment, *The Implications of Apology*, 20 LAW & SOC'Y REV. 499, 504-05 (1986) (noting evidence of the impact of apology on preventing U.S. medical malpractice litigation).

11. *See, e.g.*, Doug Wojcieszak, John Banja & Carole Houk, *The Sorry Works! Coalition: Making the Case for Full Disclosure*, 32 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 344 (2006), *available at* http://www.jointcommission.org/NR/rdonlyres/5E597FEF-6F86-480D-A1E2-CDD6CB491D3E/0/Sorry_Works.pdf; Sorry Works! Coalition, http://www.sorryworks.net (last visited Dec. 3, 2008) (describing coalition philosophy and activities).

12. *See, e.g.*, Steve S. Kraman & Ginny Hamm, *Risk Management: Extreme Honesty May Be the Best Policy*, 131 ANNALS INTERNAL MED. 963 (1999) (Lexington, Ky. Veterans Administration Hospital study); R.M. Stewart et al., *Transparent and Open Discussion of Errors Does Not Increase Malpractice Risk in Trauma Patients*, 243 ANNALS SURGERY 645 (2006); *see also* Clinton & Obama, *supra* note 6, at 2207 (describing the University of Michigan Health System program and its results).

13. *See* David M. Studdert et al., *Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 HEALTH AFF. 215 (2007) (suggesting that the likely effect of more widespread candor will be that more claims are brought by alerted patients than will be foregone by mollified ones).

14. *See, e.g.*, Gallagher, Studdert & Levinson, *supra* note 8.

15. *See* Robert B Leflar & Futoshi Iwata, *Medical Error as Reportable Event, as Tort, as Crime: A Transpacific Comparison*, 12 WIDENER L. REV. 189 (2005). We employed claims data to suggest that "an American in 1997 was as much as 40 to 50 times as likely (as an upper-bound estimate) to have filed a medical malpractice claim than was a Japanese." *Id.* at 199. We also noted, however, that the large quantity of claims paid by Japanese hospitals and liability insurers but not reflected in publicly available claims statistics has the effect of inflating that ratio considerably. *Id.* at 198-200 & n.35.

for this relative paucity of medical lawsuits? The stereotype of a nation populated by long-suffering victims with a cultural aversion to the assertion of rights has long been punctured.[16] Are there simply fewer medical injuries in Japan, due to the prevalence in hospitals of the strict quality control for which the nation's manufacturing enterprises are justly famed? When injury claims do arise, are they quickly resolved through non-punitive, harmony-promoting informal dispute resolution processes employing the traditional social lubricant of apology, as the scholarship drawing on the Wagatsuma-Rosett thesis[17] would presume?

Not exactly.

After a twelve-year-old girl died during heart surgery at Tokyo Women's Medical University Hospital in 2001 due to improper functioning of a heart-lung machine, police arrested two physicians, one for professional negligence causing death and the other for falsification of the patient's medical records. (The first was acquitted, the second convicted.[18]) More than a dozen families whose children had died or suffered serious injury at that hospital, renowned for its pediatric cardiac surgery program, formed a "victims' alliance" seeking compensation, reform of hospital safety practices, and apology for errors committed and facts concealed. After lengthy negotiations, most of the families received out-of-court settlements accompanied by expressions of regret from the hospital, but no public acknowledgement of, or apologies for, negligence or chart-doctoring.[19]

The CEO of Tokyo's well-known Hirō Hospital was arrested, along with two nurses, after a patient's death from an accidental injection of toxic disinfectant in 1999. The nurses were convicted of professional negligence causing death, and the hospital CEO of falsifying the death certificate and failing to report the case to police in a timely fashion.[20] The Supreme Court of Japan

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16. *See, e.g.*, John Haley, *The Myth of the Reluctant Litigant*, 4 J. JAPANESE STUD. 359 (1978); ERIC A. FELDMAN, THE RITUAL OF RIGHTS IN JAPAN: LAW, SOCIETY, AND HEALTH POLICY (2000); FRANK K. UPHAM, LAW AND SOCIAL CHANGE IN POSTWAR JAPAN (1987); J. Mark Ramseyer & Minoru Nakazato, *The Rational Litigant: Settlement Amounts and Verdict Rates in Japan*, 18 J. LEGAL STUD. 263 (1989).

17. *See* sources cited *supra* note 10.

18. Yasushi Tsukamoto, *Criminal Prosecution Arising from Medical Mishaps: A Japanese Perspective*, 24 MED. & L. 673, 677 (2005); *Doctor Acquitted in Girl's Death*, INT'L HERALD TRIB./ASAHI SHIMBUN, Dec. 1, 2005, at 28.

19. The case is the subject of a prize-winning book by a journalist who covered the story. NOBUAKI SUZUKI, AKIKA-CHAN NO SHINZŌ (KENSHŌ): TOKYO JOSHI IDAI BYŌIN JIKEN [AKIKA'S HEART: EXAMINING THE TOKYO WOMEN'S MEDICAL UNIVERSITY HOSPITAL CASE] (2007) (recipient of Kōdansha nonfiction award). The book recounts that the hospital's internal structure and safety practices were indeed improved in the aftermath of the highly publicized deaths and injuries.

20. 1771 HANREI JIHŌ 156 (Tokyo D. Ct., Aug. 30, 2001). The attending physician was also convicted of failing to notify police of the patient's death. For a summary of the case, see

affirmed the CEO's conviction.[21] The favorable ruling on the family's civil claim that the hospital's explanation to them about the patient's death was inadequate was upheld in the Tokyo High Court.[22]

Police marched an obstetrician in handcuffs out of Ohno Hospital in Fukushima Prefecture in 2006 upon belatedly learning of the 2004 death of one of his patients following a difficult Cesarean section delivery.[23] The arrest and prosecution sparked a nationwide outcry by medical organizations against heavy-handed intervention by the criminal justice system in the practice of medicine,[24] an outcry that has not abated with the obstetrician's recent acquittal.[25]

Preventable medical injury is widespread in Japan just as it is in other developed nations.[26] The problem of fixing accountability for medical harm in a way that promotes patient safety is front and center in Japan as well. Civil litigation over medical injury has grown in Japan at a pace outstripping the increases in other types of civil actions,[27] although its frequency is still dwarfed

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Tsukamoto, *supra* note 18, at 674-75; and *infra* notes 103-106 and accompanying text.

21. 58(4) KEISHŪ 247 (Sup. Ct., Apr. 13, 2004). The case is further discussed *infra* notes 103-106 and accompanying text.

22. 1880 HANREI JIHŌ 72 (Tokyo High Ct., Sept. 30, 2004).

23. *Obstetrician Held over Malpractice*, INT'L HERALD TRIB./ASAHI SHIMBUN, Feb. 20, 2006, at 22; Editorial, *Medical Blunders*, INT'L HERALD TRIB./ASAHI SHIMBUN, May 15, 2006, at 31 (commenting on Ohno Hospital case and others).

24. *See infra* notes 54-58 and accompanying text.

25. 16 IRYŌ HANREI KAISETSU 20 (Fukushima D. Ct., Aug. 20, 2008); *see also* Yusuke Takatsu, *Doctor Acquitted in Death After Childbirth*, INT'L HERALD TRIB./ASAHI SHIMBUN, Aug. 21, 2008, at 23; *Doctor Acquitted over Cesarean Section Death*, DAILY YOMIURI, Aug. 21, 2008, at 1; *Medical World Circles Wagons*, DAILY YOMIURI, Aug. 21, 2008, at 2.

26. A health ministry-sponsored review of 4389 randomly selected patient records at eighteen top hospitals that volunteered to participate found an adverse event rate of 6%. Of those adverse events, 23% were considered to have been probably preventable. HIDETO SAKAI, IRYŌ JIKO NO ZENKOKUTEKI HASSEI HINDO NI KAN-SURU KENKYŪ [REPORT ON THE NATIONWIDE INCIDENCE OF MEDICAL ACCIDENTS: III] 18 (2006); *see also* Shunya Ikeda, *Iryō jiko hassei hindo chōsa kara erareta wagakuni no kanja anzen no genkyō to kadai* [*Patient Safety Issues Raised by the Study of Medical Accident Incidence*], 14 KANJA ANZEN SUISHIN JĀNARU 56 (2006) (summarizing key study results). This 6% adverse event rate is not incommensurate with reports from other advanced nations, although differences in methodology make direct comparisons suspect. Cross-national data are summarized in CHARLES VINCENT, PATIENT SAFETY 42 (2006), in a chart of studies from seven countries showing adverse event rates ranging from 3-5% at the low end (United States) to almost 17% at the high end (Australia).

27. *See* TATSUO KUROYANAGI, IRYŌ JIKO TO SHIHŌ HANDAN [MEDICAL ACCIDENTS AND JUDICIAL DECISIONS] 3 tbl.1 (2002) (showing a 129% increase in medical malpractice case filings from 1990 to 2001 as compared to a 46% increase over the same period for civil cases generally). According to the Supreme Court Administrative Office, the number of medical malpractice cases filed in court grew from 234 in 1976 to 1110 in 2004, though filings have diminished since then to

by that of medical malpractice litigation in the United States, and medical liability insurance premiums in Japan are still comparatively low.[28] But the character of the Japanese debate over accountability for iatrogenic injury—harm causally related to medical care—is unique. Civil liability trends, though widely remarked upon, are not central. Rather, the debate hinges around the less frequent but intensely publicized use of the *criminal* law as a regulator of medical practice. Police investigate and prosecutors sometimes charge doctors for professional negligence and concealment of adverse events, particularly in spotlighted cases of grave harm where doctors and hospitals offered patients and families neither honest explanations nor timely, sincere apologies.

Japanese society has been opening up to principles of transparency in many areas, even in the realm of medicine with its customary secrecy.[29] But a succession of cover-ups at prestigious hospitals, exposed by repeated prosecutions accompanied by front-page reportage, has contradicted crystallizing public expectations of candor and has fueled public skepticism about the medical profession's once-unquestioned benevolence and competence, even at its top ranks.[30] The profession itself, while alarmed at and resentful of what it views as excessive police intrusion into medicine's domain, has recognized the need for greater openness.[31]

Responding to an initiative from academic medical societies, Japan's Ministry of Health, Labor, and Welfare embarked in 2005 on an innovative

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944 in 2007. Supreme Court of Japan, Iji kankei soshō jiken no shori jōkyō oyobi heikin shinri kikan [Disposition of Medically Related Litigation and Mean Duration of Proceedings 1998-2007], http://www.courts.go.jp/saikosai/about/iinkai/izikankei/toukei_01.html (last visited Dec. 4, 2008). For pre-1998 figures, see YUTAKA TEJIMA, IJIHŌ NYŪMON [A PRIMER OF MEDICAL LAW] 137 (2005).

28. The premium paid by a physician member of the Japan Medical Association liability insurance program in 2003 was ¥70,000 (US $640). General hospitals insured by Yasuda Fire & Marine Co. paid ¥16,130 (US $150) per bed in 2000. *See* Leflar & Iwata, *supra* note 15, at 201, 203; Kazue Nakajima et al., *Medical Malpractice and Legal Resolution Systems in Japan*, 285 JAMA 1632, 1633 tbl.1 (2001). A well-informed source close to the liability insurance industry who requested anonymity reported that, as of 2008, Yasuda's successor company, Sonpo Japan, charges hospitals about ¥30,000 (US $280) per bed. This is a significant percentage increase since 2000, but still far less than premiums paid by U.S. hospitals. Interview with anonymous source, in Tokyo, Japan (July 31, 2008).

29. *See, e.g.*, Robert B Leflar, *Informed Consent and Patients' Rights in Japan*, 33 HOUS. L. REV. 1, 62-63, 94-96 (1996).

30. *See* Leflar & Iwata, *supra* note 15, at 195-98.

31. *See, e.g.*, KOKURITSU DAIGAKU IGAKUBU FUZOKU BYŌINCHŌ KAIGI JŌCHI IINKAI [NAT'L UNIV. HOSP. PRESIDENTS' CONFERENCE], IRYŌ JIKO BŌSHI NO TAME NO ANZEN KANRI TAISEI NO KAKURITSU NI TSUITE – CHŪKAN HŌKOKU [INTERIM REPORT: ESTABLISHING SAFETY MANAGEMENT SYSTEMS FOR THE PREVENTION OF MEDICAL ACCIDENTS] (2000), *available at* http://www.umin.ac.jp/nuh_open /iryoujiko.pdf; *infra* notes 109-110 and accompanying text.

"Model Project," whereby independent experts in specified prefectures investigate possibly iatrogenic hospital deaths, report to the family, the hospital, and the public about the facts, and offer suggestions for preventing similar accidents in the future. The Model Project was conceived in the hopes that cases taken up by the project would rarely be the target of criminal prosecution and that the project would improve transparency within medicine, facilitate extrajudicial resolution of private damage claims, and spur systemwide quality improvement efforts. Beset by start-up difficulties and undermined by physicians' continuing unease about external peer review and potential police involvement, the Model Project has not met initial expectations for case uptake. Nevertheless, the health ministry has recently proposed legislation to build on the Model Project's process by creating a new structure that in essence would constitute a national system of peer review, thereby reforming the nation's procedures for handling the problem of medical error.[32]

Part I of this Article explains the significance in Japan, hitherto little noticed elsewhere,[33] of criminal law in regulating medical practice. The Article offers reasons of Japanese law and social structure for the role played by criminal law in medicine. Prominent among those reasons has been Japanese medicine's accountability vacuum: the weakness of other institutional mechanisms for medical quality control, such as peer review, hospital accreditation, specialty certification, licensure and discipline, death inquests, and civil liability litigation.

Part II recounts and analyzes the initial attempts of Japan's health ministry and medical establishment to address rising public concerns over medical error, against a background of inadequate information about the problem's nature and dimensions (Section II.A) and a problematic legal and institutional structure for remedying the informational deficit. In Section II.B, the Article explores the controversy over the legal requirement that police be notified of "unnatural deaths"—a requirement interpreted by the Supreme Court to apply not only to deaths from violent crime, natural disaster, and suicide, but also to deaths from potentially iatrogenic causes.[34] This duty of police notification of medically

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32. Ministry of Health, Labor & Welfare, Iryō anzen chōsa iinkai setchi hōan (kashō) taikōan [Draft of Proposed Act to Establish the Medical Safety Review Commission (tentative title)], http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/dl/080613_an.pdf (last visited Dec. 3, 2008) [hereinafter MHLW June 2008 Draft Proposal].

33. I am aware of only five publications focusing on this topic in English-language scholarly journals: Norio Higuchi, *Article 21 of the Medical Practitioners Law*, 51 JAPAN MED. ASS'N J. 258 (2008); Hiroshi Ikegaya et al., *Does Informed Consent Exempt Japanese Doctors from Reporting Therapeutic Deaths?*, 32 J. MED. ETHICS 114 (2006); Leflar & Iwata, *supra* note 15; Tsukamoto, *supra* note 18 (paper presented to the World Congress on Medical Law, Sydney, Australia in August 2004); and Ken-ichi Yoshida et al., *Death During Surgery in Japan*, 360 LANCET 805 (2002) (letter).

34. 58(4) KEISHŪ 247 (Sup. Ct., Apr. 13, 2004).

related deaths, against the background that "professional negligence causing death or injury" is an offense under the Criminal Code, has the theoretical (and sometimes practical) effect of turning hospitals into crime scenes and doctors and nurses into death inquiry suspects. This phenomenon has called forth a powerful protest from medical circles, a reaction bearing a resemblance to the medical "tort reform" movement in the United States. The controversy over police investigation of "unnatural deaths" in Japanese hospitals also compels an examination (Section II.C) of Japan's obscure and peculiar system for death inquiries, a system that has hindered systematic quality-improvement-oriented analysis of fatalities related to medical treatment.

Part III of the Article tells the story of the launching of the health ministry-funded Model Project, which is designed to strengthen the death inquest system and bring greater transparency to Japanese medicine. Section III.A explains the project's workings, and Section III.B evaluates its strengths and weaknesses. Section III.C then examines proposed legislation sponsored by the health ministry building on the Model Project to create a national peer review system, criticisms of that proposal from an insurgent antiregulatory movement within Japanese medicine, and an opposition party alternative. Finally, Section III.D considers whether recent Japanese developments might offer clues to the redesign of medical injury dispute resolution systems in the United States and other Western nations. The Article concludes that although institutional, legal, and cultural differences render one nation's initiatives problematic for others to follow, the Japanese proposals for impartial expert reviews of medical accidents could serve as a guidepost for design of new structures for compensation and prevention of medical injury.

I. THE SIGNIFICANCE OF CRIMINAL LAW IN JAPAN'S REGULATION OF MEDICAL PRACTICE

A. Criminal Prosecution for Unintentional Medical Acts

Criminal prosecutions for severe misjudgment in the conduct of medical care are not unknown in the Western world, although they are extremely rare in comparison with the number of civil malpractice actions. In the United States, one writer estimated the number of prosecutions for medical acts during 1981-2001 at just two to three dozen.[35] Across the Atlantic, the number of recent

35. James A. Filkins, *"With No Evil Intent": The Criminal Prosecution of Physicians for Medical Negligence*, 22 J. LEGAL MED. 467, 471-72 & nn.51 & 53 (2001) (describing nine appellate cases, and estimating from "15 or so" to "perhaps two dozen" more non-appellate cases during the twenty-year period of his research).

prosecutions of British physicians for gross negligence manslaughter[36] has been variously enumerated as twenty-three cases (1990-2003)[37] and thirty-eight cases (1990-2005).[38] Prosecutions of doctors sometimes occur in Canada,[39] New Zealand,[40] and France[41] as well. However, prosecutions for unintentional medical acts are seldom widely publicized,[42] and they are sufficiently uncommon that they do not constitute a source of significant apprehension for physicians in the Western nations. Nor does the application of criminal law much concern American scholarship on medical injury and patient safety: most leading works in the area do not treat the subject at all.[43]

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36. The leading British medical case recognizing criminal liability for involuntary manslaughter under a gross negligence standard is *R. v. Adomako*, [1995] 1 A.C. 171 (H.L. 1994) (appeal taken from Cent. Crim. Ct.).

37. Jon Holbrook, *The Criminalisation of Fatal Medical Mistakes*, 327 BRIT. MED. J. 1118, 1118 (2003).

38. R.E. Ferner & Sarah E. McDowell, *Doctors Charged with Manslaughter in the Course of Medical Practice, 1795-2005: A Literature Review*, 99 J. ROYAL SOC'Y MED. 309, 311 tbl.2 (2006). This review found that the number of prosecutions increased subsequent to the 1980s.

39. *See, e.g.*, R. v. Manjanatha, [1995] 131 Sask. R. 316 (upholding sentence of imprisonment). The case is described in ALAN MERRY & ALEXANDER MCCALL SMITH, ERRORS, MEDICINE AND THE LAW 24-25 (2001).

40. *See* P.D.G. Skegg, *Criminal Prosecutions of Negligent Health Professionals: The New Zealand Experience*, 6 MED. L. REV. 220, 225-34 (1998) (describing eight prosecutions for negligence of medical providers from 1982 to 1998, and commenting that compared to other Commonwealth jurisdictions, the number of such prosecutions was "remarkably large"). Professor Skegg reports, however, that since the Crimes Amendment Act 1997 raised the criterion for criminal liability from mere negligence to "*a major departure* from the standard of care expected of a reasonable person to whom [the] duty applies," *id.* at 244, only one health care practitioner (a midwife) has been prosecuted, and she was found not guilty. E-mail from Professor Peter Skegg, Univ. of Otago, to author (July 24, 2008) (on file with author); *see also* Kay Sinclair & Blair Mayston, *Cheers as Midwife Acquitted*, OTAGO DAILY TIMES, Mar. 22, 2006, at 1 (reporting on verdict).

41. *See* JOHN BELL, SOPHIE BOYRON & SIMON WHITTAKER, PRINCIPLES OF FRENCH LAW 233 (1998) ("[M]any negligence claims become criminal cases. Thus in 1990, there were 222 civil claims against doctors and 137 criminal prosecutions."); *see also id.* at 217 & n.56, 218-19 & nn.61 & 64, 226 & n.84 (examples of cases).

42. Extensive publicity has been given on both sides of the Atlantic to prosecutions of physicians for *intentional* killings of patients. The best-known examples are the prosecutions of Dr. Jack Kevorkian in the United States, *see* People v. Kevorkian, 527 N.W.2d 714 (Mich. 1994), and of Dr. Harold Shipman in the United Kingdom, *see* R. v. Sec'y of State for Health, (2001) 1 W.L.R. 292 (Q.B.). Similarly, in one highly publicized case a Japanese physician was convicted of euthanizing a dying patient. Japan v. Tokunaga, 1530 HANREI JIHŌ 28 (Yokohama D. Ct., Mar. 28, 1995), *translated in* TIMOTHY STOLTZFUS JOST, READINGS IN COMPARATIVE HEALTH LAW & BIOETHICS 332-40 (Robert B Leflar trans., 2d ed. 2007).

43. *See, e.g.*, TO ERR IS HUMAN, *supra* note 1; ACCOUNTABILITY: PATIENT SAFETY AND POLICY

In Japan, the number of criminal prosecutions of medical personnel is likewise small in comparison with the number of civil actions,[44] but these criminal investigations and trials receive intensive coverage in the media.[45] After an infamous mix-up in 1999 at Yokohama City Medical University Hospital, in which a heart patient had part of his lung tissue removed and a lung patient with a similar name underwent a heart valve procedure,[46] the pace of medical

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REFORM (Virginia A. Sharpe ed., 2004); BARRY FURROW ET AL., HEALTH LAW (2000); MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM (William M. Sage & Rogan Kersh eds., 2006); MICHAEL L. MILLENSON, DEMANDING MEDICAL EXCELLENCE: DOCTORS AND ACCOUNTABILITY IN THE INFORMATION AGE (1997); ROBERT M. WACHTER & KAVEH G. SHOJANIA, INTERNAL BLEEDING: THE TRUTH BEHIND AMERICA'S TERRIFYING EPIDEMIC OF MEDICAL MISTAKES (2004).

One leading American scholar has addressed the issue of criminal liability for unintentional medical injury as it affects patient safety efforts. *See* George J. Annas, *Medicine, Death, and the Criminal Law*, 333 NEW ENG. J. MED. 527 (1995). Among leading British scholars, Alan Merry and Alexander McCall Smith are two who gave the matter consideration early on. *See* MERRY & MCCALL SMITH, *supra* note 39; Alexander McCall Smith, *Criminal or Merely Human?: The Prosecution of Negligent Doctors*, 12 J. CONTEMP. HEALTH L. & POL'Y 131 (1995).

Criminal liability for medical mistakes was addressed by a scattering of other U.S. legal writers about a decade ago. *See, e.g.*, Filkins, *supra* note 35; Paul R. Van Grunsven, *Medical Malpractice or Criminal Mistake? An Analysis of Past and Current Criminal Prosecutions for Clinical Mistakes and Fatal Errors*, 2 DEPAUL J. HEALTH CARE L. 1 (1997); Kara M. McCarthy, Note, *Doing Time for Clinical Crime: The Prosecution of Incompetent Physicians as an Additional Mechanism To Assure Quality Health Care*, 28 SETON HALL L. REV. 569 (1997). For a recent critique of British medical jurisprudence related to the crime of gross negligence manslaughter, see Oliver Quick, *Medical Killing: Need for a Specific Offence?*, *in* CRIMINAL LIABILITY FOR NON-AGGRESSIVE DEATH 155 (C.M.V. Clarkson & Sally Cunningham eds., 2008) (favoring application of subjective recklessness standard for medical criminal prosecutions).

44. *See* HIDEO IIDA & ISSEI YAMAGUCHI, KEIJI IRYŌ KAGO [CRIMINAL MEDICAL MALPRACTICE] 1-2 (2001) (finding 137 prosecutions of medical cases in the postwar period, which is "extremely small" in comparison with the number of civil malpractice cases). The pace of medical prosecutions accelerated after this book appeared, in keeping with intensified public and prosecutorial concern with the problem of medical error. *See infra* note 47.

45. The yearly number of articles about medical error in the Nikkei Telecon 21 database of leading newspapers jumped from 383 in 1998 to 1258 in 1999, the year of the Yokohama Medical University Hospital patient mix-up case and the Hirō Hospital case, and to 3047 in 2000. The number remained in the 2700-3100 range from 2001 to 2004, though it dipped to 2239 in 2005. Yasushi Kodama, *Iryō anzen: How Safe Is Safe Enough?*, 1339 JURISUTO 67, 73 fig.2 (2007). This count does not separate articles about criminal cases from other medical error topics, but it makes it clear that the early criminal prosecutions provided the initial spur to the increased level of coverage. The number of media reports spiked again in the summer of 2008 in connection with the prosecution of the Ohno Hospital obstetrician. *See supra* note 25 and accompanying text.

46. Three physicians and two nurses were convicted of professional negligence and fined. 1087 HANREI TAIMUZU 296 (Yokohama D. Ct., Sept. 20, 2001). Both patients survived the mistaken surgeries. *See Heart, Lung Patients Mistakenly Switched*, JAPAN TIMES, Jan. 14, 1999, at 2.

investigations and prosecutions was stepped up significantly.[47] The image of squads of police deploying into hospitals to seize evidence of medical crime has become a part of public consciousness. The fatal injection at Hirō Hospital in 1999,[48] the heart-lung machine blunder at Tokyo Women's Medical University Hospital in 2002,[49] and a botched laparoscopic prostatectomy the same year by neophyte surgeons reading from the equipment manual and consulting the manufacturer's representative by phone during a thirteen-hour operation at Jikei Medical University's Aoto Hospital[50]—in each of these highly publicized cases at prominent Tokyo-area hospitals and many others, police arrested medical personnel or filed papers with prosecutors, resulting in criminal charges.[51] In many of these cases, including the last three noted above, medical personnel altered patient records, deceived family members, or otherwise attempted to obscure the truth. Often the facts were revealed only after a whistleblower within the hospital contacted a journalist, the family, or the police.[52]

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47. According to National Police Agency statistics, in 1997 police sent three medical cases to prosecutors; in 2007, they sent ninety-two. Hideo Iida, *Keiji shihō to iryō* [*Criminal Justice and Medicine*], 1339 JURISUTO 60, 61 tbl.1 (2007) (summarizing National Police Agency findings from 1997 to 2005); Nat'l Police Agency, Iryō jiko kankei todokede-tō kensū no suii, rikken sōchisū [Trends in Number of Reported Medical Accidents and of Cases Sent to Prosecutors] (May 21, 2008) (presenting 2006-2007 statistics) (on file with author). Putting the matter in historical perspective, the number of criminal prosecutions for medical acts during the fifty-three postwar years 1946-1998 was 137, or 2.6 per year. For the five years and three months from January 1999 through March 2004, seventy-nine prosecutions were initiated, a rate of 14.8 per year. HIDEO IIDA, KEIJI IRYŌ KAGO II [CRIMINAL MEDICAL MALPRACTICE II] 1 (2006).

48. *See supra* notes 20-22 and accompanying text; *infra* notes 103-106 and accompanying text.

49. *See supra* notes 18-19 and accompanying text.

50. The three physicians were convicted of professional negligence. *Bungling Doctors Held Responsible for Death*, INT'L HERALD TRIB./ASAHI SHIMBUN, June 16, 2006, at 27. This case was featured in a mass market book by a well-known urologist. HIDEKI KOMATSU, JIKEI IDAI AOTO BYŌIN JIKEN: IRYŌ NO KŌZO TO JISSENTEKI RINRI [THE STRUCTURE OF HEALTH CARE AND PRACTICAL ETHICS: THE JIKEI MEDICAL UNIVERSITY AOTO HOSPITAL CASE] (2004).

51. These cases are described in more detail in Leflar & Iwata, *supra* note 15, at 192-96. Most medical prosecutions have resulted in convictions, although the conviction rate of medical defendants is less than the 99%-plus rate at which criminal defendants in general are found guilty. *See* J. MARK RAMSEYER & MINORU NAKAZATO, JAPANESE LAW: AN ECONOMIC APPROACH 178 (1999) (overall conviction rate in 1994 of 99.9%). Medical defendants who are convicted typically receive a fine or probation or both, rather than imprisonment. IIDA & YAMAGUCHI, *supra* note 44, at 435-82 (collecting cases); Haruo Yamaguchi, *Iryō jiko no keiji shobun to purofesshonaru ōtonomii* [*Criminal Sanctions for Medical Accidents and Professional Autonomy*], 695 NIIGATA-KEN ISHIKAIHŌ 2, 2 tbl.1 (2008) (reporting four cases of imprisonment out of 253 criminal sanctions from 1950-2007). The conviction itself, however, is usually enough to force a career change, through either loss of medical license or personal shame, so effectively the punishment is quite significant.

52. *See, e.g.*, SUZUKI, *supra* note 19, at 63-69 (recounting letter to patient's family from

Strong arguments of philosophy and policy are advanced in Japan against the use of criminal law to discipline physicians and nurses for unintentional professional acts.[53] To summarize those arguments: 1) Since the acts are unintentional, the prospect of punishment offers little in the way of effective deterrence. 2) The severity of punishment (both as formal penalty and as besmirching of reputation) tends to be out of proportion to the evil punished, in a field where grave consequences may ensue from single acts of simple carelessness. 3) Police are inexpert investigators, with little understanding of the subtleties of medicine. 4) Criminal investigations often take considerable time, interfere with hospitals' own case review process, and disrupt patient care. 5) Fear of criminal liability deters physicians from undertaking risky but highly beneficial procedures, to patients' detriment, and drives doctors away from socially important but liability-prone fields such as obstetrics and emergency medicine. 6) The goal of improving patient safety is poorly served by criminal law's focus on individual blame, turning attention away from the systemic deficiencies at the root of much preventable harm. (Substituting "civil" for "criminal" and "plaintiffs' lawyers" for "police," the reader will recognize the arguments set out in this paragraph as roughly analogous to those advanced by many proponents of medical "tort reform" in the United States.)

The stridency of these criticisms reached a particularly high pitch after the humiliating arrest and handcuffing, broadcast on national news, of an obstetrician in February 2006 at Ohno Hospital in rural Fukushima Prefecture after a patient's

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anonymous whistleblower in Tokyo Women's Medical University Hospital case). One source of inside information for Japanese journalists is an anonymous Internet bulletin board, Channel 2, http://www.2ch.net (last visited Dec. 3, 2008), containing posts on alleged scandals within various Japanese institutions including hospitals.

53. The arguments are offered in various forms in mass market books, for example, HIDEKI KOMATSU, IRYŌ HŌKAI [MEDICINE'S COLLAPSE] (2006); by medical specialty societies, for example, Japanese Soc'y of Internal Med., Japan Surgical Soc'y, Japanese Soc'y of Pathology & Japanese Soc'y of Legal Med., 4 gakkai kyōdō seimei – Shinryō kōi ni kanren shita kanja shibō no todokede ni tsuite: Chūritsuteki senmon kikan no sōsetsu ni mukete [Joint Declaration of Four Societies Regarding Notification to Police of Medical Practice-Associated Patients' Deaths: Toward the Establishment of an Impartial Expert Institution] (2004), http://jsp.umin.ac.jp/previous/inkai/inkaihokoku/4kyodoseimei.html [hereinafter Joint Declaration]; before government advisory committees, for example, Ministry of Health, Labor & Welfare, Health Policy Bureau, Shinryō kōi ni kanren shita shibō ni kakaru shiin kyūmei-tō no arikata ni kansuru kentōkai [Commission on the Investigation of Causes of Medical Practice-Associated Deaths], Kore made no giron no seiri [Summary of Issues Presented] (Aug. 2007), http://www.mhlw.go.jp/shingi/2007/08/dl/s0824-4a.pdf; and in other online resources and medical blogs put out by organizations, such as the Medical Research Information Center, http://mric.tanaka.md (last visited Dec. 3, 2008) and Shūsanki iryō no hōkai o kuitomeru kai [Association to Prevent the Collapse of Perinatal Medicine], http://plaza.umin.ac.jp/~perinate/cgi-bin/wiki/wiki.cgi (last visited Dec. 3, 2008).

death from blood loss during a Cesarean section delivery.[54] The physician was later acquitted,[55] but his arrest, detention, and prosecution sparked protests by physicians' groups across the nation.[56] Employing the slogan "Medicine's collapse" (*iryō hōkai*),[57] this movement called editorial and political attention to the increasing shortage of physicians willing to attend childbirths outside metropolitan areas and to accounts of hospital emergency rooms turning away ambulances for fear of liability exposure. Targeted as one chief cause of those problems has been criminal law's intrusion into the practice of medicine.[58]

In the face of these arguments, what accounts for the emphasis Japan has placed on criminal law in the regulation of medical error? Part of the explanation relates to the structure of the criminal law itself. The language of two provisions of the Criminal Code and one provision of the Medical Practitioners' Law is construed broadly enough to encompass acts that sometimes occur in the course of medical practice. Police and prosecutors have simply considered it their professional duty to enforce the law, particularly while under the gaze of journalists and a public that is newly sensitized to the fact of widespread medical injury and counts on the criminal justice system to expose the facts and vindicate the public interest.[59] A second line of explanation has to do with the social structure of responsibility for injury in the course of medical care. This perspective concerns the need for public accountability of the medical profession for its errors—a need that historically has not been sufficiently met by professional self-regulation, administrative oversight, the death inquest system, or civil litigation.[60] The criminal justice system, its proceedings amplified by the media, stepped in to fill that gap.

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54. *See* sources cited *supra* note 23.

55. 16 IRYŌ HANREI KAISETSU 20 (Fukushima D. Ct., Aug. 20, 2008); *see also* news accounts listed *supra* note 25.

56. A nationwide protest petition and resolution was sponsored by two medical associations. Japan Soc'y of Obstetrics & Gynecology and Japan Ass'n of Obstetricians & Gynecologists, Seimei [Proclamation] (Mar. 10, 2006), http://www.jsog.or.jp/news/html/announce_10MAR2006.html.

57. The phrase was apparently coined by Dr. Hideki Komatsu in his 2006 book. *See* KOMATSU, *supra* note 53.

58. An excellent collection of materials representing this perspective can be found at Medical Research Information Center, http://mric.tanaka.md (last visited Dec. 3, 2008).

59. This viewpoint was well expressed by Hiroyuki Ohta, Director of the Criminal Planning Division of the National Police Agency, at a meeting of the health ministry's Commission on the Investigation of Causes of Medical Practice-Associated Deaths [Shinryō kōi ni kanren shita shibō ni kakaru shiin kyūmei-tō no arikata ni kansuru kentōkai] (Aug. 10, 2007), http://www.mhlw.go.jp/shingi/2007/08/txt/s0810-2.txt (official meeting transcript).

60. *See* Leflar & Iwata, *supra* note 15; Robert B Leflar, *Medical Error, Deception, Self-Critical Analysis, and Law's Impact: A Comparative Examination*, *in* LAW IN JAPAN: A TURNING POINT 404-32 (Daniel H. Foote ed., 2007).

B. Legal Grounds for Criminal Prosecutions

Prosecutors' standard charge against medical personnel under the Criminal Code of Japan is "professional *negligence* causing death or injury."[61] This crime, derived like most of the Criminal Code from the German penal code,[62] has no specific equivalent in Anglo-American jurisprudence. The rare convictions for unintentional medical acts in recent years in the United States, the United Kingdom, and Canada almost all involve charges of a higher level of *mens rea*: intent, recklessness, or (in England and Wales[63]) at least gross negligence.[64] In Japan, mere negligence is enough.[65]

A second ground for prosecution is concealment or destruction of evidence.[66] This offense has formed the basis for convictions for attempted

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61. KEIHŌ [Criminal Code], art. 211 (Gyōmujō kashitsu chishishō-tō), providing a prison sentence of up to five years and a fine of up to ¥100,000 (US $900). This crime is most commonly charged in connection with traffic offenses, but other professionals such as architects of buildings that collapsed and pilots of airplanes that crashed have also felt its bite. Articles 209 and 210 of the Criminal Code also sanction negligence causing injury and negligence causing death respectively, but they are seldom if ever employed in medical prosecutions.

62. *See* HIROSHI ODA, JAPANESE LAW 416 (2d ed. 1999).

63. R. v. Adomako, [1995] 1 A.C. 171, 193 (H.L. 1994). *See generally Death Under Anaesthetic: The Case of Dr Adomako*, 36 MED. SCI. & L. 188 (1996) (speeches before British Academy of Forensic Sciences given by *Adomako* defense counsel Lord Williams of Mostyn and prosecutor Ann Curnow); Lord Mackay of Clashfern, *Presidential Address: Involuntary Manslaughter in Relation to Patient Care*, 39 MED. SCI. & L. 277 (1999) (address to the British Academy of Forensic Sciences by the author of the *Adomako* opinion).

64. *See* Leflar & Iwata, *supra* note 15, at 214 n.110, and cases and commentary cited therein.

65. Controversy exists among academics about whether the definition of "negligence" is the same in criminal as in civil law, or whether it targets a more limited set of acts and omissions. *See, e.g.*, Manabu Yamazaki, *Kōzōteki kashitsu (2): Iryō kago* [*Structural Negligence (2): Medical Malpractice*], *in* 30 GENDAI SAIBANHŌ TAIKEI 37, 44-45 (Sukeaki Tatsuoka ed., 1999) (setting out differing views, and favoring an identical definition in both fields). The courts have not resolved the issue. In practice, exercising their discretion, prosecutors choose to indict and prosecute only a small fraction of physicians who might be sued for civil malpractice. But however defined, it is "negligence" (*kashitsu*) that article 211 of the Criminal Code sanctions and "negligence" that must be proven, not something more.

Japan shares the perspective that ordinary negligence can form the basis for prosecutions of physicians with other civil law nations such as France. *See* BELL, BOYRON & WHITTAKER, *supra* note 41, at 227 ("'Ordinary fault' (*faute ordinaire*) is the typical basis of liability for *délits*."); *id.* at 206 ("*délits*" defined as "less serious offenses [than murder or rape] requiring a mental element and carrying some form of moral disapproval (such as theft, fraud, assault, etc.)").

66. KEIHŌ [Criminal Code], art. 104 (Shōko inmetsu-tō). A related crime, for which the CEO of Hirō Hospital was convicted, *see* supra note 48, is the creation of, with the purpose to use, false official documents. KEIHŌ [Criminal Code], art. 156 (Kyogi kō-bunsho sakusei-tō).

cover-ups through alteration of patients' medical records,[67] a practice that plaintiffs' attorneys charge has been widespread in the past.[68]

The third basis for recent prosecutions of physicians is failure to notify the police in timely fashion of "unnatural deaths." This notification requirement, found in Article 21 of the Medical Practitioners' Law,[69] has been applied beyond its original scope of violent deaths, suicides, and the like, to encompass deaths possibly caused by medical management.[70] As such, it has become the target of intense controversy and criticism, as discussed below.

Police and prosecutors do not relish working up medical crime investigations. They often feel out of their depth. Cases tend to be complicated, the evidence difficult to muster and master, and the ascertainment of the standard of care and of causal relationships problematic. Expert assistance and the commitment of substantial resources are necessary. Acquittals occur more frequently in medical cases[71] than in other prosecutions, where guilty verdicts are overwhelmingly the norm,[72] and an acquittal may subject prosecutors to public obloquy and professional disgrace.[73] Nevertheless, the code provisions described above make it clear that the statutory duty of law enforcement officials to protect the public extends into the hospital. That duty accords with public expectations

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67. One of the physicians in the Tokyo Women's Medical University Hospital case was convicted on this ground. *See supra* notes 18-19 and accompanying text.

68. *See, e.g.*, HIROTOSHI ISHIKAWA, KARUTE KAIZAN WA NAZE OKIRU [WHY MEDICAL RECORDS ARE FALSIFIED] (2006); *Doctor Removed Healthy Breasts*, JAPAN TIMES, June 2, 2000, at 2 (reporting tampering with patient records to conceal normal results of pathological tests of breast tissue).

69. Ishi hō [Medical Practitioners' Law], Law No. 201 of 1948, art. 21.

70. *See infra* notes 98-105 and accompanying text.

71. *See, e.g.*, 16 IRYŌ HANREI KAISETSU 20 (Fukushima D. Ct., Aug. 20, 2008) (Ohno Hospital case); Judgment of Tokyo High Ct., Nov. 20, 2008 *reported in* Atsuko Kinoshita & Makoto Inagaki, *Medical Mishaps Hard to Rule on Criminally*, DAILY YOMIURI, Nov. 22, 2008, *available at* http://www.yomiuri.co.jp/dy/national/20081122TDY03103.htm (acquittal of Kyorin University Hospital physician); *see also Doctor Acquitted in Girl's Death*, INT'L HERALD TRIB./ASAHI SHIMBUN, Dec. 1, 2005, at 28 (acquittal of one of two physicians charged in Tokyo Women's Medical University Hospital case).

72. *See* RAMSEYER & NAKAZATO, *supra* note 51 (reporting an overall conviction rate above 99%).

73. DAVID T. JOHNSON, THE JAPANESE WAY OF JUSTICE: PROSECUTING CRIMES IN JAPAN 46, 107, 238 (2002). On the other hand, even an unsuccessful prosecution in a difficult case does not necessarily impede a prosecutor's career path if the case has been well researched and presented. Interview with Dean Masahito Inouye, University of Tokyo Faculty of Law, in Tokyo, Japan (July 22, 2008) [hereinafter Interview with Inouye]. Dean Inouye, a criminal law specialist, noted examples of prosecutors who had lost high-profile cases and later attained leadership positions within the procuracy.

of the criminal justice system.[74] When an injured patient, family member, or whistleblower brings forward a charge of death or injury from professional negligence, or when an Article 21 unnatural death notification arrives, the police will look into the matter, and if the evidence is sufficient, they will set into motion the machinery of the criminal process.[75]

C. The Social Structure of Responsibility for Medical Harm: Japanese Medicine's Accountability Vacuum

Like other professions, medicine in the Anglo-American nations is subject to discipline from a variety of sources, external and internal. Tort law—specifically, medical malpractice law—casts the longest shadow in the United States, for better or worse, and it plays an important role in the United Kingdom, Canada, and Australia as well. Perhaps more important for the routine organization of U.S. risk management activities, quasi-public accrediting organizations, such as the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance, set detailed standards and carry out periodic on-site assessment activities to exert pressure for quality improvement.[76] Medical specialty boards carry out stringent initial screening and require periodic recertification to ensure that practitioners acquire and preserve the necessary skills and keep up with the field.[77]

When things go wrong, hospital peer review committees sometimes limit, suspend, or revoke erring physicians' hospital privileges. Medicare Quality Improvement Organizations,[78] state licensure and discipline boards,[79] and in the

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74. Interview with Inouye, *supra* note 73.

75. The recent intensification, described in Part III, of the controversy over criminal law's regulatory oversight of Japanese medicine has not deterred police from investigating cases of alleged medical error. *See, e.g., Shittō misu yōgi shorui sōken [Papers Sent to Prosecutors on Suspicion of Surgical Error]*, ASAHI SHIMBUN (Yamagata ed.), Feb. 26, 2008, at 35 (describing police action subsequent to hospital's internal peer review and hospital's payment of ¥20 million [US $180,000] to family). The number of medical personnel actually prosecuted, however, is reported to have decreased from a high of twelve in 2005 to three in 2006 and none at all in 2007. Kinoshita & Inagaki, *supra* note 71.

76. *See* The Joint Comm'n, Joint Commission Fact Sheets, http://www.jointcommission.org/AboutUs/Fact_Sheets/joint_commission_facts.htm (last visited Dec. 3, 2008); Nat'l Comm. for Quality Assurance, About NCQA, http://www.ncqa.org/tabid/675/default.aspx (last visited Dec. 3, 2008).

77. *See* Am. Bd. of Med. Specialties, What Board Certification Means, http://abms.org/About_Board_Certification/means.aspx (last visited Dec. 3, 2008).

78. *See* Ctrs. for Medicare & Medicaid Servs., Quality Improvement Organizations Overview, http://www.cms.hhs.gov/QualityImprovementOrgs (last visited Oct. 14, 2008) (summary of program). The QIOs' performance is not without critics. *See, e.g.*, John Reichard, *Medicare Quality Improvement Stagnating, Senators Complain*, CQ HEALTHBEAT, Aug. 13, 2007, *available at*

United Kingdom, the General Medical Council,[80] all serve to police the profession as well.[81]

In Japan, by contrast, the analogous structures have historically been weak or dysfunctional. Tort litigation, while more common than in the past, is still infrequent at least by U.S. standards,[82] and the sting of liability insurance premiums is far less intense.[83] There has been an exiguity of peer review,[84] although the past few years have seen some improvement on that score.[85] Medical specialty societies have been remiss in assuring quality in most fields of specialty: physicians can proclaim and advertise expertise in medical specialties and practice in them without certification, and even for specialty society members, recertification requirements are lax, where they exist at all.[86] Until

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http://www.commonwealthfund.org/healthpolicyweek/healthpolicyweek_show.htm?doc_id=515505#doc515508 (reporting criticisms by Senator Charles Grassley and a GAO report).

79. For a critical view of the operation of state-level medical disciplinary structures, see Randall R. Bovbjerg, Robert H. Miller & David W. Shapiro, *Paths to Reducing Medical Injury: Professional Liability and Discipline vs. Patient Safety, and the Need for a Third Way*, 29 J. L. MED. & ETHICS 369, 374 (2001).

80. *See* General Medical Council, http://www.gmc-uk.org (last visited Dec. 3, 2008).

81. *See, e.g.*, Susan O. Scheutzow, *State Medical Peer Review: High Cost but No Benefit: Is It Time for a Change?*, 25 AM. J. L. & MED. 7 (1999).

82. *See supra* notes 15 and 27.

83. *See supra* note 28. Individual physicians in Japan are particularly less threatened by the civil liability system than their U.S. counterparts, because most are hospital employees rather than independent contractors, so it is the hospital, not the individual physician, that is the main target of civil malpractice actions. Japan has no system of independent physicians with hospital privileges.

84. *See* JOHN CREIGHTON CAMPBELL & NAOKI IKEGAMI, THE ART OF BALANCE IN HEALTH POLICY: MAINTAINING JAPAN'S LOW-COST, EGALITARIAN SYSTEM 187-90 (1998).

85. Larger hospitals have recently begun instituting internal committees to investigate adverse events. Some of these review committees, contrary to tradition, bring in outside experts to participate. Summaries of four hospital systems' internal adverse event review systems, which include outside experts in their deliberations, are set out in MINISTRY OF HEALTH, LABOR & WELFARE, IRYŌ JIKO CHŌSA NI OITE INGAI NO SENMONKA-TŌ GA KAKAWATTE IRU REI NI TSUITE [EXAMPLES OF INCLUSION OF OUTSIDE-HOSPITAL EXPERTS IN MEDICAL ACCIDENT INVESTIGATIONS] 31-48 (2007), *available at* http://www.mhlw.go.jp/shingi/2007/07/dl/s0726-7d_0019.pdf through /s0726-7d_0022.pdf (report distributed at July 26, 2007 meeting of Shinryō kōi ni kanren shita shibō ni kakaru shiin kyūmei-tō no arikata ni kansuru kentōkai [Commission on the Investigation of Causes of Medical Practice-Associated Deaths]).

86. *See* Naoki Ikegami, *Nihon no iryō seido ni okeru senmon-i no yakuwari* [*The Role of Specialists in the Japanese Health Care System*], 52 SŌGŌ RINSHŌ 3125 (2003); Interview with Dr. Tetsu Yamaguchi, CEO of Toranomon Hospital, in Tokyo, Japan (July 30, 2007) [hereinafter Interview with Yamaguchi]. As of this writing, only the specialties of cardiac and urologic endoscopic surgery have instituted certification programs. *See Docs To Be Vetted on Endoscopic Surgery*, DAILY YOMIURI, June 28, 2004, at 2. *See generally* Naoki Ikegami & John Creighton Campbell, *Japan's Health Care System: Containing Costs and Attempting Reform*, 23 HEALTH AFF.

recently, the health ministry sanctioned practitioners only after a criminal conviction (typically for reimbursement fraud, tax evasion, drug abuse, or morals violations); quality-of-care issues seldom formed the basis for disciplinary measures.[87] Japan's hospital accreditation authority, the Japan Council for Quality Health Care (*Nihon iryō kinō hyōka kikō*), operates on a far smaller scale and with a lower profile than JCAHO, its U.S. analogue. A central reason is that unlike in the United States, Japanese hospitals need not be accredited to obtain payment for services rendered, and most have not undergone the accreditation process.[88] Systematic attention to quality control, at least until the public outcry following the Yokohama City Medical University Hospital patient mix-up[89] and other notorious cases noted above, had simply never been a significant aspect of the formal structure of Japanese health care.

When the realization that medical error is remarkably common and often concealed burst upon the Japanese public's consciousness at the turn of the

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26, 35 (2004) ("[L]imited but meaningful progress has been made in the weakest part of the system, professional accountability.").

87. Interview with officials in the Ministry of Health, Labor, and Welfare, Office of Medical Safety, in Tokyo, Japan (Aug. 6, 2004). The Ministry of Health, Labor, and Welfare issues administrative sanctions to physicians, dentists, and pharmacists on advice of the Medical Ethics Council (*Idō shingikai*). In 2002, in response to the furor over highly publicized medical error cases, the Medical Ethics Council adopted a policy whereby serious malpractice could form the basis for an administrative sanction even in the absence of a criminal conviction. Since then, the Council has issued a few more license suspensions and orders for health care personnel to undergo re-training. This latter sanction has been strengthened in accordance with 2006 amendments to the Iryō Hō [Medical Services Law], Law No. 84 of 2006.

Etsuji Okamoto has gathered statistics indicating that Medical Ethics Council/MHLW sanctions numbered 392 during the thirteen-year period from 1989 to 2001, of which only eighteen arose from a patient's death or injury from professional negligence, a rate of 1.4 such sanctions per year nationwide. During the subsequent period from January 2002 to June 2005, there were 196 sanctions, of which thirty-one arose from professional negligence (8.9 per year). E-mail from Dr. Etsuji Okamoto, Nat'l Inst. of Public Health, to author (July 13, 2006) (on file with author); *see also* Etsuji Okamoto, *An Analysis of Administrative Sanctions and Criminal Prosecutions of Doctors in Japan*, 52 JAPANESE J. PUB. HEALTH 994, 996 tbl.1 (2005) (summarizing types of charges, and numbers and sanctions associated with each); Tsukamoto, *supra* note 33, at 680 ("very rare" for administrative sanctions to be imposed following medical accidents). *See generally* NORIO HIGUCHI, IRYŌ TO HŌ O KANGAERU: KYŪKYŪSHA TO SEIGI [AMBULANCES AND JUSTICE: MEDICINE AND LAW RECONSIDERED] 60-67 (2007) (summarizing system of administrative discipline for physicians).

88. Leflar & Iwata, *supra* note 15, at 191-92. As of August 2008, 2523 of Japan's 8832 hospitals had received this organization's accreditation. Japan Council for Quality Health Care, Nintei byōin kensaku [Accredited Hospitals Listing], http://www.report.jcqhc.or.jp/index.html (last visited Dec. 3, 2008).

89. *See supra* note 46 and accompanying text.

century,[90] organized medicine was caught napping, the health ministry was unprepared, and the tort system's ability to respond had institutional limits.[91] For want of other adequate mechanisms of public accountability, police and prosecutors stepped into the breach, employing the statutory weapons at their disposal, in keeping with public expectations of the criminal justice system as protector of society. Whatever the drawbacks of reliance on the criminal law as a regulator of medical practice, and they are many, prosecutions in the high-profile cases in the first years of this century did serve as a wake-up call to the health ministry and the medical profession. The Japanese criminal justice system, its workings spotlighted by the media, has been filling an accountability vacuum.

II. THE INFORMATION GAP, "UNNATURAL DEATHS," AND THE EXAMINATION OF CORPSES

A. The Information Gap on Patient Safety

Reacting to the medical prosecutions and accompanying publicity, leaders of the medical world and officials of the Ministry of Health, Labor and Welfare (MHLW) began devising measures to address perceived deficiencies in the nation's health care safety framework. The National University Hospital Council of Japan called on its member hospitals in 2000 to set up safety systems on an urgent basis.[92] MHLW established a medical safety office in 2000, gradually expanding it in the following years.[93] The health minister issued an "emergency appeal" in 2003 to require continuing medical education.[94]

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90. *See supra* notes 45-52 and accompanying text.

91. For example, there are only 24,300 practicing attorneys in all of Japan, a nation of 127 million. Japan Federation of Bar Associations, http://www.nichibenren.or.jp/en/about/index.html (last visited Dec. 3, 2008). Few of these attorneys handle medical malpractice cases on behalf of either plaintiffs or defendants, although their number is increasing. *See* Leflar & Iwata, *supra* note 15, at 202 n.46.

92. KOKURITSU DAIGAKU IGAKUBU FUZOKU BYŌINCHŌ KAIGI JŌCHI IINKAI [NAT'L UNIV. HOSPS. COUNCIL OF JAPAN], IRYŌ JIKO BŌSHI NO TAME NO ANZEN KANRI TAISEI NO KAKURITSU NI [ESTABLISHING SAFETY MANAGEMENT SYSTEMS FOR THE PREVENTION OF MEDICAL ACCIDENTS] (2001).

93. The staffing and funding of this office have been thin. Personnel increased from three to eight as of 2004. The ministry-wide budget relating to medical safety, including that for general policy, drug safety, the operation of various advisory committees and research groups, and the training of risk managers at national hospitals rose from ¥459 million (US $4.2 million) in 2001 to ¥930 million (US $8.5 million) in 2002 and ¥1.44 billion (US $13.1 million) in 2003—rapid year-on-year increases, to be sure, but still quite modest sums in comparison with the patient safety budgets of U.S. and U.K. health agencies. Interviews with officials in the Ministry of Health, Labor, and Welfare, Office of Medical Safety, in Tokyo, Japan (July 29, 2003 & Aug. 6, 2004).

94. KŌSEIRŌDŌ-DAIJIN IRYŌ JIKO TAISAKU KINKYŪ APIIRU [EMERGENCY APPEAL FOR MEDICAL

Both the health ministry and the leaders of the medical profession quickly realized that one of the critical problems the nation faced was a giant information gap. No one knew the magnitude of the medical safety problems that existed, no one had any clear idea of their nature, and no reporting systems were in place to find out. Moreover, with repeated hospital cover-ups on the front pages and in the nightly news, the public had little faith in the willingness or capacity of the profession itself to engage voluntarily in the honest investigation of medical accidents and self-critical analysis that are essential for safety improvement programs.[95]

To counter this information gap, the health ministry issued rules requiring hospitals to create internal accident tracking systems and to report, initially, near misses and, later, accidents involving harm to an independent quasi-public entity for enumeration and analysis.[96] While these efforts were getting underway, with mixed success at best,[97] the prosecution and conviction of the CEO of Tokyo's Hirō Hospital turned attention to a separate reporting requirement, originally instituted for entirely different purposes: the requirement that a physician notify police within twenty-four hours after examining a corpse and determining that the death was "unnatural."

B. "Unnatural Deaths" and Police Investigations

The "unnatural death" notification requirement, found in Article 21 of the Medical Practitioners' Law,[98] for many years had been understood to apply to

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ACCIDENT COUNTER-MEASURES BY THE MINISTER OF HEALTH, LABOR & WELFARE] (2003).

95. An outpouring of books and other mass market publications pointed accusing fingers at the medical establishment. *See, e.g.*, RESEPUTO KAIJI DE FUSEI IRYŌ O MIYABURŌ! [PUT A STOP TO INAPPROPRIATE MEDICAL TREATMENT BY DEMANDING BILLING DISCLOSURE!] (Hisashi Katsumura ed., 2002); KARUTE KAIZAN [FALSIFICATION OF MEDICAL RECORDS] (Hirotoshi Ishikawa ed., 2004); JINTSŪ SOKUSHINZAI: ANATA WA DŌ SURU [WHAT ARE YOU GOING TO DO ABOUT LABOR-INDUCING DRUGS?] (Jintsū sokushinzai ni yoru higai o kangaeru kai eds., 2003).

96. *See* Ministry of Health, Labor & Welfare, Iryō jiko jōhō shūshū-tō jigyō [Medical Accident Information Collection Project], http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/jiko/index.html (last visited Dec. 3, 2008) (outline of current rules). The entity collecting the reports is the Japan Council for Quality Health Care. *See* Nihon iryō kinō hyōka kikō [Japan Council for Quality Health Care], Iryō jiko jōhō shūshū-tō jigyō yōkō [Outline of Medical Accident Information Collection Project], http://www2.jcqhc.or.jp/html/documents/pdf/med-safe/youkou.pdf (last visited Dec. 3, 2008).

97. A brief critical evaluation of the MHLW's early efforts at setting up a reporting system can be found in Leflar & Iwata, *supra* note 15, at 208-10. One of the chief problems was that the limited contents of the reports often permitted only aggregation of the data, not the kind of close analysis of individual cases that can result in useful suggestions for prevention of future accidents.

98. Ishi hō [Medical Practitioners' Law], Law No. 201 of 1948, art. 21. Violations are punishable by a criminal fine of up to ¥500,000 (US $4,500). *Id.* art. 33-2(1).

deaths from non-medical criminal activity, sudden accidents, suicides, epidemic infections, and the like, much like the public safety and public health-oriented notification requirements standard in the United States, the United Kingdom, and other countries. But in 1994, the Japanese Society of Legal Medicine (*Nihon hōi gakkai*),[99] an association of forensic medicine specialists chiefly based in medical university faculties whose daily work involves collaboration with police on crime investigations, promulgated a set of guidelines aimed at broadening the interpretation of the definition of notifiable "unnatural deaths" to include those possibly caused by medical management.[100] The 1994 guidelines applied the police notification requirement to "unexpected deaths related to the course of medical treatment and deaths suspected of being so related."[101] The guidelines stated that unexpected deaths during or soon after procedures such as injections, anesthesia, surgery, medical tests, or childbirth; deaths possibly related to medical treatment; and sudden deaths during or soon after medical treatment whose cause is unclear should all be subject to the notification requirement.[102] The forensic pathologists' 1994 guidelines were not binding authority, and most physicians were probably unaware of them—until the Hirō Hospital case.[103]

That case arose from a patient's death in 1999 at a well-known Tokyo hospital after a nurse injected her with what the nurse thought was a heparin solution. In fact, the syringe contained a toxic disinfectant and had been left on the cart by another nurse. Following a decision reached the next day by a hospital committee, the hospital CEO ordered the death certificate to be falsified and sent no notification to the police for eleven days. He was prosecuted and convicted for both deliberate acts.[104] The Supreme Court of Japan affirmed his conviction for

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99. *See* Japanese Society of Legal Medicine, http://plaza.umin.ac.jp/legalmed/index.en.html (last visited Dec. 3, 2008).

100. The perceived need for such an interpretation was sparked in part by the controversy over heart transplantations from patients judged to be brain dead. The story of the national debate over whether the first such heart transplant in Japan was medically justified or whether it implicated "unnatural deaths"—a criminal abuse of an ambitious transplant surgeon's position in his quest for worldwide glory—is ably recounted in FELDMAN, *supra* note 16, at 82-109, 131-40; and MARGARET LOCK, TWICE DEAD: ORGAN TRANSPLANTS AND THE REINVENTION OF DEATH 130-46 (2002).

101. *Nihon hōigakkai "ijōshi" gaidorain* [*Japanese Society of Legal Medicine "Unnatural Death" Guidelines*], 48 NIHON HŌIGAKU ZASSHI 357 (1994).

102. *Id.*

103. *See, e.g.*, Toshiharu Furukawa, *Shinryō ni kanren shita "ijōshi" ni tsuite* [*On "Unnatural Deaths" Related to Medical Practice*], 102 NIHON GEKA GAKKAI ZASSHI 554 (2001); Yoshiki Ogawa, *Iryō jiko to ishi no todokede gimu* [*Medical Accidents and Physicians' Duty of Notification*], 3 KEIJIHŌ JĀNARU 40, 42 & n.6 (2006).

104. 1771 HANREI JIHŌ 156 (Tokyo D. Ct., Aug. 30, 2001). The two nurses were convicted of professional negligence and received suspended sentences. The attending physician was convicted of violating Article 21 and received a fine and license suspension. None of these defendants appealed their convictions. A Tokyo metropolitan hospital bureau official, who was advised of the

violating the Article 21 requirement of notification within twenty-four hours, rejecting his contention that the requirement to notify police on pain of a criminal fine violated the constitutional privilege against self-incrimination.[105] In upholding the conviction, the Court recognized that the Article 21 "unnatural death" notification requirement could properly be applied to at least some iatrogenic deaths.

The Hirō Hospital CEO's conviction sent earthquake shocks through Japanese medicine.[106] A great many patients die in hospitals. Which of these deaths should be considered "unnatural" and therefore notifiable to police? Would a reluctance to contact police, if an iatrogenic death later somehow comes to light, intensify the public's criticism of the medical profession for concealing its mistakes? On the other hand, would a practice of routine notification to police of every case of possible malpractice, as a health ministry guidance manual seemed to recommend,[107] have the effect of inviting police investigators into hospitals for fishing expeditions, disrupting patient care and subjecting doctors and nurses to the threat of prosecution for professional negligence?

The Japan Surgical Society,[108] one of the two largest and most influential medical specialty organizations, took the view that some kind of reporting to outside authority was advisable. The surgeons' group issued a somewhat muddled position paper (before the Supreme Court decision in the Hirō Hospital case) contesting the idea that Article 21 *requires* notification of deaths possibly connected to medical management. The Surgical Society's position paper advanced the idea that deaths caused by foreseeable complications related to surgery performed with appropriate informed consent should not be considered "unnatural," but nevertheless called on its members as an ethical matter *voluntarily* to send "reports" (as distinguished from notifications) to police *or* to some other independent entity, when there is clear malpractice or strong suspicion of serious malpractice, resulting either in death *or* in serious injury.[109]

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death but did not notify police, was found not guilty. For a summary of the case, see Tsukamoto, *supra* note 18, at 674-75.

105. 58(4) KEISHŪ 247 (Sup. Ct., Apr. 13, 2004). The hospital CEO did not appeal his conviction for falsifying the death certificate. A good summary of the case and its implications is to be found in Ogawa, *supra* note 103.

106. *See, e.g.*, Tsukamoto, *supra* note 18.

107. Kōseishō hoken iryō-kyoku kokuritsu byōin-bu risuku maneijimento sutandaado manyuaru sakusei iinkai [Ministry of Health, Labor & Welfare Health Ins. Bureau, Nat'l Hosps. Office, Risk Management Standard Manual Drafting Comm.], Risuku maneijimento manyuaru sakusei shishin [Guide for Drafting Risk Management Manuals] (2000), *available at* http://www1.mhlw.go.jp/topics/sisin/tp1102-1_12.html ("The director of the facility is to notify local police quickly of cases of death or injury resulting from or suspected to have resulted from medical malpractice.").

108. *See* Japan Surgical Society, http://www.jssoc.or.jp (last visited Dec. 3, 2008).

109. Nihon geka gakkai [Japan Surgical Soc'y], *Shinryō kōi ni kanren shita kanja no shibō,*

After the Supreme Court's decision in the Hirō Hospital case, the prestigious Science Council of Japan followed with a report acknowledging, like the Japan Surgical Society position paper, the importance of promoting the transparency in health care that the public is coming to expect, but calling for communicating accident information to police on a more limited basis. Deaths clearly the result of medical negligence should be notifiable, stated the Science Council, but those where negligence is less clear should first be reviewed by experts before determining whether police should be notified.[110] Other organizations issued still different guidelines. Among doctors, hospital administrators, and their legal advisors, confusion has reigned.[111]

C. Japan's Problematic Death Inquest System

Adding to the confusion is Japan's splintered, underdeveloped system for death inquests, a structure hindering systematic quality-improvement-oriented analysis of fatalities related to medical treatment. As leading forensic pathologist Tatsuya Fujimiya observed, the Japanese death inquest system "does not investigate . . . non-criminal death in any depth" and fails to focus on prevention of future accidents.[112] The following overview of the death inquest system

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shōgai no hōkoku ni tsuite [*Reporting Medical Practice-Associated Deaths and Injuries*], *reprinted in* Hiroyuki Katō, *Iryō jiko jōhō no hōkoku no mondaiten* [*Issues in Reporting Medical Accident Information*], 1249 JURIST 69, 70-71 (2003).

110. NIHON GAKUJUTSU KAIGI [SCI. COUNCIL OF JAPAN], IJŌSHI-TŌ NI TSUITE – NIHON GAKUJUTSU KAIGI NO KENKAI TO TEIGEN [UNNATURAL DEATHS ETC. – OPINION AND RECOMMENDATIONS OF THE SCIENCE COUNCIL OF JAPAN] (2005), *available at* http://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-19-t1030-7.pdf.

111. *See* Yasushi Kodama, *Ishihō 21-jō o meguru konmei* [*The Confusion Surrounding Article 21 of the Medical Practitioners' Law*], 1249 JURIST 72 (2003); Norio Higuchi, *Iryō ni okeru kihan to sofuto rō* [*Norms and Soft Law in Medicine*], 1 SOFT LAW J. 39, 51-53 (2005) (hypothetical case illustrating potential for confusion); Tsukamoto, *supra* note 18, at 677.

According to one survey, many physicians are under the erroneous impression that a medically related death need not be reported to police as long as the patient gave informed consent to the procedure involved, or if the reasons for the death were explained to the family. Ikegaya et al., *supra* note 33.

One count on which the Ohno Hospital obstetrician was recently acquitted was an alleged Article 21 violation. The district court found that since the patient's death during Cesarean section delivery was not proven to have been caused by negligence, it was not an "unnatural" death, so notification of police was not required. 16 IRYŌ HANREI KAISETSU 20 (Fukushima D. Ct., Aug. 20, 2008). Whether other courts will accept the apparent link between negligence and "unnaturalness" remains to be seen.

112. Tatsuya Fujimiya, *Legal Medicine and the Death Inquiry System in Japan: Their Development and a Comparative Study*, *in* MEDICINE AND THE LAW: PROCEEDINGS OF THE 19TH INTERNATIONAL SYMPOSIUM ON THE COMPARATIVE HISTORY OF MEDICINE, EAST AND WEST 129, 152, 156 (Yasuo Otsuka & Shizu Sakai eds., 1998) (article from a 1994 symposium); *see also*

examines the problems of that system from a patient safety standpoint—problems that the health ministry's "Model Project" and proposed legislative reform, addressed in Part III of this Article, are designed to ameliorate.

Autopsies are conducted in a considerably smaller proportion of all deaths in Japan than in the United States or other Western nations.[113] They are performed by members of two rival specialties, clinical pathology (*byōrigaku*) and forensic pathology (*hōigaku*). Clinical pathologists, typically hospital employees, conduct hospital autopsies in cases where there is no question of "unnatural death"—the majority of cases. Forensic pathologists, who are usually based in university medical faculties or local medical examiners' offices, perform medicolegal autopsies when a death might be classed as "unnatural."[114]

Medicolegal autopsies, the kind performed by forensic pathologists, fall into two classes: judicial autopsies (*shihō kaibō*) for cases determined to be criminal or for which criminal investigation is required, and non-judicial autopsies for what are considered "public health" purposes. The non-judicial autopsies are split again, depending on where they take place: administrative autopsies (*gyōsei kaibō*) in a few urban areas with medical examiner systems set up under the post-World War II American occupation, and "consented autopsies" (*shōdaku kaibō*) in the rest of Japan.[115]

Tsukamoto, *supra* note 18, at 678 ("[T]he medical examiner system in Japan is far from satisfactory.").

113. A 1998 World Health Organization survey placed Japan's autopsy rate lowest among twenty-two developed nations, at 4% compared to 12% in the United States, 20% in Canada, 24% in the United Kingdom, and 37% in Sweden. *See* Etsuo Okazaki, *Anzen na iryō o kizuku ue de no byōrii no yakuwari* [*The Role of Pathologists in Building Safe Medical Care*], 34 GENDAI IRYŌ 904, 905 fig.1 (2002); *see also* Stephen J. McPhee, *Maximizing the Benefits of Autopsy for Clinicians and Families: What Needs To Be Done*, 120 ARCHIVES PATHOLOGY LABORATORY MED. 743, 744 (1996) (estimating the overall rate in the United States at 10-12%). More recent single-nation data place Japan's autopsy rate even lower, at 3.1%, *see infra* note 114, compared with the rate in England and Wales of 22%, *see* NAT'L CONFIDENTIAL ENQUIRY INTO PATIENT OUTCOME AND DEATH, THE CORONER'S AUTOPSY: DO WE DESERVE BETTER?, 6 (2006), *available at* http://www.ncepod.org.uk/2006Report/introduction.html.

114. In 2005, medicolegal autopsies were performed in 13,570 cases. KEISATSUCHŌ [NAT'L POLICE AGENCY], HEISEI 19-NEN-CHŪ TODŌFUKEN-BETSU SHITAI SHUSŌSŪ [AUTOPSIES HANDLED, BY PREFECTURE] (2007). Hospital autopsies were performed in 19,337 cases. NIHON BYŌRI GAKKAI [JAPANESE SOCIETY OF PATHOLOGY], 48 NIHON BYŌRI BŌKEN SHŪHŌ [ANNUAL OF PATHOLOGICAL AUTOPSY CASES IN JAPAN] 1007 (2006). Together, these autopsies constitute 3.1% of the 1,083,796 total deaths in Japan for that year. MINISTRY OF HEALTH, LABOR & WELFARE, VITAL STATISTICS OF JAPAN 139 (2006) (data on file with author).

115. The best explanation of this convoluted system is found in Ken-ichi Nakane, *Wagakuni no kenshi seido* [*Japan's Death Inquest System*], 2007 REFUARENSU 96. The brief description presented here generally follows the structure of Nakane's analysis, although not all the critical comments should be attributed to him. For English-language descriptions of the system, see

When a death is criminal or suspected as such by the initial police inspection, the case is handled in uniform fashion throughout Japan. The police or prosecutor may apply to the district court for a judicial autopsy.[116] Judicial autopsies are conducted at national expense, typically by forensic pathologists.[117] Consent of the next of kin is not required. The focus is on evidence of crime, so seldom does the judicial autopsy result in a precise determination of non-criminal causes of death possibly related to medical management.[118] Even if the autopsy report were to contain such information, neither the family nor the hospital is typically allowed access during the police investigation, which may take months or years.[119] If the case is dropped, the autopsy report usually remains permanently inaccessible.[120]

In contrast to the unified system for criminal death investigations, inquiries into deaths of unknown cause for which criminal investigation is not required differ considerably from one jurisdiction to another. Among the five urban prefectures with medical examiners' offices, three (Tokyo, Osaka, and Hyogo) carry out significant numbers of administrative autopsies.[121] These medical examiners' offices, which have authority over about one-tenth of deaths nationwide,[122] are independent of the police and conduct autopsies, at prefectural expense, for public health purposes.[123] These autopsies require neither judicial authorization nor family consent. Practice regarding disclosure of administrative

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Fujimiya, *supra* note 112; and Ken-ichi Yoshida, *Report of Unusual Deaths and the Postmortem Inspection System*, *in* ENCYCLOPEDIA OF FORENSIC AND LEGAL MEDICINE 123 (2005).

116. KEIJI SOHŌ HŌ [Code of Criminal Procedure], arts. 225 & 229.

117. Police pay roughly ¥250,000-300,000 (US $2300-2800) for a judicial autopsy. Interview with Professor Ken-ichi Yoshida, Univ. of Tokyo Faculty of Med., in Tokyo, Japan (July 16, 2008) [hereinafter 2008 Interview with Yoshida].

118. *See* Fujimiya, *supra* note 112, at 147-52; Yoshida, *supra* note 115, at 126-27.

119. *E.g.*, Masahiko Idegawa, *Shiino shiraberu (3): Keiji shihō no genkai – kaibō kiroku kaiji made 3-nen* [*Death Investigations (3): The Limits of Criminal Justice – 3 Years Until Disclosure of Autopsy Record*], ASAHI SHIMBUN, Sept. 16, 2005, at 3 (reporting Hyogo case in which the prosecution delayed family access to autopsy results adverse to the hospital).

120. *See* Fujimiya, *supra* note 112, at 153; Ikegaya et al., *supra* note 33, at 116; Ryōko Hatanaka, Wagakuni ni okeru iryō jiko chōsa taisei no genzai [The Current Structure of Medical Accident Investigations in Japan], Medical Accident Information Center Symposium, Nagoya, Japan (May 27, 2006).

121. Nakane, *supra* note 115, at 110-13. The other two medical examiners' offices, in Kanagawa Prefecture (Yokohama area) and Aichi Prefecture (Nagoya area), are scarcely functioning. *Id.* at 111-12 & nn.60-65.

122. STATISTICS AND INFO. DEP'T, MINISTRY OF HEALTH & WELFARE, STATISTICAL ABSTRACTS ON HEALTH AND WELFARE IN JAPAN 2004, at 31 (2005).

123. Administrative autopsies are carried out under authority of the Shitai kaibō hozon hō [Corpse Autopsy Preservation Law], Law No. 204 of 1949, art. 8.

autopsy reports to the families and hospitals involved apparently varies.[124]

All other areas of Japan lack well-functioning medical examiners' offices, and in these regions death inquests outside the criminal sphere are carried out under a rickety system whose results vary considerably. After a police inspection finds that a death case does not require criminal handling, a police surgeon (*keisatsui*) typically enters "natural death" on the death certificate, and that is the end of the matter. The police surgeon is usually a general practitioner on contract with the police,[125] too often lacking forensic expertise[126] and without much interest in exploring possible non-criminal death causes. In these regions without medical examiners' offices, non-judicial medicolegal autopsies may be conducted only with the family's consent.[127] But for cultural reasons there is considerable resistance among the bereaved to sullying a family corpse.[128] So these "consented autopsies" (*shōdaku kaibō*) are often difficult to arrange.

One result of this splintered death inquest system is that the performance of non-judicial medicolegal autopsies for public health purposes is a relatively rare event in most of Japan—the areas lacking well-functioning medical examiner systems.[129] Imprecise cause-of-death determinations are said to be especially

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124. *See* HIDEAKI SHIROYAMA ET AL., SHINRYŌ KŌI NI KANREN SHITA SHIBŌ NO CHŌSA BUNSEKI MODERU JIGYŌ NO HŌ-SEIDO TO UNYŌ NI KAN-SURU KENKYŪ [THE OPERATION AND LEGAL STRUCTURE OF THE MODEL PROJECT FOR THE INVESTIGATION AND ANALYSIS OF MEDICAL PRACTICE-ASSOCIATED DEATHS] 5-8 (2006) (reporting disclosure of autopsy results in Osaka and Hyogo; no information on Tokyo); Interview with Professor Ken-ichi Yoshida, Univ. of Tokyo Faculty of Med., in Tokyo, Japan (July 17, 2007) (reporting nondisclosure of autopsy results in some cases in Tokyo) [hereinafter 2007 Interview with Yoshida]; Interview with Dr. Takashi Nagata, in Tokyo, Japan (Aug. 3, 2007) (same).

125. Fujimiya, *supra* note 112, at 147, 153, 154.

126. *See* Yoshida, *supra* note 115, at 124 (police surgeons have "usually not experienced forensic practice").

127. Shitai kaibō hozon hō [Corpse Autopsy Preservation Law], Law No. 204 of 1949, art. 7.

128. Prominent among these reasons is the desire to bring the body from the hospital for Buddhist funeral services. *See, e.g.*, LOCK, *supra* note 100, at 306-09 (anthropologist's exploration of public resistance in Japan to dissections); Fujimiya, *supra* note 112, at 148, 153-54.

Among East Asian societies, Japan is not the most resistant to the performance of autopsies. The autopsy rate in the Republic of Korea is considerably lower. Interview with Masashi Fukayama, Univ. of Tokyo Faculty of Med., in Tokyo, Japan (July 27, 2006); Interview with Yoshinao Katsumata, Dir., Nat'l Research Inst. for Police Sci., in Kashiwa City, Japan (July 27, 2006).

129. Tatsushige Fukunaga, *Shibō shindan/shitai ken-an shisutemu no genjō to mondaiten* [*Death Determinations and the Postmortem Inquest System*], 74 KAGAKU 1298 (2004). In the three regions with functioning medical examiner systems, autopsies were conducted in 2003 in 24-66% of deaths classed as "unnatural." In regions without well-functioning medical examiner systems, autopsies were conducted in far fewer deaths deemed "unnatural"—e.g., Kyoto (1% or less), Fukuoka (<1%), western Tokyo (4%). *Id.* 1299-1301.

prevalent in these areas.[130]

Among the various problems that have been identified with regard to Japan's death inquest system, the most important is its heavy emphasis on the investigation of crime, rather than on the determination of non-criminal causes of death in a fashion that might aid in future prevention.[131] To be sure, since professional negligence is a crime, police investigation and judicial autopsy are possible in cases of suspected malpractice. But the decision about the need for judicial autopsy, in most of the country, is made by law enforcement personnel (such as a detective or police surgeon) rather than by a qualified pathologist. If a judicial autopsy is carried out, it is performed by a forensic pathologist who may lack sufficient expertise in examining non-criminal death causes. Often, neither the family nor the hospital can obtain the autopsy results in timely fashion, if at all.[132] In most of Japan, if a family seeks a *non*-judicial inquiry into a death from a suspected iatrogenic cause, the autopsy may well be carried out at the same hospital where the death occurred, raising concerns about impartiality.[133] And in some regions that lack a medical examiner system, the family must often foot the bill.[134] If the medical facility itself seeks to carry out a hospital autopsy to

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130. Fukunaga, *supra* note 129.

131. *See, e.g.*, Fujimiya, *supra* note 112, at 156; Toshihiro Suzuki, Iryō jiko-shi kenshō shisutemu o kangaeru [A System for Investigating Accidental Medical Deaths], 1st International Forum on Patient Safety, Tokyo, Japan (Jan. 23, 2006) (on file with author); Ken-ichi Yoshida, Eibei-ken shokoku ni manabu iryō kanren-shi todokede/chōsa no kin-mirai [Notification and Review of Medical Practice-Associated Deaths in Japan: Lessons for the Near Future from Anglo-American Countries], 1st International Forum on Patient Safety, Tokyo, Japan (Jan. 23, 2006) (on file with author).

132. Hisako Takeichi, Ken-ichi Yoshida & Kazuto Inaba, *Shihō kaibō ni okeru izoku e no jōhō kaiji no mondaiten [Problems of Disclosure of Judicial Autopsy Information to the Bereaved]*, 595 HŌGAKU SEMINĀ 76-80 (2004); Yoshida, *supra* note 115, at 127; *supra* notes 119-120 and accompanying text.

133. In Aichi prefecture (Nagoya), for example, consented autopsies are performed at a different hospital than the one where the death occurred. *See* SHIROYAMA ET AL., *supra* note 124, at 5. This practice of switching autopsy sites, which prevails in Osaka prefecture as well, is designed in part to mitigate possible family concerns that the autopsy report might be part of an internal cover-up. *See, e.g.*, SUZUKI, *supra* note 19, at 57 (suspecting hospital deception in the Tokyo Women's Medical University Hospital case, the family refused consent to hospital autopsy).

Legitimate family concerns about colleague-protective autopsy reports are by no means confined to Japan. *See* Kevin E. Bove & Clare Iery, *The Role of Autopsy in Medical Malpractice Cases, II: Controversy Related to Autopsy Performance and Reporting*, 126 ARCHIVES PATHOLOGY LABORATORY MED. 1032, 1035 (2002) (noting U.S. cases generating suspicion of concealment "intended to provide protection to a colleague").

134. *See* Fujimiya, *supra* note 112, at 149, 153; Fukunaga, *supra* note 129, at 1300, 1302 (describing family payment responsibility in Yokohama and surrounding Kanagawa prefecture, and implying that in other prefectures the situation is similar); Nakane, *supra* note 115, at 111.

determine the cause of death, it must obtain the family's consent—often no easy task[135]—and bear the expense itself.[136]

In sum, Japan's death inquest system has provided little assistance in elucidating iatrogenic harm and ascertaining possible preventive measures. Neither medical circles nor families bereaved could confidently rely on the system's effectiveness in support of medical safety.

The year 2004 was a particularly stormy one for Japanese medicine and health policy administration. As the year dawned, the patient safety enterprise was a ship scarcely out of port. The dimensions of the medical error problem were uncertain, its causes not well specified, and approaches to ameliorating its effects scattershot and unfocused. The number of civil malpractice filings was mounting,[137] but peer review of physicians for patient-endangering practices was ill-developed and administrative discipline virtually nonexistent. In April 2004, the Supreme Court affirmed the conviction of the CEO of Hirō Hospital for failing to notify police of the "unnatural death" there.[138] Notifications to police of medically related "unnatural deaths" had increased eight-fold from 1998 to 2004 (Figure 1),[139] as many physicians and hospitals, confused by contradictory guidelines about Article 21's proper scope and no doubt seeking to avoid the fate of the Hirō Hospital chief, chose to err on the side of caution and send notifications whenever circumstances raised the possibility of professional negligence.[140] But the death inquest system that these notifications set in motion

135. *See* Fujimiya, *supra* note 112, at 148. Often, after the long, complicated process involving police officers and a police surgeon's examination, the family simply desires to take the remains away for mourning rituals, rather than subject the corpse to autopsy. *See* Yoshida et al., *supra* note 33, at 805.

136. 2008 Interview with Yoshida, *supra* note 117.

137. *See* sources cited *supra* note 27.

138. *See* notes 103-106 and accompanying text.

139. *Iryō jiko, jiken todokede 200-ken toppa – keisatsuchō matome, sakunen 35% zō* [*Notifications of Medical Accidents, Incidents Top 200, 35% Increase from Last Year – Police Agency Study*], NIHON KEIZAI SHIMBUN, Apr. 30, 2004, at 30 (increase from thirty-one in 1998, before the notorious Yokohama switched-patient-surgery and Hirō Hospital cases, to 255 in 2004). This enumeration included reports of injuries as well as deaths. The number of formal police investigations opened and cases sent to prosecutors on the basis of these notifications jumped from nine in 1998 to ninety-one in 2004, remaining roughly at that level since then. NAT'L POLICE AGENCY, *supra* note 47.

140. Hatanaka, *supra* note 120. Despite this eight-fold increase, it is likely that only a small proportion of medical practice-associated deaths were reported to police. *See* SAKAI, *supra* note 26 (estimating that adverse events occur in 6% of all hospitalizations).

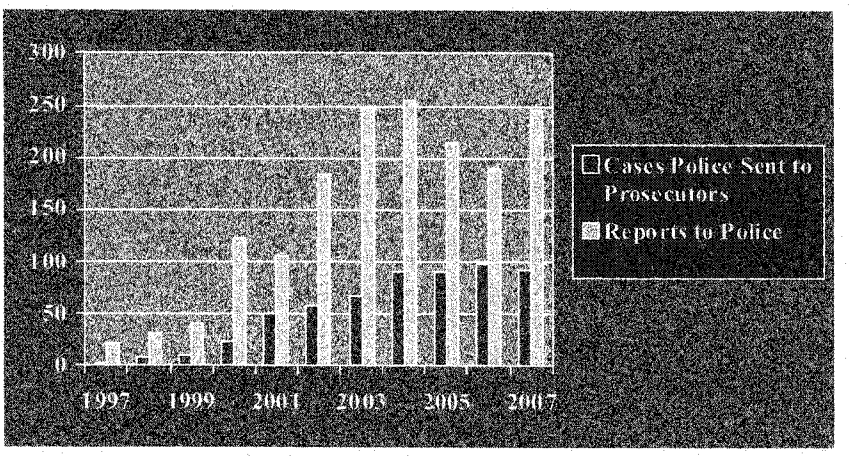

FIGURE 1: Medical Accidents Reported to Police and Cases Police Sent to Prosecutors, Japan, 1997-2007
Source: National Police Agency, Iryō jiko kankei todokede-tō kensū no idō, rikken sōchisū [Trends in Reports of Medically Related Cases and of Cases Sent to Prosecutors] (2008) (on file with author).

offered little basis for confidence that iatrogenic harm would be discovered, much less prevented. In the midst of these inauspicious circumstances, the "Model Project" was conceived and fashioned.

III. THE "MODEL PROJECT" AND THE PROPOSED NATIONAL PEER REVIEW SYSTEM

A. Inception and Operation of the Model Project

Japan's medical leaders deplored intensified police involvement in the monitoring of medical practice, but also felt keenly the weakening of public trust in medicine and understood the need for clearer accountability in the handling of medical accidents. Four medical specialty societies, representing internists, surgeons, clinical pathologists, and forensic pathologists, issued a joint declaration in April 2004 calling for the creation of a new system to conduct reviews of possibly iatrogenic deaths, inform the parties of the facts found, and offer preventive solutions.[141] The proposed new entity would be staffed by impartial experts and would be separate from the police.[142] The idea appealed to other medical groups, allowing them to paper over (at least temporarily) their differences in support of the concept of what came to be called "third party" (*dai-san-sha,* i.e., independent both of the hospital at which the accident occurred and

141. Joint Declaration, *supra* note 53.
142. *Id.*

of the patient and family) review.[143]

The health ministry, its medical safety office understaffed and beset with difficulties in the operation of the accident reporting system,[144] saw the proposal as an opportunity to move safety efforts forward and agreed to fund the effort on a five-year trial basis, perhaps to serve as a model for a nationwide peer review system. The Ministry of Justice and the National Police Agency adopted a stance of implicit acquiescence, giving up none of their jurisdiction to enforce the laws relating to medical crime and making no definitive public commitment to change any practices, but content to allow the experiment to proceed without hindrance.[145]

The health ministry launched the "Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths" in September 2005, initially in four regions, expanded to eight as of this writing.[146] The Model Project (*moderu jigyō*) works in the following manner.[147]

When a patient dies in circumstances possibly related to medical management, the hospital may apply to the region's Model Project office for an investigation. The initiative must come from the hospital, not the patient's family, though the family's consent is necessary.[148] Cases falling within the

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143. Nihon igakkai kamei no omo na 19 gakkai no kyōdō seimei [Joint Declaration of the 19 Chief Societies of the Japanese Association of Medical Sciences] (2004), http://www.mhlw.go.jp/shingi/2007/08/dl/s0810-6b_0005.pdf.

144. *See supra* notes 96-97 and accompanying text.

145. *See Kensatsukan: Kokumin no me tsune ni ishiki* [*Prosecutors: Always Conscious of the Public's Gaze*], YOMIURI SHIMBUN, May 30, 2006, at 7 (interviewing Prosecutor-General Kunihiro Matsuo); Ken-ichi Yoshida, *Iryō kanrenshi: Shinryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō – Tokyo chiiki heisei 17-nendo no sōkatsu* [*Medical Practice-Associated Deaths: The Model Project on Medical Practice-Associated Death: 2005 Summary for the Tokyo Region*], 24 BYŌRI TO RINSHŌ BESSATSU 535, 536 (2006).

146. In Japanese, the Model Project is styled *Shinryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō*. The Project was launched in Tokyo, Osaka, Aichi (Nagoya) and Hyogo (Kobe) prefectures, and has been expanded to include Ibaraki, Niigata and Fukuoka prefectures and the Sapporo area in Hokkaido as well. Okayama and Miyagi are the next prefectures targeted for inclusion. *See* Shinryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō dai-18-kai un'ei iinkai giji shidai [Reference Materials for the 18th Meeting of the Model Project Steering Committee] attachments 3-1 to -3 (July 23, 2008), *available at* http://www.med-model.jp/download/proceedings18.pdf [hereinafter Model Project July 2008 Reference Materials].

147. The basis for much of the outline of the Model Project's methods in the following two paragraphs is set out in the website for the Model Project, http://www.med-model.jp (last visited Dec. 4, 2008). The remainder has been gleaned from interviews with various people familiar with the project's workings. An English-language summary of Model Project procedures is available in SHIROYAMA ET AL., *supra* note 124, at 63-90.

148. The usual explanation for this apparent anomaly is that the hospital management is more likely to be aware of the existence of the Model Project than the family. Interview with Katsushi

scope of Article 21, however that scope is understood, must still be reported to the police. (If, after prompt initial inquiry, the police suspect crime and decide to proceed with an investigation and judicial autopsy, the case is not submitted to the Model Project.) Regional offices, each headed by a physician coordinator, vary somewhat in their approach—the Osaka office always consults the police before accepting a case, for example, while the Tokyo office sometimes has not when no Article 21 notification was thought necessary—but in general an investigation proceeds according to a standard approach.

If the Model Project's regional office accepts the case, the office quickly assembles a team of three physicians not connected with the hospital—a clinical pathologist, a forensic pathologist, and a specialist in the field of the patient's treatment—to conduct a thorough autopsy to determine the cause of death. A separate "evaluation committee" obtains the patient's medical records, interviews hospital staff involved in the patient's care, and encourages the hospital to conduct its own investigation. This evaluation committee includes a member of the autopsy team, an attorney, and outside medical experts nominated by the various specialty societies. The evaluation committee prepares a report setting out the facts of the case, a medical (not legal) evaluation of the course of care, and conclusions on how the accident could have been prevented. This report, together with the autopsy report and other relevant material, is shared with both the family and the hospital, originally by a target date of three months after the case's submission. After review by the Model Project's Tokyo-based steering committee, which includes eminent physicians, academics, and attorneys from both plaintiff and defense bars, a summary of the report is made public, with names of patient, medical staff, hospital, and location redacted.

Although as a formal matter, the Model Project has nothing to do with liability claims, the evaluation committee's report is potentially available for use as evidence in both civil[149] and criminal litigation.[150] However, it is envisaged

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Tahara, Director, Ministry of Health, Labor and Welfare, Office of Medical Safety, in Tokyo, Japan (June 23, 2006) [hereinafter Interview with Tahara].

149. For discussions of a 2003 Tokyo High Court decision allowing disclosure of part of a hospital's internal report concerning a patient's death to the patient's family, see Leflar & Iwata, *supra* note 15, at 207-08; and Manabu Wagatsuma, *Iryō jiko keika hōkokusho no teishutsu gimu* [*The Duty to Submit Reports on the Course of Medical Accidents*], 183 JURIST 42 (2006).

150. Interview with Tahara, *supra* note 148. Japanese law, in which judges are the fact-finders, has few of the restrictions on admissibility of relevant evidence found in common-law systems relying on juries for fact determinations.

According to a memorandum of understanding between MHLW and the Ministry of Justice, if the police demand information obtained by a Model Project evaluation committee, the project managers are "not absolved from the duty [to comply with the police demand]" ("*gimu o manugareru koto de wa nai*"). This phrase is sufficiently ambiguous to admit of two interpretations: one by alarmed representatives of medical groups that police demands *cannot* be refused, and another, by Model Project representatives seeking to reassure physicians, that police

that the formulation of the report may foreclose the need for most civil litigation and discourage the bringing of prosecutions.[151] Suspicions on the part of the bereaved about what befell the patient are the reason for many lawsuits and complaints to police. The evaluation committee report clarifies the facts, allaying these suspicions. With regard to civil claims, where the facts found indicate the likelihood of a successful claim, it is thought that the evaluation committee's authoritative report may facilitate a rapid settlement.[152] With regard to criminal prosecutions, in most cases taken up by the Model Project, the police initially receive an Article 21 notification and then decline to open an investigation.[153] As of this writing, police have evinced an attitude of restraint, standing back while the Model Project evaluations run their course.[154]

B. The Model Project: A Tentative Evaluation

As a concept, there is much to be said in favor of the Model Project. The

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demands *should not* be refused but are not legally compulsory. During at least the early period of the Project's operation, apparently the police did not make any such demands for information. Interview with Ryōko Hatanaka, Shakai gijutsu kenkyū kaihatsu sentā [Research Institute of Science and Technology for Society] in Tokyo, Japan (June 15, 2006) [hereinafter Interview with Hatanaka].

151. *See, e.g.*, Hikaru Tanaka, *Iryō jiko funsō shori seido no dōnyū kentō; Kōrōshō "saiban yori jinsoku" ni kitai* [*Study of Introducing Dispute Resolution System for Medical Accidents; MHLW Expectation: "Quicker than Lawsuits"*], ASAHI SHIMBUN, June 29, 2005, at 3.

152. *Id.*

153. Interview with Akira Maemura, Reporter, *Nikkei Shimbun*, in Tokyo, Japan (Aug. 13, 2008) [hereinafter Interview with Maemura]; *see also* Mitsuru Sawa & Seisaku Uchigasaki, *Iryō kanrenshi moderu jigyō: Kono 1-nen o furikaette – Iryō kanrenshi ni kansuru moderu jigyō ni jian o todokedeta byōin no tachiba kara* [*Looking Back on One Year of the Model Project for Medically Related Deaths: The Perspective of a Participating Hospital*], 108 NIPPON GEKA GAKKAI ZASSHI 89 (2007) (reporting an example of a case at Itabashi Hospital in Tokyo where the hospital initially notified police, who after initial inquiries determined the case to be non-criminal and referred it back to the Model Project); Model Project July 2008 Reference Materials, *supra* note 146, at attachment 1 (of 202 hospital death cases in which the Model Project was contacted, only twenty-three were declined by the Project on grounds that a judicial or administrative autopsy was called for by the police or medical examiner). In four of the first twenty-three cases submitted to the Model Project, however, the hospitals made no Article 21 notification. Katsushi Tahara, Presentation at the University of Tokyo, Shinryō kōi ni kanren shita chōsa bunseki moderu jigyō ni tsuite [The Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths] (July 8, 2006) (on file with author).

154. *See* SHIROYAMA ET AL., *supra* note 124, at 11 (example of police restraint in Aichi Medical University Hospital case). Those managing the Model Project have counted on criminal justice officials to recognize that if evidence gathered through Model Project investigations becomes fodder for prosecutions of medical personnel, the Model Project would immediately be viewed by the medical world as merely a tool of the police, dooming the project to utter failure.

quality of the case reviews, on the whole, is likely superior to those typically undertaken in the past: three experts from different fields participate in each autopsy and are joined by other specialists on the evaluation committee.[155] The fact that the reviews are conducted by outside experts, typically of high reputation, brings objective, up-to-date knowledge to bear on the review process.[156] This also insulates the process from widespread public suspicion of internal self-protection generated by the string of hospital cover-ups exposed over the last several years. Heavy police involvement is avoided, absent exceptional circumstances.[157] The gain in transparency is dramatic: information gathered in the Model Project review is made available in detailed form both to the family and to the hospital, although the summary released to the public is less comprehensive.[158] The evaluation committee's specific recommendations for quality improvement should assist the formulation of particularized preventive measures against future injury, especially if the recommendations are widely circulated. The trustworthiness of the evaluation committee reports may prove to facilitate speedy extrajudicial redress for deserving families.

However, the Model Project got off to a somewhat rocky start, and case uptake has not met original expectations. MHLW aimed to conduct 200 autopsies during the first year of the project's operation.[159] In fact, over the first 2¾ years only seventy cases had been undertaken by the project, a rate of just twenty-five cases per year.[160] The reasons for the low case uptake are complex. Cooperation from hospitals in the participating regions is uneven. In part, this is because the Model Project's existence was at first little known to physicians and hospital administrators, and its purposes were poorly understood.[161] Some physicians and

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155. Putting members of the rival specialties of clinical pathology and forensic pathology on the job together should also have the long-term effect of diminishing the tribal antagonism between the two groups.

156. *See* Judy Kinkelaar Ring & Barry Slotky, *Independent Review Supports Transparency*, 5 PATIENT SAFETY & QUALITY HEALTHCARE 48, 48 (2008).

157. *See supra* notes 153-154 and accompanying text.

158. For summaries of cases completed through July 2008, see Model Project July 2008 Reference Materials, *supra* note 146, at attachment 2.

159. MODEL PROJECT CENT. OFFICE, SHINRYŌ KŌI NI KANREN SHITA SHIBŌ NO CHŌSA BUNSEKI MODERU JIGYŌ: HEISEI 18 NEN-DO JIGYŌ JISSHI HŌKOKUSHO [REPORT ON THE OPERATION OF THE MODEL PROJECT FOR THE INVESTIGATION AND ANALYSIS OF MEDICAL PRACTICE-ASSOCIATED DEATHS FOR THE YEAR 2006] 26 (2007), *available at* http://www.med-model.jp/download/download_jigyou18.pdf. This number may have been set on the high side by MHLW personnel to justify an adequate budget. Interview with Maemura, *supra* note 153.

160. Model Project July 2008 Reference Materials, *supra* note 146, at attachment 1. Of seventy cases undertaken, only fifty-seven reports have been completed and submitted to families and hospitals as of this writing. *Id.*

161. Tetsu Yamaguchi, Address at the 106th Annual Meeting of the Japan Surgical Society: Ijōshi no todokede to iryō kōi ni kanren shita shibō no chōsa bunseki moderu jigyō [Unnatural

hospitals, concerned that reports produced by Model Project evaluation committees might be used by police as evidence of medical crime,[162] may have withheld cases from the project for that reason. As noted above, applications to submit cases to the Model Project for review must come from hospitals, not from aggrieved families (though family consent is necessary). While this stricture may have been understandable as an initial means of encouraging hospital participation, it has tended to rule out cases in which hospitals judge that their interests would be adversely affected by outside review. Then as the project progressed with relatively few cases submitted, hospital administrators may have found no compelling trend to invoke the project's process, no herd to follow.[163]

A second set of reasons for the Model Project's slow start relates to family concerns. As explained above, there exists a widespread cultural resistance to consenting to autopsies, which are at the core of the Model Project's method.[164] Also, as a practical matter, family members' first concern is with mourning the deceased. Often, only after the first stage of grieving do they turn attention to the possibility that substandard medical care might have occurred; but after cremation, autopsy is no longer possible.[165]

Even though the Model Project has undertaken fewer cases than expected, it has encountered various difficulties in implementation, and limitations have become evident that must be addressed before its methods and design can be expanded to a nationwide scale. First, personnel are stretched thin: the project is

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Death Notification and the Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths] (Mar. 29, 2006).

162. *See* SHIROYAMA ET AL., *supra* note 124, at 15; Interview with Hatanaka, *supra* note 150. The 2006 arrest of the Ohno Hospital obstetrician, *Medical Blunders*, *supra* note 23, lent some cogency to this concern, since the Fukushima police acted on the basis of the hospital's own internal self-critical investigation. *Sanka-i taihō ni konwaku; chōshu 1-nen, naze ima – Fukushima kenritsu byōin/teiō sekkai misu-shi [Perplexity over Doctor's Arrest in Fukushima C-section Death – Why a Year After Inquiry?]*, ASAHI SHIMBUN, Mar. 8, 2006, at 2. However, Fukushima is not one of the Model Project regions, so perhaps police restraint there was less to be expected.

163. Interview with Dr. Yasuyuki Sahara, Chief, Ministry of Health, Labor & Welfare, Office of Medical Safety, in Tokyo, Japan (July 15, 2008) [hereinafter Interview with Sahara].

164. *See* Fujimiya, *supra* note 112 (reluctance to consent to autopsies); Yoshida, *supra* note 145, at 535; Yōko Takeda, Kōseirōdōshō no shinryō ni kanren suru shibō no chōsa bunseki moderu jigyō – chōsei kangoshi (kōdinētā) no shigoto [The Role of the Coordinating Nurse in the MHLW Model Project on Medical Practice-Associated Death], 1st International Forum on Patient Safety, in Tokyo, Japan (Jan. 23, 2006) (on file with author).

During the first two years and nine months of the Model Project, of the 202 cases about which Project offices were initially contacted, 132 were never undertaken by the Project. The most common reason (forty-one cases) was the family's lack of consent. Model Project July 2008 Reference Materials, *supra* note 146, attachment 1. One would surmise that reluctance to allow an autopsy often contributed to the refusal of consent.

165. Interview with Sahara, *supra* note 163.

staffed on a part-time basis by physicians and nurses, almost all of whom have other full-time jobs. Delays in completing reports have been the rule: The mean time from submission of a case to explanation of the final report to family and hospital is 10.1 months,[166] compared to the originally contemplated deadline of three months.[167]

Second, the Model Project has been hampered by the weaknesses in Japan's death inquest system. Currently, the project is confined to regions where sufficient pathology expertise is available. The number of clinical (hospital) pathologists is not large, and the count of forensic pathologists is even smaller.[168] In many prefectures there may be only one or two forensic pathologists based at the local university.[169] The three-specialist autopsy, which is standard practice in the Model Project, is logistically difficult in these regions and is likely a cause of delay and unneeded expense even in regions with greater numbers of pathologists. A more efficient evaluation system should be considered, involving a less intensive commitment of professional resources, utilization of advanced imaging technology, and coordination with hospitals' internal investigation committees in instances where those committees have demonstrated effectiveness.

Third, variations in standards applied to Model Project case reviews have engendered significant criticisms. Dr. Tetsu Yamaguchi, CEO of Tokyo's well-known Toranomon Hospital and a leader of the Model Project's steering

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166. MODEL PROJECT CENT. OFFICE, SHINRYŌ KŌI NI KANREN SHITA SHIBŌ NO CHŌSA BUNSEKI MODERU JIGYŌ: JIGYŌ JISSHI HŌKOKUSHO [REPORT ON THE OPERATION OF THE MODEL PROJECT FOR THE INVESTIGATION AND ANALYSIS OF MEDICAL PRACTICE-ASSOCIATED DEATHS] 81-82 (2008), *available at* http://www.med-model.jp/download/download_jigyou19.pdf. None of the completed final reports met the initial three-month deadline. *Id.* One survey found the delays to have been a significant source of frustration to the families involved. Norihiro Nakajima, Hisako Takeichi & Ken-ichi Yoshida, Moderu jigyō no hyōka – Irai iryō kikan to moderu jigyō kaibō jūjisha no shiten kara [Evaluation of the Model Project from the Perspectives of the Participating Hospitals and Autopsy Physicians] (2007) (unpublished draft report to MHLW) (on file with author). However, a leader of the Model Project's steering committee suggested that what is most important is taking the time to get the reports right, and that the delays may have the positive effect of interposing a cooling-off period between families and hospitals. Interview with Yamaguchi, *supra* note 86.

167. MODEL PROJECT CENT. OFFICE, *supra* note 159, at 10 (noting extension of deadline from three to six months).

168. There are 1928 hospital pathologists working in Japan. Only 119 forensic pathologists have been accredited by the Japan Society of Legal Medicine to perform complete autopsies. Inclusion of graduate students and research assistants who assist with autopsies in university forensic pathology departments pushes the total up to 253. Dai-3-kai shiin kyūmei-tō kentōkai sankō shiryō [The Commission on the Investigation of Causes of Medical Practice-Associated Deaths] 27-28 (2007), http://www.mhlw.go.jp/shingi/2007/06/dl/s0608-4d_0010.pdf. Forensic autopsies are also performed by non-certified personnel trained in the field. Yoshida, *supra* note 115, at 125.

169. Interview with Yoshida, *supra* note 124.

committee, has emphasized that the training of physicians in reviews of clinical practices based on consistent standards is a critical need.[170]

Fourth, the Model Project addresses only death cases. Its chief impetus was the medical world's strong distaste for police involvement in the review of medical practices, and it is usually an Article 21 "unnatural death" notification that triggers police involvement. The exclusion of cases of serious injury may have served the useful initial purpose of keeping the number of case reviews within manageable limits while the enterprise was gearing up. But limiting the project's scope also means that the benefits accruing from systematic impartial external peer review, such as objective evaluation, transparency, and building of public trust,[171] are correspondingly confined to death inquiries. This restriction also limits the number and scope of evaluations from which quality improvement lessons can be drawn. The system would have to be adapted considerably to handle the much broader range of injury cases.

Fifth, the Model Project lacks explicit statutory authorization. It has been operating solely under health ministry auspices, relying on voluntary cooperation by medical providers and patients. If an evaluation committee requests documentation on a case and the hospital refuses to provide it, the committee lacks legal power to obtain that information.[172] This problem requires a legislative remedy if independent reviews are to be instituted nationwide.

Sixth is the question of long-term funding. The intensive case reviews conducted in the Model Project require considerable time commitments from participating experts and the part-time project staff, much of that time volunteered. The Project's annual budget has increased from an initial ¥102 million (US $0.9 million)[173] to ¥127 million (US $1.1 million) in FY 2008 and ¥177 million (US $1.6 million) in FY 2009.[174] But this is a modest budget indeed. It has sufficed so far, due in part to experts' and staffers' enthusiasm for participating in a unique endeavor seen as having national significance, and in part to the unexpectedly small number of cases submitted. But volunteer enthusiasm is unlikely to sustain such an endeavor in the long run. In an era of budget and personnel retrenchment in the public sector and financial constraints in health care,[175] it will take a substantial political commitment to expand the

170. Interview with Yamaguchi, *supra* note 86.

171. *See* Ring & Slotky, *supra* note 156.

172. Interview with Tahara, *supra* note 148.

173. MINISTRY OF HEALTH, LABOR & WELFARE, HEISEI 17-NENDO YOSAN (AN) NO GAIYŌ (KŌSEIRŌDŌSHŌ ISEIKYOKU) [2005 DRAFT BUDGET FOR MHLW HEALTH POLICY BUREAU], *available at* http://www.mhlw.go.jp/topics/2005/bukyoku/isei/yosan1.html.

174. E-mail from Dr. Yasuyuki Sahara, Chief, Ministry of Health, Labor & Welfare, Office of Medical Safety, to author (Aug. 25, 2008) (on file with author).

175. *See, e.g.*, *Hoken no gensoku hataraku shikumi ni* [*Toward a System that Functions on Insurance Principles*], NIHON KEIZAI SHIMBUN, June 4, 2008, at 27.

enterprise nationwide after the five-year trial period ends in 2010.

Finally, and most significantly, lurking in the background of the medical safety debate is the specter of criminal prosecution. The boundary between cases subject to prosecution for the crime of professional negligence causing death or injury[176] and cases merely subject to civil liability or administrative sanction needs clearer delineation. As with any definition of a crime, the line between acts that are punishable and acts that are not inevitably will be indistinct in some cases, subject to interpretation and most importantly to prosecutorial discretion. But for any system of peer review to work, health care personnel need reliable assurance that ordinary human errors will not invite police interrogation.

Still, the Model Project carries within it the seeds of significant advances. In the midst of a society still largely structured on a vertical, hierarchical basis where collaboration among different disciplines is difficult, the project has collected under one roof physicians from varied and sometimes rival fields of medicine, nurses, plaintiffs' and hospital lawyers, academics, and health bureaucrats. These may be strange bedfellows with different motives and goals, or as the Japanese saying puts it more picturesquely, *dōshō-imu* ("same bed, different dreams"), but they are gaining experience working together in a common enterprise and creating a model for interdisciplinary cooperation. The need for a system of impartial review of medical accidents is clearly recognized, and the Model Project serves as a road test for the creation of such a system. Through the Model Project experience, recognition of the importance of reforming the nation's fragmented death inquest system is beginning to grow. Experience may prove that the expert reports generated by the project's reviews will lead to smoother resolution of medical injury claims, setting a guidepost for alternative dispute resolution systems—a guidepost from which other nations seeking better ways of handling medical injury disputes, including the United States, may find useful direction.

C. The Proposed National Peer Review System and Its Critics

Pursuant to resolutions passed in 2006 by the Committees on Health, Labor and Welfare of the Japanese Diet,[177] a blue-ribbon commission under health ministry auspices studied the possibility of expanding the Model Project's

176. *See supra* notes 61, 65 and accompanying text.

177. Sangiin Kōseirōdō Iinkai [House of Councillors Comm. on Health, Labor & Welfare], Resolution Relating to Proposals for Revision of the Health Insurance Law and the Medical Care Law, at 21 (June 13, 2006), *available at* http://www.mhlw.go.jp/shingi/2007/06/dl/s0608-4d_0009.pdf; Shūgiin Kōseirōdō Iinkai [House of Representatives Comm. on Health, Labor & Welfare], "Anzen de shitsu no takai iryō no kakuho, jūjitsu ni kansuru ken" ni tsuite ketsugi [Resolution Concerning the Provision and Assurance of Safe, High-Quality Health Care], at 21 (June 16, 2006), *available at* http://www.mhlw.go.jp/shingi/2007/06/dl/s0608-4d_0009.pdf.

method of independent expert review of medical accidents nationwide.[178] Their study included a series of public hearings, public comments on three successive proposals, and informal negotiations with stakeholders from the health care sector, the ruling Liberal Democratic Party, and patients' groups.[179] In June 2008, the commission proposed new legislation building on the basic structure of the Model Project, but modifying it to address most of the Project's weaknesses noted above. The proposed legislation aims to create what would amount to a national system of peer reviews, *external* to the hospitals involved, of fatal medical accidents.

The proposal would establish "regional medical accident review commissions" to conduct the medical-practice-associated death inquiries that are currently the responsibility of the police under the infamous Article 21.[180] The purpose of the commissions' reviews would not be to determine liability, but rather to use the information found in cause-of-death investigations to develop recommendations for improving medical safety.[181] Physicians would be obligated to report to hospital management cases of inpatient deaths suspected either to have resulted from medical error or to have been caused by an unforeseen result of medical treatment, and hospital management in turn, after checking the facts, would have a duty to notify the regional commissions of these cases.[182] Physicians' and hospitals' existing obligation under Article 21 to notify the police of such cases would be extinguished.[183] Bereaved families could also invoke regional commission review, without hospital consent, and regardless of

178. The blue-ribbon commission is the Shinryō kōi ni kanren shita shibō ni kakaru shiin kyūmei-tō no arikata ni kansuru kentōkai [Commission on the Investigation of Causes of Medical Practice-Associated Deaths], chaired by Dean Masahide Maeda of Shuto University Tokyo. Its proceedings and reports are available at http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/index.html (follow "Shiin kyūmei-tō no kentō ni tsuite" hyperlinks near the bottom of the page).

179. Ministry of Health, Labor & Welfare, Shinryō kōi ni kanren shita shibō no shiin kyūmei-tō no arikata ni kansuru kadai to kentō no hōkōsei [Working Plan on Issues Regarding the Investigation of the Causes of Medical Practice-Associated Deaths (First Proposal)] (Mar. 2007), *available at* http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/dl/2a.pdf; Dai-2-ji shian [Second Proposal] (Oct. 2007), *available at* http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/dl/2e.pdf; Dai 3-ji shian [Third Proposal] (Apr. 2008), *available at* http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/kentou/dl/2f.pdf.

180. *See supra* notes 98-111 and accompanying text.

181. MHLW June 2008 Draft Proposal, *supra* note 32, arts. 1 & 12, para. 1. The health ministry proposal's nickname, "*jiko-chō*," is taken from the name of the medical accident review commissions, *iryō jiko chōsakai*.

182. *Id.* art. 32, paras. 2(1), 2(4), 3.

183. *Id.* art. 33. Article 21 itself would remain on the books, so notification to police of deaths from violent crimes, suicide, contagious infection, and the like would still be required.

whether the hospital management had notified the case to the commission.[184] The regional commissions, composed chiefly of medical experts but also including non-medical members, would be tasked with reviewing the cases (in cooperation with but independently of hospitals' internal review processes),[185] compiling reports on the cases, and suggesting prevention measures. The regional commissions would have the power not only to question health care personnel involved in the incidents and to conduct autopsies, but (unlike Model Project evaluation committees) could also compel the production of documents and reports from the hospital.[186]

Hospital management would have an explicit legal duty to explain honestly to the family the circumstances and causes of the patient's death.[187] In cases involving system errors (in addition to mistakes by individual caregivers), prefectural governments would be given new authority to impose "improvement orders" on hospitals.[188] A National Medical Accident Review Commission would gather reports compiled by the regional commissions, analyze them, and formulate and disseminate nationwide recommendations for the prevention of similar accidents in the future.[189]

The criminal justice system would still have a role to play under the health ministry's proposal, albeit a diminished one, since the Criminal Code provision sanctioning "professional negligence causing death or injury" would remain.[190] The regional commissions would be required to report cases to police in the following four situations:

1) deaths suspected to have been intentionally caused (e.g.,

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184. *Id.* art. 15. This would expand families' rights compared with the Model Project structure. *Cf. supra* note 148 and accompanying text.

185. Third Proposal, *supra* note 179, para. 32. An exception would be made for a category of large high-level hospitals deemed to have adequate internal review processes, *tokutei kinō byōin*. These hospitals would be authorized to conduct their own case reviews in lieu of regional commission review, as long as the review team included members external to the hospital. *Id.* paras. 33-35.

186. MHLW June 2008 Draft Proposal, *supra* note 32, art. 17.

187. *Id.* art. 32, para 1. Some Japanese courts have already determined that such a duty exists as a matter of contract law, as an implied term of the patient-provider agreement. *See, e.g.*, 1907 HANREI JIHŌ 112, 124-25 (Kyoto D. Ct., July 12, 2005); 1194 HANREI TAIMUZU 243 (Tokyo D. Ct., Jan. 30, 2004), *aff'd in relevant part*, 1880 HANREI JIHŌ 72 (Tokyo High Ct., Sept. 30, 2004) (on both contract and tort grounds); *see also* Leflar & Iwata, *supra* note 15, at 212-13 (describing cases).

188. MHLW June 2008 Draft Proposal, *supra* note 32, art. 32, para. 6.

189. *Id.* art. 4, para. 6.

190. KEIHŌ [Criminal Code], art. 211, para. 1; *see also supra* notes 61-65 and accompanying text.

euthanasia);[191]

2) deaths suspected to have resulted from "grave negligence" (*jūdai na kashitsu*),[192] defined as "extreme deviation from standard medical care";[193]

3) deaths involving the suspected concealment, alteration, or forging of medical records with the purpose of covering up the facts;[194] and

4) deaths suspected to have resulted from repeated negligence by a practitioner who has caused similar medical accidents, or engaged in other suspected similar serious misconduct.[195]

Families could still lodge complaints independently with the police, a right that is guaranteed under the Criminal Procedure Code.[196] The National Police Agency has informally agreed, however, to "recommend" to complainants that cases first be presented to the regional commissions for expert evaluation.[197] In an attempt to reassure the medical profession, the police agency has also informally agreed to respect the commissions' evaluations and to carry out its law enforcement responsibilities using the commissions' conclusions as its primary basis.[198]

The health ministry proposal was hammered out through negotiations among various stakeholders within and outside government, including medical groups, top Diet members with health policy interests, the National Police Agency, and the ministries of justice and finance. The proposal has been agreed to in principle by the governing Liberal Democratic Party (LDP) and the Japan Medical Association leadership, and it is supported by patients' rights groups.[199]

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191. MHLW June 2008 Draft Proposal, *supra* note 32, art. 25, para. 1.

192. Third Proposal, *supra* note 179, paras. 39, 40(3).

193. *Id.* para. 40(3); MHLW June 2008 Draft Proposal, *supra* note 32, art. 25, para. 2. The regional commissions would make case-by-case determinations taking into account factors such as the size of the health care facility, the geographical environment, the level of experience of the caregivers, whether an emergency situation existed, and whether the facility had adequate overall safety systems in place. *Id.*

194. *Id.* art. 25, para. 3.

195. *Id.*

196. KEIJI SOSHŌ HŌ [Code of Criminal Procedure], arts. 230-32 (kokuso no kenri).

197. Ministry of Health, Labor & Welfare, Iryō anzen chōsa iinkai (kashō) no iken boshū ni tsuite [Request for Public Comments on Medical Safety Review Commission Proposal] 11 (2008), *available at* http://www.mhlw.go.jp/seisaku/dl/05a.pdf [hereinafter MHLW Request for Public Comments].

198. *Id.* at 10.

199. *See* Masafumi Tatematsu & Atsuhiko Hayashi, *Iryō jiko chōsa no soshiki-zukuri: Giron*

Nevertheless, the proposal sparked a firestorm of criticism and as of this writing is by no means certain of enactment. The criticisms have come mainly from physicians and some medical groups, as well as from members of the opposition Democratic Party of Japan. The chief criticisms of the proposed legislation are these:

> 1) The definition of "grave negligence" in the legislation is insufficiently precise. Practitioners would not know what acts would be considered illegal. This uncertainty would tend to retard innovative non-standard practices.[200]
>
> 2) The regional review commissions constitute an unnecessary expansion of government. Patients and doctors should work out problems among themselves, without creation of a new bureaucratic apparatus.[201]
>
> 3) Reports compiled by the review commissions, and even documents and interview notes obtained during their investigations, could be available for use against hospitals and health care personnel in criminal, civil, and administrative discipline proceedings.[202]
>
> 4) The main beneficiaries of the review commissions' reports will be plaintiffs' attorneys, who will use the review commissions' reports to

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ōzume, chūmon aitsugu [*Building a Structure for Medical Accident Review: Debate Enters the Endgame; Demands Pile Up*], ASAHI SHIMBUN, May 22, 2008, at 33 (noting positions of various groups); Iryōban jikochō: Kinkyū kōkai shimpō [Emergency Public Symposium on the Medical Accident Review Commission Proposal], in Tokyo, Japan (Aug. 4, 2008) (statements of patients' group leaders) (on file with author).

200. *See, e.g.*, Masahiro Kami, Iryō kaikaku no genzai [Medical Reform Today], 6th Annual Urology Seminar, in Tokyo, Japan (Aug. 2, 2008) (on file with author). The definition of "grave negligence" is of concern to many medical specialty societies. Nihon Igakkai [Japan Ass'n of Med. Sciences], "Iryō no anzen no kakuho ni muketa iryō jiko ni yoru shibō no gen'in kyūmei saihatsu bōshi no arikata ni kansuru shian – dai-3-ji shian" ni kansuru Nihon Igakkai no kenkai [Opinion of the Japan Association of Medical Sciences on the "Third Proposal Concerning a Medical Safety-Oriented System for Cause-of-Death Investigations and Prevention of Recurrences of Fatal Medical Accidents"], *available at* http://jams.med.or.jp/news/007.html (last visited Dec. 4, 2008) [hereinafter JAMS Opinion].

201. *See, e.g.*, Kami, *supra* note 200.

202. Statement of Hirotoshi Nishizawa, President, Zen Nihon Byōinkyokai [All Japan Hosp. Ass'n] (May 12, 2008) (on file with author). According to the health ministry's explanation, however, interview notes and other groundwork on which final commission reports are based would not be released to investigatory authorities absent a court order. MHLW Request for Public Comments, *supra* note 197, at 11.

bolster their cases.[203]

5) The proposal is punitive rather than ameliorative in its methods and perspectives. It does not eradicate criminal law's intervention into medical practice. It would accelerate, not retard, "*iryō hōkai*," medicine's collapse.[204]

Taking account of these criticisms, Senator Kan Suzuki of the Democratic Party of Japan (DPJ) put forward a counterproposal, the "Patients' Support Act," in June 2008.[205] The DPJ proposal has points in common with that of the health ministry, but differs in important respects.

The focus of the DPJ proposal is not so much on elucidating the causes of medical accidents and preventing them, as it is on facilitating the resolution of disputes between hospitals and patients and families. The DPJ proposal would lodge the responsibility for reviewing medical accidents (serious injuries as well as deaths) not in regional commissions established by government, as in the health ministry's plan, but rather in the hospitals themselves.[206] A key concept in the DPJ plan is internal mediation:[207] hospitals would be required to employ or

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203. Kami, *supra* note 200. The lawyer-bashing tactic draws on U.S. tort reform rhetoric.

204. A common theme of the medical blogs is a criticism of what is said to be the health ministry proposal's punitive nature. *See infra* note 217.

205. Iryō ni kakaru jōhō no teikyō, sōdan shien oyobi funsō no tekisei na kaiketsu no sokushin narabi ni iryō jiko-tō no saihatsu bōshi no tame no Iryō Hō-tō no ichibu o kaisei suru hōritsu (kashō) an kosshi shian (tsūshō: Kanja shien hōan) [Outline of Proposed Act To Amend the Medical Services Law To Provide Information Relating to Medical Care, Counseling/Support and Proper Resolution of Disputes, and Prevent Recurrence of Medical Accidents (tentative title); Short title: Patients' Support Act] (June 2008) (on file with author) [hereinafter DPJ June 2008 Proposal]; *see also* The Democratic Party of Japan, Jūten seisaku 50 [50 Key Policies], http://www.dpj.or.jp/special/jyuten50/01.html#04 (summary on DPJ website) (last visited Dec. 4, 2008); Kempou38 no burogu, Minshutō sangiin-iin Suzuki Kan-shi ni kiku: "Iryō jiko-chō" no "Suzuki shian" to Kōrōshō no kashitsu [Interview with DPJ Senator Kan Suzuki: The "Suzuki Proposal" for Medical Accident Review Commission and MHLW's Negligence], http://ameblo.jp/kempou38/entry-10102377584.html (June 2, 2008) (blog interview of Sen. Kan Suzuki, summarizing key aspects of his proposal and criticizing the MHLW proposal).

206. DPJ June 2008 Proposal, *supra* note 205, tit. 1, art. 3, para. 2.

207. The standard Japanese phrase is *naibu ADR* [internal ADR]. A noted proponent of this concept is Professor Yoshitaka Wada. YOSHITAKA WADA & TOSHIMI NAKANISHI, IRYŌ KONFURIKUTO MANEJIMENTO: MEDIEISHON NO RONRI TO GIHŌ [MEDICAL CONFLICT MANAGEMENT: MEDIATION THEORY AND SKILLS] (2006); YOSHITAKA WADA, IRYŌ ADR [MEDICAL ADR] (forthcoming 2009). The use of the American acronym "ADR" in Japanese is an indication that the Wagatsuma-Rosett idea of harmonious extrajudicial dispute settlement, *supra* note 10, has never really penetrated Japanese medicine. The concept of alternative dispute resolution, at least in the medical context, had to be imported from abroad.

contract for mediators to "promote understanding of medical care by patients and families and dialogue with health care providers, and to assist in resolution of disputes."[208] If within-hospital mediation fails and a family rejects the hospital's explanations or proposed resolution of the dispute, the family would have the recourse of seeking either an external expert review of the case or external mediation through a prefectural Medical Safety Support Center.[209]

The DPJ proposal, like the health ministry's, would place on hospitals and doctors an explicit statutory duty of honest explanation of any adverse events to patients and families.[210] For prevention of future accidents, reports would go for analysis and dissemination of recommendations to a designated existing entity,[211] probably the Japan Council for Quality Health Care.[212]

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208. DPJ June 2008 Proposal, *supra* note 205, tit. 1, art. 2, para. 3. The contrast between the DPJ's emphasis on internal hospital ADR as the key resolution point for medical injuries and the health ministry's emphasis on external, government-sponsored expert review calls to mind the debate in the United States over what some call the privatization of justice—the trend to outsource conflicts once the bailiwick of the state-erected judicial system to private-sector dispute resolution mechanisms. However, if private ADR fails, under the DPJ proposal the family could still invoke public processes, in contrast to private arbitration foreclosing access to U.S. courts by the losing party.

209. *Id.* tit. 1, art. 3, para. 3. The meaning of the condition for seeking external review or mediation, *viz.* that the family "cannot accept" (*nattoku dekinai*) the hospital's response, depends on an interpretation in context of the ambiguous concept *nattoku* (acceptance, satisfaction). "*Nattoku*" can include a range of acceptance behaviors from satisfied agreement to a grudging, resigned willingness to go along with what is proposed because nothing better is worth trying to obtain in the circumstances. The use of the negative, *nattoku dekinai*, in the DSP plan sets the trigger for external review outside the latter, "grudging willingness" end of the range. This means that in effect families would invoke the external review or mediation mechanisms only if they find the hospital's framing of the dispute and proposed resolution of it intolerable. Critics charge that families, dependent on information and interpretations provided by the hospital and on the assistance of a hospital-employed mediator, would often be buffaloed in this setting. *E.g.*, Interview with Toshihiro Suzuki, in Tokyo, Japan (Aug. 8, 2008) (a high-profile plaintiffs' attorney).

Nothing in the DPJ plan would foreclose families from seeking assistance from private attorneys or filing complaints with police. In this respect the DPJ and health ministry proposals do not differ.

210. DPJ June 2008 Proposal, *supra* note 205, tit. 3, arts. 2-3. For a summary of court decisions on the issue, see *supra* note 187.

211. DPJ June 2008 Proposal, *supra* note 205, tit. 1, art. 3, para. 4.

212. A friendly commentator described the DPJ's proposed accident analysis and recurrence prevention plan as an "expanded image" of the Japan Council for Quality Health Care's existing medical accident information collection system. Sanka iryō no kore kara [Obstetrical Medicine's Future] blog, http://obgy.typepad.jp/blog/2008/06/post-1341-26.html (June 13, 2008) [hereinafter Obstetrical Medicine's Future]. *Cf.* Outline of Medical Accident Information Collection Project, *supra* note 96 (website describing the Council's project).

The health ministry's proposal, by contrast, would lodge the quality improvement

A key selling point of the DPJ proposal, to the medical profession at least, is that it would abolish Article 21 outright. No longer would physicians or hospitals have the obligation to report medical practice-associated "unnatural deaths" to the police.[213] Police involvement would presumably be triggered only if patients or families lodged complaints or whistleblowers leaked damaging allegations.[214] The DPJ proposal, however, like the health ministry's proposal, would not change the Criminal Code's underlying sanction against professional negligence causing injury or death.[215]

Although much of the medical establishment supports the health ministry's proposal,[216] a groundswell of opposition, fed by influential medical blogs,[217] on the part of individual physicians has touched off an avalanche of protests to Diet members, forcing them to pay attention to an issue that most had ignored in the past. The blogs and protests are manifestations of an insurgent antiregulatory movement within the medical profession, sparked by the 2006 arrest of the Ohno Hospital obstetrician.[218] This movement aims at halting the asserted "collapse" of Japanese medicine by removing or minimizing criminal law's intrusion into medical practice and reducing the health ministry's oversight role, as well as by providing greater support to doctors practicing obstetrics and emergency medicine.[219]

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information dissemination function in the proposed National Medical Accident Review Commission. *See supra* note 189 and accompanying text. This decision likely reflects dissatisfaction with the Japan Council for Quality Health Care's past performance on this score.

213. DPJ June 2008 Proposal, *supra* note 205, tit. 3, art. 4.

214. Police and prosecutors are likely to oppose this feature of the DPJ proposal, since it would eliminate a key source of information about truly unacceptable hospital practices. Interview with Maemura, *supra* note 153.

215. *See* Obstetrical Medicine's Future, *supra* note 212 (quoting Sen. Shinya Adachi, M.D., a key supporter of the DSP proposal).

216. The Japan Medical Association, representing doctors owning private-practice clinics, has endorsed the health ministry proposal, although there is dissent among the ranks. *See* Tatematsu & Hayashi, *supra* note 199. The Japanese Association of Medical Sciences, an umbrella organization of 105 medical specialty societies, polled its members in spring 2008; of fifty-two responses, thirty-five member societies favored the health ministry plan, seven favored it with conditions, five were opposed, and five gave other responses. JAMS Opinion, *supra* note 200.

217. *See e.g.*, Medical Research Information Center Merumaga, http://mric.tanaka.md (last visited Dec. 4, 2008); Lohas Medical Blog, http://lohasmedical.jp/blog (last visited Dec. 4, 2008). A list of approximately eighty other blogs, e-mail magazines, and the like can be found on the website of the Association to Prevent the Collapse of Perinatal Medicine (Shūsanki iryō no hōkai o kuitomeru kai), http://plaza.umin.ac.jp/~perinate/cgi-bin/wiki/wiki.cgi?page=%A5%EA%A5%F3%A5%AF# p8 (last visited Dec. 4, 2008).

218. *See supra* notes 54-58 and accompanying text.

219. Interview with Masahiro Kami, Professor, Univ. of Tokyo Inst. of Med. Sci., in Tokyo, Japan (Aug. 4, 2008) [hereinafter Interview with Kami].

The politics surrounding the rival proposals on medical accident review have been unusual.[220] The opposition DPJ controls the upper house of the Diet, so the ruling Liberal Democratic Party (LDP) cannot ram the health ministry's proposal through without compromise. The health ministry itself, never a heavyweight among Japan's governing agencies, has been further weakened by public wrath over recent episodes of bureaucratic incompetence.[221] Yoichi Masuzoe, the popular LDP Minister of Health, Labor, and Welfare[222] whose selection as Minister was based partly on his televised criticisms of bureaucratic overreaching and underperforming, actually linked informally with DPJ critics and put the brakes on his own ministry's first two proposals in 2007, in effect blocking their submission to the Diet.[223] Patients' rights groups, normally critics of the health ministry and the ruling LDP, are backing the health ministry's current proposal;[224] meanwhile, members of the opposition DPJ (a party many of whose leaders come from a progressive background with a history of supporting victims' group causes), are advancing a proposal seen by many as threatening injured patients' rights with medical provider domination.[225]

How this complex political configuration will be resolved is unclear at the time of this writing, as Prime Minister Fukuda's September 2008 resignation and the upcoming general election have left Japanese politics in a state of flux.[226] But there appears to be sufficient room for adjustment of opposing positions that some revised proposal, incorporating aspects of the two rival plans, should be feasible. Both schemes agree on this: the importance of ascertaining, to the extent possible, the causes of potentially iatrogenic harm and honestly informing patients and families of the course of events. The two proposals differ only with regard to the structure of ascertainment. And the recent highly publicized

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220. *See id.*; Interview with Masahide Maeda, Dean, Shuto Univ. Tokyo, in Tokyo, Japan (Aug. 7, 2008) (Chair of the blue-ribbon study commission described in *supra* note 178 and accompanying text) [hereinafter Interview with Maeda]; Interview with Akira Maemura, *Nikkei Shinbun* medical and legal affairs reporter, in Tokyo, Japan (Aug. 13, 2008); Interview with Toshihiro Suzuki, Professor, Meiji Univ. Law Sch., in Tokyo, Japan (Aug. 8, 2008).

221. Chief among these episodes is the mismanagement of the nation's pension records by the branch of the ministry responsible for social security. *See* Mari Yamaguchi, *Social Security Scandal Shakes Japan*, WASH. POST, Sept. 2, 2007, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/09/02/AR2007090200146_2.html.

222. Masuzoe, a former University of Tokyo professor, samurai drama actor, and popular TV talk show figure, led the Liberal Democratic Party ticket nationally in votes received during the last Upper House election. He belongs to none of the LDP factions.

223. Interview with Kami, *supra* note 219; Interview with Maeda, *supra* note 220.

224. Tatematsu & Hayashi, *supra* note 199.

225. *See supra* note 209 (criticisms of internal hospital ADR proposals).

226. *See* Hisako Ueno & Bruce Wallace, *Japan Prime Minister Yasuo Fukuda Resigns*, L.A. TIMES, Sept. 2, 2008, *available at* http://www.latimes.com/news/nationworld/world/la-fg-fukuda2-2008sep02,0,7865629.story.

acquittal of the Ohno Hospital obstetrician has lent considerable impetus to efforts to enact a national medical accident review system centered on professional analysis rather than criminal investigation.[227]

D. Significance for Health Policy in Western Nations

What messages might the recent Japanese experience offer to health policy and medical jurisprudence specialists in the United States and other Western nations? Differences in institutional and legal structures and in cultural assumptions counsel caution in drawing lessons from another nation's journey. Still, the following points may be worthy of consideration.

1) Those concerned about the onerous impact of tort law on medical practice might take comfort from the scarcity of police investigators in the hospital corridors of Western countries, and from the absence of physicians and nurses in police detention cells.

2) When the public distrusts the integrity of hospital case review processes and doubts the candor of providers' explanations of adverse events, pressure will mount for external review of those events. Likewise, to the extent providers (and their insurers) are not forthcoming about compensation, apology for injury, and recurrence prevention measures, external review may be sought. When judicial processes are easily accessible, are perceived as trustworthy and fair, and function swiftly and efficiently, they fulfill this external review function admirably. But neither American courts litigating medical malpractice, nor Japanese courts litigating medical crime, have met these ideals.[228] Wariness about courts' proper functioning has led both American and Japanese societies to consider alternative means of adverse event examination and dispute resolution.

The Japanese experiment with impartial expert review, external to the hospital involved, is a response to highly publicized error episodes shaking much

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227. *See, e.g.*, Kensaku Fujiwara, Yukiko Takanashi & Atsuko Kobayashi, *Kensatsugawa no ronri hitei: Sanka-i ni muzai* [*Prosecutors' Theory Rejected, Obstetrician Acquitted*], YOMIURI SHIMBUN, Aug. 21, 2008, *available at* http://www.yomiuri.co.jp/iryou/news/iryou_news/20080821-OYT8T00310.htm (quoting health minister Masuzoe's intention to present a bill in the extraordinary Diet session then anticipated during autumn 2008); *Iryō jiko kaimei: shikumi-zukuri kyūmu* [*Urgent Task: Building a Structure for Medical Accident Review*], NIHON KEIZAI SHIMBUN, Aug. 20, 2008, at 1 (calling for medical review system by a "neutral and specialized entity"); Editorial, *Medical Safety Panels Should Be Set Up Soon*, DAILY YOMIURI, Aug. 21, 2008, at 4 (same); *Sankai-i muzai: iryō saisei no kikkake ni* [*Obstetrician Not Guilty: Opportunity for the Rebirth of Medicine*], ASAHI SHIMBUN, Aug. 21, 2008, at 3 (same).

228. Indeed, public dissatisfaction with the judiciary in general is higher in the United States than in Japan. *See* John O. Haley, *Litigation in Japan: A New Look at Old Problems*, 10 WILLAMETTE J. INT'L L. & DISP. RESOL. 121, 139 (2002) ("Public opinion polls . . . routinely show that [Japanese] judges, along with the police and prosecutors, enjoy unusually high levels of public trust . . . , especially when viewed in comparison to other countries, including the United States.").

of the public's faith in medicine's integrity, when Japanese medicine's self-policing mechanisms were seen to have failed. Conditions in other nations' health care systems differ, and the torque of reform drives ameliorative efforts in divergent directions—more centralized in Japan, for example, and more pluralistic in the United States.[229] Still, the concept of case review by expert panels staffed chiefly by independent medical specialists along with representation from other pertinent disciplines (such as law, engineering, systems management, and others), without foreclosing recourse to the courts, is attractive in the context of any modern medicolegal system.

3) Ultimately, this author hopes that compensation for harm suffered by patients whose condition is worsened by medical treatment, and the cost of needed medical care for those patients, will be provided on an "avoidable harm" or "preventable harm" basis rather than on a fault basis, at least for some designated categories of medical accidents.[230] Sweden currently operates such a system.[231] Virginia[232] and Florida[233] have taken limited steps in that direction regarding no-fault compensation for families of infants with neurological damage at childbirth, and Japan is in the final preparatory stages of launching an analogous birth damage compensation system.[234] Neither Japan nor the United

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229. For instance, both the Japanese health ministry's proposal for a few regional medical accident review commissions reporting to a single national commission and its system for reporting adverse events to the Japan Council for Quality Health Care are far more centralized in nature than the system of Patient Safety Organizations (PSOs) to be set up under the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-21 to 299b-26 (Supp. 2005). Under the Department of Health and Human Services' final rule implementing the 2005 law, PSOs numbering in the hundreds or thousands will apply for certification to receive adverse event and near-miss information developed by health care providers, analyze it, and disseminate accident-prevention suggestions, without necessarily undertaking any evaluation of the care provided. *See* Patient Safety and Quality Improvement, 42 C.F.R. §§ 3.10 to 3.552 (2008).

230. For excellent overviews of proposals to overhaul the medical tort system along these lines, see Randall R. Bovbjerg & Laurence R. Tancredi, *Liability Reform Should Make Patients Safer: "Avoidable Classes of Events" Are a Key Improvement*, 33 J. L. MED. & ETHICS 478 (2005); Michelle M. Mello et al., *"Health Courts" and Accountability for Patient Safety*, 84 MILBANK Q. 459 (2006).

231. *See, e.g.*, Susan Hershberg Adelman & Li Westerlund, *The Swedish Patient Compensation System: A Viable Alternative to the U.S. Tort System?*, 89 BULL. AM. C. SURGEONS 25 (2004).

232. VA. CODE ANN. §§ 38.2-5000 to -5021 (2007 & Supp. 2008).

233. Fla. Stat. Ch. 766.301 to .316 (2005 & Supp. 2008); *see also* Randall R. Bovbjerg, Frank A. Sloan & Peter J. Rankin, *Administrative Performance of "No-Fault" Compensation for Medical Injury*, 60 L. & CONTEMP. PROBS. 71 (1997) (examining the operation of the Virginia and Florida systems).

234. *See* Editorial, *Compensation for Cerebral Palsy*, JAPAN TIMES, Jan. 10, 2008, at A2, *available at* http://search.japantimes.co.jp/cgi-bin/ed20080110a2.html; Japan Council for Quality Health Care, Sanka iryō hoshō seido [The Japan Obstetric Compensation System] (2008), *available*

States is yet at the happy stage of expanding this concept to cover a broader range of medical injuries. But review of adverse events by impartial experts is at the core of all such endeavors. The method of impartial expert review of medical practice-associated deaths, which Japan's Model Project has adopted, is one guidepost along the road to this type of systemic reform.

CONCLUSION

The Japanese health care system inflicts preventable injury on its patients at rates that are likely commensurable with those measured in Western nations. Awareness of the problem burst on Japan in 1999 and 2000, contemporaneously with the release of *To Err Is Human*[235] by the Institute of Medicine in the United States, as reports on a series of health care calamities at famous hospitals graced the front pages of Japanese newspapers. Most of these disasters were not accompanied by the apologies to victims or harmonious resolution of disputes through which the conventional wisdom holds that Japan smoothes its social frictions. Instead, they were exposed despite cover-ups and attempts to deceive patients and families.

The story of medical error demonstrates once more that the trajectories of national responses to common crises are often strongly affected by each society's legal and institutional structure. In contrast to most Western nations, in Japan the criminal law has played a significant role in the regulation of harmful medical practice, much to the consternation of the medical profession.

Criminal law's prominence in Japanese regulation of medical error, seldom remarked on outside Japan,[236] is in part attributable to the structure of the law itself. Professional negligence causing death or injury is a crime, as is the failure to notify police of "unnatural deaths," now interpreted to encompass deaths from medical mismanagement. In part, however, the role played in Japanese medicine by criminal law has been a matter of *faute de mieux*: police and prosecutors initiated criminal investigations and prosecutions because no other social mechanisms were adequate to police the medical world. The Japanese criminal justice system filled an accountability vacuum.

Reacting to the loss of public trust in medicine brought about by repeated revelations of error and deception, and dismayed by the prospect of police intrusion into medical matters, leaders of the Japanese medical profession presented a plan for impartial expert review of medical practice-associated deaths, with reports provided to the family, the hospital, and the public. Funded by the health ministry, this five-year "Model Project" commenced in 2005 in several prefectures. The project attempts to overcome numerous structural and

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at http://www.sanka-hp.jcqhc.or.jp/outline/index.html (description of the compensation system).

235. TO ERR IS HUMAN, *supra* note 1.

236. *See supra* note 33 and accompanying text.

institutional obstacles, including a splintered, underdeveloped, and secretive death inquest system. Despite a slow start, the project has the potential to bring a new level of transparency to the medical world, to identify and disseminate ways of preventing future harm, and to facilitate the speedy resolution of medical disputes, reserving the intervention of the criminal justice system for only the most hideous cases. The project represents an attempt at wedging ajar a portal historically closed in Japan, illuminating some of the medical profession's weaknesses long kept in shadow, and encouraging the kind of quality improvement in medicine for which other sectors of Japan's economy have long been famed.

Building on the Model Project's methods, Japan's health ministry has proposed what amounts to a national system of peer reviews, external to the hospitals involved, of potentially iatrogenic hospital deaths. The opposition party has countered with a rival proposal, the political scene is in flux, and at this writing neither proposal has become law. But the highly publicized arrest, detention, and prosecution of an obstetrician for a patient's death during childbirth in rural Fukushima prefecture, and his acquittal in August 2008, seem to have crystallized Japanese public opinion around the view that the criminal justice system is too heavy-handed a tool for proper regulation of medical quality. A systemic reform based on the concept of impartial non-criminal external review of medical accidents, if enacted, could serve as one guidepost for other nations seeking to design improved structures for compensation and prevention of medical injury.

Opening Stem Cell Research and Development: A Policy Proposal for the Management of Data, Intellectual Property, and Ethics

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INTRODUCTION

Intellectual property scholars and the biomedical community have noted a decline in the tradition of openness and sharing in the biomedical sciences over the past thirty years.[1] This decline appears to be a function of multiple factors. First, and best known, are changes in intellectual property (IP) law, specifically the Federal Circuit's re-interpretation of patent law to expand the scope of patentable claims;[2] the passage of the Bayh-Dole Act of 1980, allowing universities to patent inventions made in the course of federally-funded research;[3] and the creation of new legal rights and mechanisms for the privatization and commercialization of scientific data.[4] Second, and perhaps as a direct consequence, universities and their life science researchers have significantly increased interaction with the private sector, whether through accepting sponsored research, licensing IP, or spinning off companies.[5] These activities have dramatically increased the exchange of discoveries, capital, and labor across the industrial-academic interface, and they have added more private money to the

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1. *See, e.g.*, NAT'L RESEARCH COUNCIL, SHARING PUBLICATION-RELATED DATA AND MATERIALS: RESPONSIBILITIES OF AUTHORSHIP IN THE LIFE SCIENCES 1 (2003) [hereinafter SHARING DATA & MATERIALS], *available at* http://newton.nap.edu/catalog/10613.html.

2. *See* Rebecca S. Eisenberg, *Biotech Patents: Looking Backward While Moving Forward*, 24 NATURE BIOTECH. 317, 318 (2006) (noting how "[o]ver the past quarter century, following the Supreme Court's broad directive in *Diamond v. Chakrabarty*, the Federal Circuit has gradually eviscerated what once appeared to be time-honored categorical exclusions from the patent system for such subject matter as 'business methods' and 'mathematical algorithms' in favor of a 'big tent' approach to patent eligibility").

3. Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200-212 (2000) (specifically empowering federal research grantees and contractors to seek patent protection on subject inventions made using government funds and to license those inventions with the goal of promoting their utilization, commercialization, and public availability); *see generally* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 68 LAW & CONTEMP. PROBS. 289 (2003).

4. *See, e.g.*, J.H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 LAW & CONTEMP. PROBS. 315, 319-21 (2003) (arguing at 320 that these "new laws pose the danger of disrupting the normative customs at the foundation of public science, especially the traditional and cooperative sharing ethos, by producing both the pressures and the means to enclose the scientific commons and to greatly reduce the scope of data in the public domain").

5. *See, e.g.*, DAVID C. MOWERY ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES 85-98 (2004); P. Mirowski & E. Sent, *The Commercialization of Science and the Response of STS*, *in* THE HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES 635-89 (Michael Lynch, Olga Amsterdamska & Ed Hackett eds., 2008).

mix of research support for university life sciences.[6] But the increase in university participation in economic life has also introduced tensions between the emerging commodification of knowledge[7] and longstanding scientific norms regarding open access and dissemination of research results, data, research tools, and other scientific advances.[8]

In traditional sociological accounts, the advance of science is predicated upon mechanisms of open information, peer review, and materials exchange, which are socially reinforced by norms that undergird open access.[9] Knowledge that is withheld from community scrutiny cannot be validated or agreed upon by the community. On this basis, it is presumed that greater degrees of openness promote not only efficiency in the advance of science, but also trust in the scientific endeavor by society.[10] Moreover, in standard economic accounts, the mechanisms of open exchange also have important efficiency, equity, and ethical implications in terms of the direct contributions that science makes to social welfare, particularly in the development of new technologies, products, and services. In theory, actors across industrial and state sectors can put scientific knowledge to efficient and equitable use when it is freely accessible as a public good, assuming full information and virtually costless transactions.[11] When the

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6. *See* Henry Etzkowitz, *Bridging the Gap: The Evolution of Industry–University Links in the United States*, *in* INDUSTRIALIZING KNOWLEDGE: UNIVERSITY–INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES 203-233 (Lewis Branscomb & Fumio Kodama eds., 1999).

7. *See* Reichman & Uhlir, *supra* note 4, at 319 (noting the "progressive privatization and commercialization of scientific data" and "the attendant pressures to hoard and trade them like other private commodities").

8. *See generally* PAUL A. DAVID, THE DIGITAL TECHNOLOGY BOOMERANG: NEW INTELLECTUAL PROPERTY RIGHTS THREATEN GLOBAL 'OPEN SCIENCE,' *available at* http://129.3.20.41/eps/dev/papers/0502/0502012.pdf; *see also* Sara Boettiger & Alan B. Bennett, *Bayh-Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECH. 320-23 (2006); Rebecca S. Eisenberg, *Bargaining Over the Transfer of Proprietary Research Tools: Is this Market Failing or Emerging?*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 223 (Rochelle Dreyfuss et al. eds., 2001).

9. *See* ROBERT K. MERTON, *The Normative Structure of Science*, *in* THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 267 (1973); Paul A. David, *Common Agency Contracting and the Emergence of 'Open Science' Institutions*, 88 AM. ECON. REV. 15 (1998); Michael Polanyi, *The Republic of Science: Its Political and Economic Theory*, 1 MINERVA 54 (1962).

10. *See* NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 50 (2006) [hereinafter REAPING THE BENEFITS] ("The tradition of sharing materials and results with colleagues speeds scientific progress and symbolizes to the nonscientific world that the goals of science are to expand knowledge and to improve the human condition. One reason for the remarkable success of science is the communal nature of scientific activity.").

11. *See, e.g.*, Ian M. Cockburn & Rebecca M. Henderson, *Publicly Funded Science and the*

results of scientific investigation are withheld in secrecy or maintained as private property, practical applications may be delayed, directed only towards lucrative markets, or priced in ways that are socially inefficient or unjust.[12]

However, it is not clear that efficiency and equity in the applications of science are always better served by greater openness. In terms of efficiency, openness can introduce a "free rider" problem, undermining incentives to invest in developing scientific discoveries that can contribute to social welfare. Indeed, this is arguably why our IP laws grant private exclusive rights for inventors to develop inventions into useful applications.[13] Furthermore, in terms of equity, as Chander and Sunder argue in *The Romance of the Public Domain*, freely accessible materials and information are not necessarily accessed equally by all: Those with greater ability to exploit an open access information resource, such as those with greater knowledge, social stature, or control over complementary assets, will tend to benefit disproportionately.[14] They suggest, however, that "[t]here are strategies available . . . to help . . . restructure the distribution of benefits . . . especially the possibility of creating 'limited commons property' regimes for . . . information."[15] The solution for greater efficiency as well as equity in the exploitation of science, it seems, lies in finding a proper balance or hybridization between openness and enclosure, public good and private asset. Striking the most efficient and equitable balance between public and proprietary science is quite difficult in practice, in no small measure because the very categories of basic and applied science are breaking down in practice.[16] Nevertheless, many legal commentators warn that with Bayh-Dole, the pendulum may have swung too far towards a private competitive model of university science.[17]

Productivity of the Pharmaceutical Industry, in 1 INNOVATION POLICY AND THE ECONOMY 1 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., MIT Press 2001); Richard R. Nelson, *The Role of Knowledge in R&D Efficiency*, 97 Q. J. ECON. 453 (1982).

12. *See* Patrick L. Taylor, *Research Sharing, Ethics, and Public Benefit*, 25 NATURE BIOTECH. 398 (2007).

13. Economist Richard Nelson observes more generally that "[t]echnology itself is a hybrid term with two roots—one 'technique,' referring to a way of doing something, and the other 'logy' referring to theory. . . . [e]ven in rivalrous industries, institutional mechanisms have developed that tend to keep the 'logy' public, even though the technique is kept private. . . . This practice . . . makes considerable sense from a social point of view." *See* Nelson, *supra* note 11, at 467-68.

14. Anupam Chander & Madhavi Sunder, *The Romance of the Public Domain*, 92 CAL. L. REV. 1331 (2004).

15. *Id.* at 1337.

16. Rebecca S. Eisenberg & Richard R. Nelson, *Public vs. Proprietary Science: A Fruitful Tension?*, 131 DAEDALUS 89, 90-91 (2002).

17. See, for example, the various papers in the special issue of *Law and Contemporary Problems* devoted to the public domain, 66 LAW & CONTEMP. PROBS. (SPECIAL ISSUE) (2003),

In response to dominant patterns of propertization, competition, and decentralization in the modern life sciences, new forms of "open and collaborative" research have, as if by necessity, recently emerged. These have centered in fields like open source bioinformatics software, genomic and other databases, and to a lesser extent, wet-lab biology.[18] These novel forms of collaboration, pooling, and sharing have arisen from both private and public sectors, or at the interface between the two. Some of these collaborative initiatives, such as the SNP Consortium developed by the pharmaceutical industry,[19] have emerged from the efforts of private entities worried about the cumulative inefficiencies of too much upstream patenting.[20] Government funders and international pressures promoting greater data sharing among scientists have driven others, such as the Human Genome Project and International Haplotype Map Project.[21] Concerned scientific innovators themselves have developed other projects adopting more open behaviors, such as the BioBricks Foundation at MIT, which seeks to coordinate a synthetic biology "commons"—a resource owned and used by a community for common benefit.[22] These important efforts emanating from the public and private sectors, however, remain the exception rather than the rule, and broad areas of biomedical research have yet to experiment with such novel collaborative architectures seeking the blend of openness and exclusion with the greatest scientific and public utility.

Presently, the exploding field of stem cell research is characterized by a lack of any deeply collaborative architecture, yet it is a field that arguably requires

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available at http://www.law.duke.edu/journals/journaltoc?journal=lcp&toc=lcptoc66winterspring2003.htm.

18. For a good overview of some of these efforts, see Arti K. Rai, *"Open and Collaborative" Research: A New Model for Biomedicine*, *in* INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES: SOFTWARE AND BIOTECHNOLOGY 131, 140-45 (Robert W. Hahn ed., 2005).

19. *See, e.g.*, Robert Langreth, Michael Waldholz & Stephen D. Moore, *DNA Dreams: Big Drug Firms Discuss Linking Up To Pursue Disease-Causing Genes*, WALL ST. J., Mar. 4, 1999, at A1. The SNP Consortium systematically identifies localized variations in the genetic code, known as single nucleotide polymorphisms or SNPs ("snips"). This consortium of twelve pharmaceutical and technology companies, the Wellcome Trust, and leading academic centers of the Human Genome Project made data for over one million SNPs available.

20. *See* Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183 (2004) (documenting a trend whereby private biotechnology firms are increasingly engaging in "property-preempting investment," injecting scientific data and discoveries into the public databases to forestall blocking property claims further downstream the innovation process).

21. *See* Rai, *supra* note 18, at 141-43. See *infra* Section II.C a discussion of these kinds of initiatives.

22. Arti Rai & James Boyle, *Synthetic Biology: Caught Between Property Rights, the Public Domain, and the Commons*, 5 PLOS BIOLOGY 0389 (2007), http://biology.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pbio.0050058.

more coordination than others due to the particular trajectory of its development. There is broad agreement, although not consensus, among life scientists that stem cells, and in particular human embryonic stem cells (hESCs), hold unique promise for advancing biomedicine, especially in the areas of toxicology, pharmacology, functional regeneration, and developmental biology.[23] These cells maintain a state that is almost identical to early embryonic cells and therefore may be directed to mature into any cell type found in humans. For developmental biology, hESCs represent an integral tool for studying human development and differentiation in the Petri dish, as limited sources of human embryonic tissue are available for research. For regenerative medicine, hESCs provide a rich source for cell therapeutic efforts at the site of disease or injury—in essence a flexible building block to make replacement tissues. In addition, hESCs, or the mature cells derived from them, may be cultured with various chemical compounds to discover new drugs or assay the toxicity of chemicals in a human cell system.

However, as in other areas of biomedical research, serious technical and proprietary barriers have arisen.[24] Beyond problems in patents and data sharing, ethical and regulatory complications cloud the prospects for stem cell research and development (R&D) to a greater extent than other fields in the life sciences.[25] Indeed, the proprietary, regulatory, and technical characteristics of the stem cell field present a set of limiting conditions or "bottlenecks" that stand to constrain and divert R&D efforts and investments.[26] Furthermore, IP scholars and policymakers promoting open forms of life science research and collaboration have tended to ignore the ways in which these areas of complexity and constraint can be mutually compounding.[27]

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23. For a detailed overview of the potential of stem cell research, see DEP'T OF HEALTH & HUMAN SERVS., REGENERATIVE MEDICINE (2006) [hereinafter REGENERATIVE MEDICINE], http://stemcells.nih.gov/info/scireport/2006report.htm; see also George Q. Daley & David T. Scadden, *Prospects for Stem Cell-Based Therapy*, 132 CELL 544 (2008).

24. *See infra* Section I.A-B.

25. In the United States, federal policy prohibits the use of federal research money to create new hESC lines, and federally funded researchers may not work on any lines created after August 2001. OFFICE FOR HUMAN RESEARCH PROTS., DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INVESTIGATORS AND INSTITUTIONAL REVIEW BOARDS REGARDING RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS, GERM CELLS AND STEM CELL-DERIVED TEST ARTICLES 3 (2002) [hereinafter GUIDANCE FOR INVESTIGATORS], *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/stemcell.pdf (stating that "[r]esearch on existing [hESC] lines may be conducted with Federal support if the cell lines meet the U.S. President's criteria which he announced on August 9, 2001").

26. This thesis is developed *infra* Part I.

27. The paucity of literature dealing with the interaction of the technical, proprietary, and ethical domains is a key premise of this article, although there are a few notable exceptions. *See, e.g.*, Kenneth S. Taymor, Christopher Thomas Scott & Henry T. Greely, *The Paths Around Stem*

Drawing on an interdisciplinary analysis spanning law and bioethics, economics, and stem cell biology,[28] we argue that opening stem cell R&D and maximizing public benefits from public investment will require striking a better balance between the public and private domains and developing the integrative management of data sharing, IP rights, and ethics-driven regulation. In particular, a coordinated effort addressing these bottlenecks could help facilitate an efficient, equitable, and ethically accountable advance of stem cell research. In Part I of this Article, we discuss in more detail the problems and complexities constraining the advance of stem cell research within three traditional policy domains: the technical, the proprietary, and the ethical. We also review the efforts that have been organized to address those problems, and we argue why those efforts must go further and deeper. In Part II, we propose a series of design principles for collective action in stem cells based on the previous discussion and policy models observed in other fields. These design principles address the conceptual and pragmatic aspects of institution-building in a complex environment. In Part III, we outline a proposed mechanism to coordinate the conduct and governance of human stem cell R&D: a collaboration among funders, researchers, science journals, and academic institutions to 1) build a data architecture for stem cell work that spans a rich array of technical, proprietary, and ethical information, and 2) develop and execute common solutions in technology licensing to free up R&D. In Part IV, we discuss incentives from the perspectives of major institutional actors to participate in the proposed collaboration, as well as the unique aspect of our proposal to integrate solutions spanning the technical, proprietary, and ethical domains.

I. BOTTLENECKS IN THE TECHNICAL, PROPRIETARY, AND ETHICAL DOMAINS

The expansion of public funding for stem cell research at both the federal and state levels has been grounded in its potential for advancing public health

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Cell Intellectual Property, 24 NATURE BIOTECH. 411, 411-13 (2006).

28. Each of the authors has previously raised critiques and advanced suggestions for the conduct of stem cell R&D—including issues of ethical governance, IP and technology licensing, and technical data sharing. KARL BERGMAN & GREGORY GRAFF, CTR. FOR INTELLECTUAL PROP. STUDIES & PUB. INTELLECTUAL PROP. RESEARCH FOR AGRIC., COLLABORATIVE IP MANAGEMENT FOR STEM CELL RESEARCH AND DEVELOPMENT (2007); Karl Bergman & Gregory D. Graff, *The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development*, 25 NATURE BIOTECH. 419 (2007); David E. Winickoff, *Bioethics and Stem Cell Banking in California*, 21 BERKELEY TECH. L.J. 1067 (2006); David E. Winickoff, *Governing Stem Cell Research in California and the USA: Towards a Social Infrastructure*, 24 TRENDS IN BIOTECH. 390 (2006); Krishanu Saha, Navigating to the Right Stem Cell Line (2006) (unpublished manuscript, on file with author).

and human welfare.[29] However, the technical, proprietary, and regulatory environment (consisting of closed information, congested IP entitlements, and regulatory uncertainty) presents formidable challenges for the conduct of research and the development of applications based on that research. Many are claiming the essential technical building blocks of stem cell research—including the cell lines themselves—as private assets, following trends of extensive patenting seen elsewhere in the life sciences.[30] Further, the lack of disclosure and standardization of technical data involved in stem cell research acts as a limiting factor on the advance of this novel line of research.[31] Problems of congested IP and data-withholding are certainly not unique to stem cell research, but we contend that these issues are aggravated in the stem cell research context.[32]

Further compounding these special challenges, there remains broad political and ethical disagreement over the conditions under which this line of research should advance, if at all. Stem cell research challenges common notions of the natural and the sacred, introducing new ways to use and manipulate nascent human life, gametes, and trans-species hybrids.[33] These aspects of stem cell science have produced a deeply contested ethical terrain and a lack of regulatory harmonization. As we explore in this Section, conditions within each of these three domains—the technical, proprietary, and ethical—present serious problems for the pace of innovation, the distribution of resulting health benefits, and the public accountability of research. Furthermore, these problems may be mutually reinforcing.

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29. Individual states have collectively allocated $3.33 billion for stem cell research, with three billion dollars of that from California alone. JAMES W. FOSSETT, ROCKEFELLER INST., FEDERALISM BY NECESSITY: STATE AND PRIVATE SUPPORT FOR HUMAN EMBRYONIC STEM CELL RESEARCH (2007), *available at* http://www.rockinst.org/pdf/health_care/2007-08-09federalism_by_necessity_state_and_private_support_for_human_embryonic_stem_cell_research.pdf.

30. *See* Jeanne F. Loring & Cathryn Campbell, *Intellectual Property and Human Embryonic Stem Cell Research*, 311 SCIENCE 1716, 1716-17 (2006); Sander Rabin, *The Gatekeepers of hES Cell Products*, 23 NATURE BIOTECH. 817, 817-19 (2005); *see also* Bergman & Graff, *The Global Stem Cell Patent Landscape*, *supra* note 28.

31. Stem cell scientists as a whole have articulated the need to determine the characteristics that define hES cells by sharing data across many cell lines. *See* Emma L. Stephenson, Peter R. Braude & Chris Mason, *International Community Consensus Standard for Reporting Derivation of Human Embryonic Stem Cell Lines*, 2 REGENERATIVE MED. 349 (2007); Editorial, *Registries and Banks*, 10 NATURE CELL BIOLOGY 111 (2008).

32. *See infra* Section I.A-B.

33. David E. Winickoff, *Bioethics and Stem Cell Banking in California*, *supra* note 28, at 1070.

A. Technical Domain: Scientific Data and Materials Sharing

Potential problems of data and materials sharing within stem cell research occur in the context of larger concerns about the erosion of the public domain in scientific data and materials. The deposition and sharing of materials—including reagents, tissue, and cell lines—and data associated with published research findings play an important role in the life-sciences community.[34] The sharing of data and materials has long been necessary for scientific experimentation and confirmation of results. Computational analysis of data now drives many fields of science, such as bioinformatics and the empirical environmental sciences.[35] However, new laws and practices threaten to produce both "the pressures and the means to enclose the scientific commons and to greatly reduce the scope of data in the public domain."[36] Furthermore, traditional norms around sharing research materials are running headlong into the desire of institutions to protect IP in materials and research tools, giving rise to the proliferation of material transfer agreements even among nonprofit research institutions.[37]

The larger science policy community has made restrictions on data, information, and materials derived from scientific research a central theme for over twenty years.[38] Recently, the National Research Council has taken up the topic in a series of influential reports.[39] Under traditional assumptions, scientific findings and data enter the public domain through publication and become part of the commonly accessible scientific knowledge base. According to the National Research Council, practices around data release at the time of publication are far from adequate from the perspective of the public good.[40] Recently enacted and announced policy changes at some scientific journals, such as *Science* and *Nature*, have attempted to promote better practices.[41] However, these journal

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34. SHARING DATA & MATERIALS, *supra* note 1, at 17.

35. NAT'L. RESEARCH COUNCIL, BITS OF POWER: ISSUES IN GLOBAL ACCESS TO SCIENTIFIC DATA 1-17 (1997) [hereinafter BITS OF POWER]; *see also* Reichman & Uhlir, *supra* note 4, at 318.

36. Reichman & Uhlir, *supra* note 4, at 320.

37. REAPING THE BENEFITS, *supra* note 10, at 128-31; Katherine Ku & James Henderson, *The MTA—Rip It Up and Start Again?*, 25 NATURE BIOTECH. 721 (2007).

38. REAPING THE BENEFITS, *supra* note 10, at 50.

39. *See, e.g.*, NAT'L. RESEARCH COUNCIL, A QUESTION OF BALANCE: PRIVATE RIGHTS AND THE PUBLIC INTEREST IN SCIENTIFIC AND TECHNICAL DATABASES 15 (1999) [hereinafter A QUESTION OF BALANCE]; BITS OF POWER, *supra* note 35; SHARING DATA & MATERIALS, *supra* note 1.

40. *See, e.g.*, A QUESTION OF BALANCE, *supra* note 39, at 15; SHARING DATA & MATERIALS, *supra* note 1, at 1.

41. *See* Nature, Guide to Publication Policies of the Nature Journals (July 14, 2008), http://www.nature.com/authors/gta.pdf (editorial policy for *Nature* requiring authors "to make materials, data and associated protocols available in a publicly accessible database . . . or, where one does not exist, to readers promptly on request."); Science, General Information for Authors,

policies are far from uniform across scientific publishing,[42] and it is unclear how well such policies are actually enforced.[43]

In the case of data, there may be two sources of tension regarding traditional norms and practices around sharing. The best-known source consists in what members of the legal and scientific community see as new practices of delay and secrecy resulting from the penetration of private investment into university life sciences.[44] Reichman and Uhlir document problems with the current system of publication, blaming cultural changes within science as well as new legal protections over data in copyright law for threatening the science commons.[45]

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http://www.sciencemag.org/about/authors/prep/gen_info.dtl (last visited Nov. 13, 2008) (editorial policy for *Science* requiring that "after publication, all data necessary to understand, assess, and extend the conclusions of the manuscript must be available to any reader of *Science*" subject to "discipline-specific conventions or special circumstances." And "[a]fter publication, all reasonable requests for materials must be fulfilled. A charge for time and materials involved in the transfer may be made. *Science* must be informed of any restrictions on sharing of materials [Materials Transfer Agreements or patents, for example] applying to materials used in the reported research. Any such restrictions should be indicated in the cover letter at the time of submission, and each individual author will be asked to reaffirm this on the Conditions of Acceptance forms that he or she executes at the time the final version of the manuscript is submitted. The nature of the restrictions should be noted in the paper. Unreasonable restrictions may preclude publication."); *see also 2008 Information for Authors*, 319 SCIENCE 634 (2008), *available at* http://www.sciencemag.org/cgi/issue_pdf/admin_pdf/319/5863.pdf (published, abbreviated version of publication policies for *Science*).

42. Heather A. Piwowar, Roger S. Day & Douglas B. Fridsma, *Sharing Detailed Research Data Is Associated with Increased Citation Rate*, PLoS ONE, Mar. 2007, at 1, http://www.plosone.org/article/info:doi%2F10.1371%2Fjournal.pone.0000308; Heather A. Piwowar & Wendy W. Chapman, *A Review of Journal Policies for Sharing Research Data*, NATURE PRECEDINGS, Mar. 20, 2008, http://precedings.nature.com/documents/1700/version/1/files/npre20081700-1.pdf.

43. Differences between the journal data sharing policy and actual practice have been commented on in the scientific editorial literature. *See, e.g.*, Editorial, *Got Data?*, 10 NATURE NEUROSCIENCE 931 (2007).

44. *See* REAPING THE BENEFITS, *supra* note 10, at 50-51 (noting how the increase in patenting and relevance of science to the commercial world have put pressures on norms of openness and access in science); *see also* Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, *in* SCIENTIFIC INNOVATION, PHILOSOPHY, AND PUBLIC POLICY 145, 145 (Ellen Frankel Paul, Fred D. Miller, Jr. & Jeffrey Paul eds., 1996).

45. Reichman & Uhlir, *supra* note 4, at 321 ("First, as a growing commercial or cultural phenomenon, the data may have been conditionally deposited or imperfectly revealed at the time of publication. Second, recent changes to copyright law make it possible to control online access to the supporting data, even though the data as such are technically ineligible for copyright protection. Third, European states have adopted a new *sui generis* database right, which allows scientists to directly control access to and reuse of aggregations of facts, whether these have been disclosed as part of their research publications or made available as a separate database . . . . Finally, . . . a

The second source stems from the enhanced capacity to produce, manage, and disseminate data through new information technologies.[46] Advances in database technology and networking power create opportunities both for accelerating knowledge creation and for engaging in new forms of rent-seeking.[47] As technological constraints on sharing are removed and new sharing opportunities enabled, the prevailing norms must be renegotiated.[48]

Both sets of conditions have given rise to renewed debates about the manner and timing of data release in the sciences,[49] and evidence of a problem is mounting. Recent studies of the genetics research community suggest that "data withholding" is common.[50] Patrick Taylor, a legal scholar and member of the General Counsel's Office at Harvard, recently concluded in a literature review that data sharing needs to be enhanced across the life sciences.[51] Whether framed as a problem or opportunity, one thing is clear: the potential power to move science forward through deeper data sharing is vast.

Like data, the exchange of biological research materials is also subject to competing norms of propertization and openness, within both the scientific and university licensing communities. Although patenting by nonprofit research institutions has been embraced and promoted through public policies such as the Bayh-Dole Act, concerns are mounting that proprietary claims in research materials and "tools" are impeding research, even in non-commercial settings.

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combination of digital rights management technologies and standard-form contracts may enable publishers to impose limits on the redissemination and use of supporting data even after formal publication of a scientific article.") (footnotes omitted).

46. *See, e.g.*, Rebecca S. Eisenberg, *Patents and Data Sharing in Public Science*, 15 INDUS. & CORP. CHANGE 1013 (2006).

47. *See generally* YOCHAI BENKLER, THE WEALTH OF NETWORKS (2006).

48. This process through which new technologies and new normative and social structures co-emerge illustrates what science and technologies studies scholars have termed "co-production." *See* STATES OF KNOWLEDGE: THE CO-PRODUCTION OF SCIENCE AND SOCIAL ORDER (Sheila Jasanoff ed., 2004).

49. *See, e.g.*, Rebecca S. Eisenberg & Arti K. Rai, *Harnessing and Sharing the Benefits of State-Sponsored Research: Intellectual Property Rights and Data Sharing in California's Stem Cell Initiative*, 21 BERKELEY TECH. L.J. 1187, 1189-91 (2006) ("Another important focus of debate has been the timing of data disclosure. The traditional trigger for data sharing in academic research is publication of research results. Large data sets, though, may not be ripe for publication in a prestigious journal until long after they are generated. Thus, research projects that aim to create large data sets over an extended period of time have presented special challenges for the implementation of data sharing norms.").

50. David Blumenthal et al., *Data Withholding in Genetics and the Other Life Sciences: Prevalences and Predictors*, 81 ACAD. MED. 137, 137-45 (2006); Taylor, *supra* note 12, at 398-401; C. Vogeli et al., *Data Withholding and the Next Generation of Scientists: Results of a National Survey*, 81 ACAD. MED. 128, 128-36 (2006).

51. Taylor, *supra* note 12, at 400.

Despite a 1999 NIH Guidance promoting the sharing of research tools and materials,[52] an in-depth survey conducted under the auspices of the National Research Council on IP rights in genomics concluded that access to materials and the proliferation of Material Transfer Agreements (MTAs) are serious problems.[53] Indeed, MTAs are nearly omnipresent in the practice of the biological sciences.[54]

An MTA sets contractual rights and obligations when one party transfers cell lines or other materials to another, usually focusing on terms for the physical handling, use, and further distribution of the material. In some cases, MTAs are essential for communicating important ethical terms concerning use of the transferred materials. However, obtaining materials across laboratories can often be delayed or encumbered by these contracts as well as by purposeful withholding prompted or enabled by the need for signing them.[55] MTAs can even be written to include onerous provisions concerning downstream patent rights that might be derived from work on these materials; if these terms are not accepted, the transfer of biological materials may not take place.[56]

Within the field of stem cell research, the sharing of materials has been a much more obvious problem than the sharing of data. This has largely been due to a combination of the Bush Administration's restrictive funding policies[57] and the commanding patent position of the Wisconsin Alumni Research Foundation

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52. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,090 (Dec. 23, 1999) [hereinafter NIH Principles and Guidelines].

53. The largest survey to date on materials transfer practices among researchers was commissioned by the National Academies of Sciences. *See* JOHN P. WALSH, CHARLENE CHO & WESLEY M. COHEN, NAT'L ACAD. OF SCI., COMM. ON INTELLECTUAL PROP. RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS, PATENTS, MATERIAL TRANSFERS AND ACCESS TO RESEARCH INPUTS IN BIOMEDICAL RESEARCH 2-3 (2005) (reporting "substantial evidence" that "difficulties in accessing proprietary research materials, whether patented or unpatented" are more important than patents in hindering research); REAPING THE BENEFITS, *supra* note 10, at 3.

54. Ku & Henderson, *supra* note 37, at 721.

55. Zhen Lei, Rakhia Juneja & Brian Wright, Implications of Intellectual Property Protection for Academic Agricultural Biologists (Jan. 2008) (unpublished manuscript, on file with authors).

56. *See* Sean O'Connor, *The Use of MTAs To Control Commercialization of Stem Cell Diagnostics and Therapeutics*, 21 BERKELEY TECH. L.J. 1017, 1017-18 (2006). It is difficult to dispute that requirements for signing MTAs constitute, in the very least, a transaction cost not encountered when freely exchanging research materials. It is more difficult to establish whether MTAs result in a global net decrease in the overall exchange of biological materials within the contemporary life sciences research community. For, without some of the assurances provided under these contracts, some materials might not be able to be shared at all, particularly given how the life sciences—and particularly the field of stem cells—is constantly expanding in terms of the volume, sophistication, and ethical sensitivity of the research materials necessarily employed.

57. The number of viable federally-approved hESC lines has dropped to twenty-one.

(WARF),[58] the technology transfer arm of the University of Wisconsin. Based on work in the laboratory of James Thompson that was funded by a combination of NIH and a biotechnology company, Geron, WARF received several broad foundational patents that cover both derivation techniques for hESCs as well as many of the cell lines approved for federal funding under President Bush's policy.[59] The case of using stem cell line materials has become a notorious example of the dilemmas posed by strong IP in the life sciences: While strong rights can create incentives for private funding of research, in this case by Geron and its investors, they can also lead to serious delays in follow-on innovation due to restricted access to existing materials and research tools. Long considered the standard for evaluating the behavior of any other human pluripotent lines, the WARF cell lines are among the most widely used lines in the field. WARF has used its patents and its physical control of these stem cell lines to exert a dominant position in the stem cell research community.[60] For many stem cell scientists in both the private and public sectors, WARF's restrictive licensing policies with respect to both derivation methods and the stem cell lines themselves have impeded access to research materials and the advance of research.[61]

A combination of legal and policy interventions has helped free up the use of Wisconsin's proprietary cell lines.[62] First, in October 2001, the Public Health Service completed a Memorandum of Understanding with WARF and its affiliated nonprofit stem cell provider, WiCell, which enabled any NIH-funded investigator in the country to receive WARF stem cells and a license to practice WARF's patented inventions for an access fee of no more than $5000.[63] Previously, university researchers had faced the specter of having to negotiate individual licenses from WARF for any conduct of stem cell research, whether using the WARF cell lines or not. Second, in January 2007, under the shadow of a patent reexamination that threatened to limit the scope of the patents' claims

58. The Wisconsin Alumni Research Foundation is the nonprofit technology transfer office of the University of Wisconsin-Madison. It is a significant source of research support, independent of federal grants. It currently contributes about $45 million per year, giving the university's research programs a "margin of excellence." *See* Wisconsin Alumni Research Foundation, http://www.warf.ws (last visited Nov. 13, 2008).

59. Rabin, *supra* note 30, at 817.

60. For a detailed and extremely useful history of WARF stem cell licensing practices, see O'Connor, *supra* note 56, at 1027-48.

61. Loring & Campbell, *supra* note 30; Meredith Wadman, *Licensing Fees Slow Advance of Stem Cells*, 435 NATURE 272, 272-73 (2005), *available at* http://www.nature.com/nature/journal/v435/n7040/pdf/435272a.pdf.

62. *See generally* R.S. Eisenberg & A.K. Rai, *Proprietary Considerations*, *in* 1 HANDBOOK OF STEM CELLS 793-98 (Robert Lanza et al. eds., 2004).

63. Wadman, *supra* note 61, at 272.

and increasing political pressure from the stem cell community to further improve access to stem cell lines,[64] WARF announced changes to its licensing policies that would provide greater access to its foundational cell lines.[65] The patent challenge ultimately failed. Although the United States Patent and Trademark Office (USPTO) issued a preliminary ruling rejecting some aspects of these patents that had been challenged by public interest groups,[66] the key claims were later definitively upheld.[67] Nevertheless, before the final USPTO ruling came down, WARF instituted a policy change that eliminated the previous requirement that industry sponsors of academic research receiving any rights back from the university—such as an option to negotiate a license or patent rights to subsequent inventions—needed a commercial license from WARF or risked patent litigation. The new policy also formalized permission for the transfer of non-WARF stem cell lines from lab to lab without need for a special license from WARF.[68]

Even if the licensing policies on WARF's lines are further opened, the sharing of other hESC lines is encumbered by a series of general challenges with the production, legal status, and transfer agreements associated with hESC lines. Some of this is due to new technological developments. New derivation techniques, especially the widely touted induced pluripotent stem (iPS) cell lines

64. *See, e.g.*, Constance Holden, *Prominent Researchers Join the Attack on Stem Cell Patents*, 317 SCIENCE 187 (2007). Patent challenges come in two forms. An infringing business can sue for a declaration of patent invalidity. This method can be risky and also very expensive: the challenger's continuing use of the patent may lead to damages if the challenge is unsuccessful, and the lawsuits themselves are often very costly. Alternatively, challengers can petition the USPTO directly to "reexamine" the patent. This is what occurred in the WARF case. This is usually a far less costly procedure. However, whereas an invalidation lawsuit features multiple opportunities for discovery, cross-examination of experts, and judges and juries independent of the USPTO, a reexamination features only limited opportunity to present evidence and cross-examine. For a reexamination, the USPTO is the decision-maker. *See* Aurora Plomer et al., *Challenges to Human Embryonic Stem Cell Patents*, 2 CELL STEM CELL 13, 14 (2008).

65. Wisconsin Alumni Research Found., *Wisconsin Alumni Research Foundation Changes Stem Cell Policies To Encourage Greater Academic, Industry Collaboration*, WARF NEWS, Jan. 23, 2007, http://www.warf.ws/news/news.jsp?news_id=209.

66. The groups were the Foundation for Taxpayer and Consumer Rights and the Public Patent Foundation in New York. The core of the patent challenge is that the achievement of James Thomson, the patent holder, was obvious to many of the scientists working in the field. *See, e.g.*, Constance Holden, *U.S. Patent Office Casts Doubt on Wisconsin Stem Cell Patents*, 316 SCIENCE 182 (2007).

67. Constance Holden, *Wisconsin Stem Cell Patents Upheld*, 319 SCIENCE 1602 (2008).

68. Carl Gulbrandsen, Letter, *WARF's Licensing Policy for ES Cell Lines*, 25 NATURE BIOTECH. 387, 387 (2007). This policy also certifies that the California Institute of Regenerative Medicine can proceed with its grant-making powers without first requiring a WARF license for stem cell work.

may rapidly increase the number of pluripotent cell lines with properties similar to embryonic-stem cells.[69] The USPTO has ruled that iPS derivation techniques are outside the scope of the WARF patents.[70] This may help alleviate blockage with respect to the WARF lines, but new proprietary struggles will soon ensue over access to this new technique.[71]

Other special challenges of sharing hESC lines exist. These materials require significant expertise via current methods to maintain an undifferentiated state for distribution. They also require extensive characterization to ensure that they contain no genetic abnormalities or adventitious agents.[72] Cell banking has helped reduce this burden on individual labs for distribution, but this infrastructure has yet to relieve much of the routine work necessarily associated with cell line sharing.[73] Finally, hESCs must go through an institutional review by the recipient's institution, likely having to satisfy a complex patchwork of regulations, discussed in Section C below. Together, these challenges of maintaining the quality of hESCs, satisfying institutional review, and negotiating MTAs constitute complex barriers to sharing hESC within the stem cell research community.

In comparison, data sharing issues are less debated, but equally significant. Indeed, stem cell research may be particularly hindered by problems of data access because conducting follow-up work requires rich data sets detailing the characteristics of cell lines. Scientific researchers and institutions that want to use stem cells in their research are confronted with two major challenges: the

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69. *See* W.E. Lowry et al., *Generation of Human Induced Pluripotent Stem Cells from Dermal Fibroblasts*, 105:8 PNAS 2883, 2883-88 (2008); In-Hyun Park et al., *Reprogramming of Human Somatic Cells to Pluripotency with Defined Factors*, 451 NATURE 141 (2008); Kazutoshi Takahashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861 (2007); Kazutoshi Takahashi & Shinya Yamanaka, *Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors*, 126 CELL 663 (2006); Junying Yu et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, 318 SCIENCE 1917 (2007).

70. Holden, *supra* note 67, at 1603.

71. *Id.*

72. Duncan E. Baker et al., *Adaptation to Culture of Human Embryonic Stem Cells and Oncogenesis* In Vivo, 25 NATURE BIOTECH. 207 (2007); International Stem Cell Initiative, *Characterization of Human Embryonic Stem Cell Lines by the International Stem Cell Initiative*, 25 NATURE BIOTECH. 803 (2007).

73. Lyn E. Healy, Tenneille E. Ludwig & Andre Choo, *International Banking: Checks, Deposits, and Withdrawals*, 2 CELL STEM CELL 305 (2008); P. Pearl O'Rourke, Melinda Abelman & Kate Gallin Heffernan, *Centralized Banks for Human Embryonic Stem Cells: A Worthwhile Challenge*, 2 CELL STEM CELL 307 (2008).

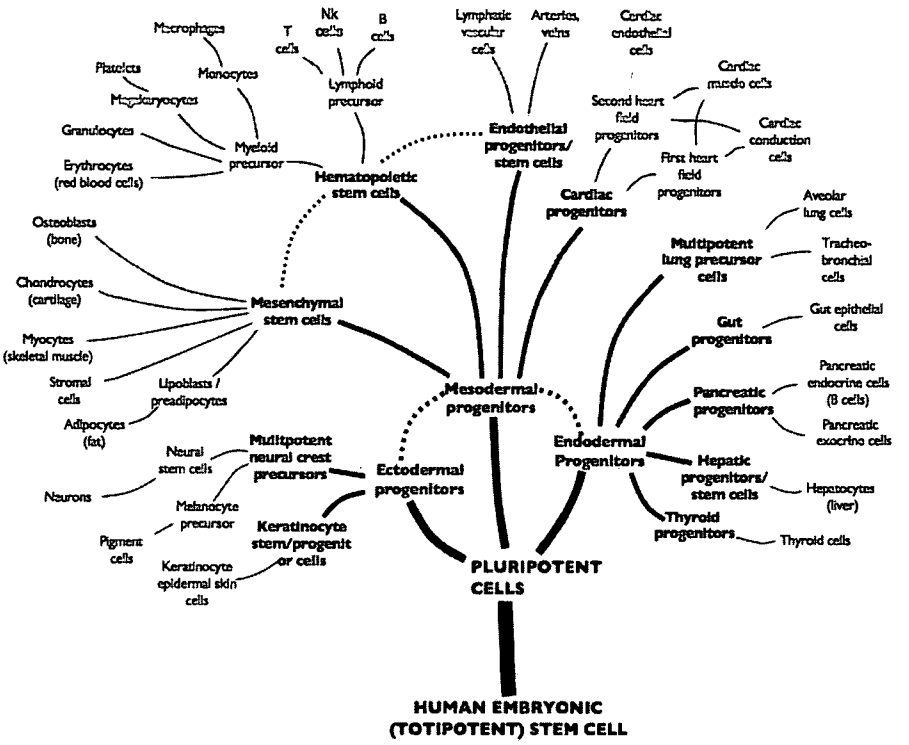

FIGURE 1. The Tree of Cellular Differentiation
Major thoroughfares in obtaining differentiated cell types from human embryonic stem cells are denoted by thicker lines. Note that not all lineages are shown.

navigation of stem cell behavior through a vast number of potential cell fates (Figure 1) and the integration of many disparate technical tools.[74] Stem cells, whether adult or embryonic, have the remarkable ability to differentiate into a large number of cell types (see Figure 1),[75] but to conduct research, a scientist

74. Material from this Section is based on conversations with stem cell scientists by the authors, as well as talks presented at the conference, "Institutional Landscape in Stem Cell Research & Development: Problems & Solutions." For an overview of this conference in the published literature, see Monya Baker, *Thickets and Gaps Blocking Stem Cell Science*, NATURE REPORTS STEM CELLS (Mar. 6, 2008), http://www.nature.com/stemcells/2008/0803/080306/full/stemcells.2008.42.html (last visited Nov. 13, 2008) (describing conference hosted by U.C. Berkeley Stem Cell Center that featured stem cell scientists, industry leaders, and policy actors from across the United States on Feb. 6, 2008); and U.C. BERKELEY STEM CELL CENTER, RAPPORTEUR'S REPORT: INSTITUTIONAL LANDSCAPE IN STEM CELL RESEARCH & DEVELOPMENT (2008), http://stsc.berkeley.edu/Events/StemCellFeb6-Rapporteur%27s%20Report.pdf [hereinafter RAPPORTEUR'S REPORT] (providing rapporteur's report and conference agenda).

75. REGENERATIVE MEDICINE, *supra* note 23.

must know how mature their stem cell population is (or, in terms of Figure 1, exactly where along the cellular tree of differentiation the cell population resides). Obtaining full knowledge about differentiation is not simple: The differentiation of a stem cell is heavily dependent not only on its genome, but also on the cell's culture history. For example, the particular growth factors that have been added to the media, the substrate of the cell culture, and the duration of such events all affect a cell's differentiation.[76] The appropriate use of these cells depends on understanding the condition of their derivation and propagation stages (Figure 2).[77] In each of the many technical stages during routine use of stem cells for medical research (Figure 2), many technologies are needed—including cell lines, growth factors, culture substrates, implantable materials, and genetic engineering vectors—each of which can affect stem cell behavior.[78] A wide array of possibilities exists for integrating different technologies. This wide array is rarely explored experimentally in one lab for all important cell lineages (e.g., undifferentiated embryonic stem cells, neurons, cardiac progenitors, pancreatic endocrine cells). Labs and even whole institutions can have specialized expertise with only a few cell types or lineages.

Recent work in the stem cell scientific community suggests that the need for descriptive details associated with cell lines will only increase, which in turn will further accentuate these challenges.[79] Research has thus far focused largely on details of the culturing history, but as scientists gain access to more stem cell

76. Genetic and epigenetic intrinsic factors as well as soluble and matrix extrinsic factors are cell fate determinants of stem cells. Michele Boiani & Hans R. Scholer, *Regulatory Networks in Embryo-derived Pluripotent Stem Cells*, 6 NATURE REVS. MOLECULAR CELL BIOLOGY 872 (2005); Laune A. Boyer, Divya Mathur & Rudolf Jaenisch, *Molecular Control of Pluripotency*, 16 CURRENT OPINION GENETICS & DEV. 455 (2006); Rudolf Jaenisch & Adrian Bird, *Epigenetic Regulation of Gene Expression: How the Genome Integrates Intrinsic and Environmental Signals*, 33 NATURE GENETICS 245 (2003).

77. For example, culture methods using low oxygen can prevent subsequent cardiac differentiation. Toshihiko Ezashi, Padmalya Das & R. Michael Roberts, *Low O_2 Tensions and the Prevention of Differentiation of hES Cells*, 102 PROC. NAT'L ACAD. SCI. 4783 (2005).

78. Even regular *in vitro* culture of stem cells requires media and substrates to work faithfully with growth and differentiation factors. David Schaffer, *Exploring and Engineering Stem Cells and Their Niches*, 11 CURRENT OPINION CHEMICAL BIOLOGY 355 (2007). Genetic manipulation of such cells would likely use genetic engineering reagents, and if such cells are used to produce implantable cell therapies—a celebrated goal of stem cell R&D—one can expect cell carriers and scaffolds to be involved. Freshly harvested stem cells themselves rarely grow by themselves outside the body. A series of carefully engineered tools assay and manipulate the behavior of these cells to produce R&D.

79. International hESC characterization projects have listed more stringent technical criteria to ensure that a population of cells retains stem cell characteristics. Personal Communication with Jonathan Auerbach, President, GlobalStem, Inc. (June 2006—July 2008); *see also* Baker et al., *supra* note 72.

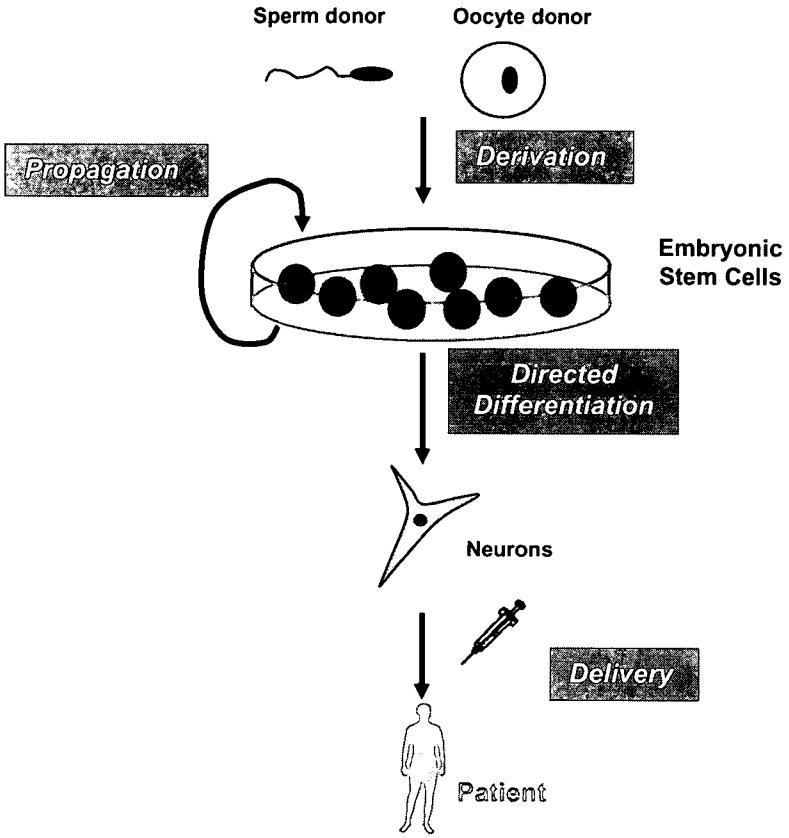

FIGURE 2. The Many Technical Stages of Embryonic Stem Cell Research
Four key methodological stages are delineated in gray for one particular application. In the application schematically shown, mature neurons are created from stem cells, which are then implanted into a patient to induce regeneration. This schematic only illustrates one application of stem cells in regenerative medicine. Other uses of stem cells (e.g., toxicology, pharmacology, and developmental biology) typically will need to generate cell lines of specific phenotypes, all of which will move through controlled derivation, propagation, and differentiation stages.

lines they are beginning to explore genetic and epigenetic effects[80] and are actively developing nascent tools to connect genetic data with gene expression data on an integrated website.[81] Even the diet of egg donors can influence the

80. Baker et al., *supra* note 72; International Stem Cell Initiative, *supra* note 72.

81. Personal Communication with Auerbach, *supra* note 79; Personal Communication with Dr. Mahendra Rao, Vice President, Research, Stem Cells and Regenerative Medicine, Invitrogen

phenotype of an embryonic stem cell line by producing different epigenetic effects on particular chromosomal loci.[82] It is not surprising that scientists have already tried to document all known information about hESC lines, such as sex and ethnicity.[83] However, obtaining further information about the donor is rarely possible, since identity is concealed to protect privacy.

Journal articles have limited capacity to communicate much of this data, as methodological details of stem cell culturing history, genome, and derivation are rarely published fully in the main text of journal articles: many times they are edited out or moved to supplemental information that is not as readily accessible. This is in part because standards on reporting around derivation and characterization are still developing along with the fast-moving frontier of the field itself.[84] Furthermore, important information is frequently obtained through negative results, which are less likely to be published.[85]

The general difficulty of obtaining essential technical details about the numerous technologies regularly employed in experiments or applications creates a bottleneck for stem cell R&D. This process of gathering information involves significant and redundant legwork for every scientist.[86] Facing grant and publication deadlines, scientists read the scientific literature and call close colleagues in order to choose a technology to work with. In cases where scientists devote considerable time to do this legwork, even after extensive communication with their network of colleagues, scientists are uncertain whether they have the most up-to-date information available, knowing that there are many experts with relevant data outside of their personal network.[87] Work typically must proceed at the risk of depending upon poorly chosen tools or materials that could

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Corporation (April—June 2006).

82. Acetylation patterns on the oocyte are connected to maternal diet. *See* David I.K. Martin, Robyn Ward & Catherine M. Suter, *Germline Epimutation: A Basis for Epigenetic Disease in Humans*, 1054 ANNALS N.Y. ACAD. SCI. 68 (2005).

83. Donor characteristics are beginning to be provided on the U.K. stem cell bank catalogue and other websites. *See, e.g.*, The Stem Cell Community, www.stemcellcommunity.org (last visited Nov. 13, 2008).

84. *See, e.g.*, Stephenson, Braude & Mason, *supra* note 31.

85. For example, if a scientist seeks particular properties in stem cell derivatives (e.g., test neurons from hESC line "A"), then prior details of difficulties in differentiating a hESC line into the desired lineage are exceedingly important (e.g., hESC line "A" is difficult to differentiate into neurons). Only recently has this phenomenon been studied and published systematically for particular lineages. Kenji Osafune et al., *Marked Differences in Differentiation Propensity Among Human Embryonic Stem Cell Lines*, 26 NATURE BIOTECH. 313 (2008).

86. *See* RAPPORTEUR'S REPORT, *supra* note 74; Personal Communication with Auerbach *supra* note 79.

87. *See* RAPPORTEUR'S REPORT, *supra* note 74; Personal Communication with Auerbach, *supra* note 79.

compromise the success of the work.[88] In addition, inquiries relying on comparison across multiple cell lines, such as across disease-specific hESC lines, remain closed due to incomplete and sparse data.

B. Proprietary Domain: Patent Rights and Innovation

IP scholars in the biological sciences have long warned that private patent rights in biomedical technologies may foster an "anti-commons" or "patent thicket" whereby a proliferation of property claims and their frequent litigation can discourage commercial development.[89] The emergence of many densely packed patent claims—whether actually overlapping in technical subject matter or simply interdependent or complementary in the marketplace—raises uncertainty about freedom to operate and imposes transaction costs. Even the owners of dominant patents may not themselves be assured of reaching market unhindered. As a result, companies may under-invest in the development of technology applications.[90] Although the anti-commons effect in biomedicine is difficult to measure and remains controversial,[91] the National Research Council recently concluded that the patent landscape in biomedicine, already complicated in certain areas of research such as gene expression and protein-protein interactions, could become considerably more burdensome over time.[92]

In a best-case scenario under the conditions of an anti-commons or patent

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88. *See* RAPPORTEUR'S REPORT, *supra* note 74; Personal Communication with Auerbach, *supra* note 79.

89. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE. 698 (1998); Peter Lee, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659 (2004); Carl Shapiro, *Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119-50 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001).

90. *See* Gregory D. Graff, Gordon C. Rausser & Arthur A. Small, *Agricultural Biotechnology's Complementary Intellectual Assets*, 85 REV. ECON. & STAT. 349 (2003); Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293 (1996); Norbert Schultz, Francesco Parisi & Ben Depoorter, *Fragmentation in Property: Towards a General Model*, 158 J. INSTITUTIONAL & THEORETICAL ECON. 594 (2002); Carl Shapiro, *supra* note 89; Rosemarie Ham Ziedonis, *Don't Fence Me In: Fragmented Markets for Technology and the Patent Acquisition Strategies of Firms*, 50 MGMT. SCI. 804 (June 2004); Soma Dey, Are Patents Discouraging Innovation? (June 2006) (unpublished manuscript, on file with the Department of Business Policy, National University of Singapore).

91. *See, e.g.*, Richard A. Epstein & Bruce N. Kuhlik, *Is There a Biomedical Anticommons?*, REGULATION, Summer 2004, at 54, 54-58 (arguing that Heller and Eisenberg overstate the case against patent protection at both the theoretical and empirical levels); John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005).

92. REAPING THE BENEFITS, *supra* note 10, at 2.

thicket, a company that commercializes a complex biomedical product would need to spend significant resources negotiating and paying multiple royalty "tolls" to the owners of rights to "thoroughfare" enabling technologies infringed by that product. In a worst-case scenario, even after concluding legal analysis and deals assumed to establish reasonable freedom to operate, a company may find its product infringing yet other (previously unidentified) patents, inciting costly litigation or settlements. Most commonly, however, a patent thicket can be expected to result in innovation malaise born of unwillingness on the part of investors to put money behind projects because of the uncertainty over whether a cost-viable path to market will be found for the new, unproven technology. Of course, the most valuable of treatments—in terms of expected revenues—will invariably find willing investors and thus find their way to market through licensing deals, settlements, or even mergers or acquisitions. When enough money is on the table, the sheer size of potential winnings can drive deals to completion. Projects in the "long tail" with negligible valuations are terminated for reasons other than IP. We would expect the remaining projects in the middle range of potential payoffs, between the two extremes, to be at the greatest risk of getting sidelined because of IP concerns.

Could an anti-commons or patent thicket become a significant drag on the development of stem cell based therapies? As a preliminary matter, it is important to point out that patent and innovation issues are intertwined with the discussion of materials sharing and MTAs developed in the previous Section. As mentioned above, WARF's restricted licensing strategy depended both on the physical control of stem cell lines and their ownership of the underlying IP.[93] WARF's foundational patents have clearly shaped the field: Such ownership of a "thoroughfare" technology has arguably slowed movement in the field and by some accounts dampened stem cell innovation in the start-up sector.[94] Furthermore, WARF's newly announced policy does nothing to change the fact that any entity seeking to commercialize hESC technology will have to negotiate a commercial license from WARF. There has been ample policy attention paid to this problem, and it remains to be seen how liberally WARF will make such licenses available.

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93. *See* O'Connor, *The Use of MTAs*, *supra* note 56, at 1044-48.

94. *See* Loring & Campbell, *supra* note 30. Of course, such assessment must be made relative to the likely pace of progress in the absence of incentives for Geron to fund stem cell research at the University of Wisconsin. Perhaps the same inventions would have emerged from the Thompson lab solely from NIH-funded research, or perhaps the inventions would never have occurred at all. However, given that the grounds of the patent reexamination filed with the USPTO in 2006 were that the inventions by Thompson were obvious to those versed in the art, it is hard to defend a counterfactual scenario in which hESCs would not have been created somewhere, by someone in the field, and even within a roughly comparable time frame. *See supra* text accompanying note 64.

But single-minded attention to the WARF patent as the extent of proprietary hold-ups in the field would be a mistake. First, as mentioned earlier, stem cell scientists have developed cell reprogramming techniques to produce pluripotent stem cells (iPS) without using WARF's patented embryonic stem cell methods. In the wake of litigation on the WARF patents, it was determined that this iPS technique and associated cell lines would not infringe WARF's patents.[95] There is still scientific disagreement about whether iPS cell lines could ever fully replace the need for hESCs in either research or therapeutics,[96] but these techniques have been deemed a major discovery with the potential to avoid the need for human embryos in the production of useful stem cell research tools and therapies. Meanwhile, patent applications on these new techniques and cell lines are reportedly flooding the patent office, creating the potential for serious constraints on these materials down the road.[97]

Second, patents covering derivation techniques and stem cell lines seem to be the tip of the iceberg of existing stem cell patents, and conditions in the field could set the stage for a classic patent thicket problem that will hinder innovation. Several analyses show a significant rate of accumulation of new patents over stem cells and related technologies,[98] with problematic implications for downstream innovation.[99] Indeed, given the particular characteristics of stem cells as an enabling technology—i.e., a necessary technology for undertaking a broad range of new research endeavors and commercial applications—the field may be particularly susceptible to the emergence of a patent thicket.

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95. *See* Holden, *supra* note 67.

96. *See id.* at 1603 ("ES cells are still needed to validate iPS cells, and even if iPS cells prove viable substitutes for ES cells in research, some scientists believe they will never be suitable for cell therapy."); Insoo Hyun et al., *New Advances in iPS Cell Research Do Not Obviate the Need for Human Embryonic Stem Cells*, 1 CELL STEM CELL 367 (2007).

97. *See* Holden, *supra* note 67, at 1603.

98. *See* DAVID CAMPBELL, MICHEL NOISEUX & GRÉGOIRE CÔTÉ, POTENTIAL FOR STEM CELLS SCIENCE AND TECHNOLOGY IN CANADA: GREAT PROMISES AND CHALLENGES (2004), http://www.science-metrix.com/pdf/SM_2003_015_IC_Stem_Cells_Potential_Canada.pdf; WOLFGANG GLÄNZEL ET AL., STEM CELLS: ANALYSIS OF AN EMERGING DOMAIN OF SCIENTIFIC AND TECHNOLOGICAL ENDEAVOUR (2004), http://www.steunpuntoos.be/rapportstamcellen_June2005.pdf; Robert W. Esmond, Robert A. Schwartzman & Ted J. Ebersole, *Stem Cells: The Patent Landscape*, 18 INTELL. PROP. & TECH. L.J. 1 (2006); Robert C. Scheinfeld & Parker H. Bagley, *The Current State of Embryonic Stem Cell Patents*, N.Y.L.J., Sept. 26, 2001, at 3, *available at* http://www.law.com/jsp/article.jsp?id=900005523511#.

99. *See* Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENG. L. REV. 665 (2004-2005); Todd N. Spalding & Michele M. Simkin, *How Will Patents Impact the Commercialization of Stem Cell Therapeutics?*, 2 J. PHARMACEUTICAL INNOVATION 23 (2007), *available at* http://springerlink.com/content/rtx5013k15882g00/fulltext.html.

A substantial number of patents have been granted in the relatively young field of stem cells,[100] yet the road to actual stem cell products remains long. Such products will have to navigate a significant number of additional property claims if future patenting rates follow current trends: Annual rates of patent filings have grown rapidly in recent years, along with more modest but significant gains in actual patent grants.[101] Ownership of stem cell patents is fragmented across multiple organizations, with no single organization dominating the field. The largest patent holding accounts for just three percent of the patents in the field.[102] This landscape implies that the task of coordinating access to complex enabling technologies could involve an intensive process of searching and negotiating. Furthermore, in contrast to most fields of technology, government and academic institutions own a very large share of the patents in stem cells: fully forty-four percent of the stem cell patents in the United States (compared to an average of less than three percent in most fields of technology).[103] Given that academic and public research organizations file for patent protection primarily in order to license the technologies and not to build integrated patent portfolios, there may be an even greater dispersion of technology ownership than would be observed in fields more dominated by companies with strategic product development and IP management goals.

Moreover, the technical content of the stem cell patent landscape is highly complex, with stem cell lines, stem cell preparations, and growth factors subject to intense patenting activity.[104] The sheer complexity of the "tree" of mammalian cellular differentiation has important efficiency implications, with numerous lineages emanating from pluripotent stem cells and branching off to arrive at fully differentiated functional tissue cells (Figure 1). It is likely that the complex set of technologies—the growth factors, hormones, other proteins, small molecules, and culture conditions—necessary to control the early stages of differentiation (represented by the heavier lines in Figure 1) will not have many alternatives, while they are likely to be owned separately. Nevertheless, they represent the major (patented) "thoroughfares" that will need to be traversed by many seeking different cellular destinations.

C. Ethical Domain: Ethical and Regulatory Complexity

As if technical and proprietary complexities were not enough, few issues in the life sciences have been as ethically and politically contested as the production

100. *See* Bergman & Graff, *Global Stem Cell Patent Landscape*, *supra* note 28, at 422.

101. *See id.* at 420.

102. *See id.* at 421.

103. *See id.*

104. *See id.*

and use of stem cells.[105] Both in the United States and abroad, sharp divisions on the moral status of the embryo have engendered conflict in the domain of political morality[106]—the terrain on which ethics connects with politics, where human values meet formal and informal forms of collective governance such as laws, regulations, and standards.[107] Beyond the threshold issue of whether embryo rights ought to prevent state funding of the work, the large-scale implementation of stem cell research entails many other problematic issues around the procurement of human tissue, different techniques of deriving stem cell lines, and particular applications of the technology.

The ethical and political landscape for stem cell research has given rise to two major problems for the efficient and accountable governance of the work. First, in the United States, the moratorium on the creation of new hESC lines has resulted in a vacuum not only of research funding, but also of federal regulation. As mentioned above, current federal policy limits national public funding to research conducted on hESC lines created before August 2001.[108] As a result, even as private and state-funded hESC research moves ahead, a national approach to regulation is lacking. This means that rules within and across many jurisdictions are either absent or unclear. Observing this regulatory gap at the federal level, the National Academies of Sciences has published recommended guidelines for the conduct of hESC research, but these remain voluntary.[109] The core of the system they recommend is the establishment of an additional layer of oversight at institutions conducting the research, a Stem Cell Research Oversight Committee (SCRO) that functions in parallel to the Institutional Review Board featured in Federal Human Research Subject Protections.[110]

The response of various states to the federal situation has produced a second problem for stem cell governance: within the United States, state funding

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105. *See* PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH (2004), *available at* http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf.

106. For more on "political morality," see MICHAEL L. GROSS, ETHICS AND ACTIVISM: THE THEORY AND PRACTICE OF POLITICAL MORALITY 1-2 (1997) (defining political morality as "the moral principles governing public policy and the cognitive and behavioral mechanism citizens use to preserve the ethical foundation of civil society").

107. For an ethical analysis of the stem cell field that deals explicitly with the institutional quandaries of moral disagreement in civil society, see Rebecca Dresser, *Stem Cell Research: The Bigger Picture*, 48 PERSP. BIOLOGY & MED. 181 (2005).

108. *See* GUIDANCE FOR INVESTIGATORS, *supra* note 25.

109. NAT'L RESEARCH COUNCIL & INST. OF MED., GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH (2005) [hereinafter NRC-IOM GUIDELINES].

110. *Id.* at 44-48. Federal funding agencies require that all institutions receiving federal money bring their research into compliance with this so-called "common rule," and its IRB requirement. 45 C.F.R. § 46.109 (2005).

programs have given rise to a proliferation of state regulatory regimes, creating a patchwork that is increasingly difficult to navigate.[111] In the United States, the November 2004 election marked a sea change in the public funding environment for hESC research when the voters of California approved the so-called California Stem Cell Research and Cures Initiative.[112] This program earmarked $3 billion in direct state spending, excluding interest payments, for stem cell research and related work over the next ten years.[113] Following California's lead, many other states saw economic and political opportunity in the national stalemate and initiated their own programs of funding for stem cell research.[114] These include Connecticut,[115] Wisconsin,[116] Illinois,[117] Massachusetts,[118] New

111. Susan Stayn, *A Guide to State Laws on hESC Research and a Call for Interstate Dialogue*, 5 MED. RES. L. & POL'Y REP. 718 (2006).

112. *See* Connie Bruck, *Hollywood Science: Should a Ballot Initiative Determine the Fate of Stem-Cell Research?*, NEW YORKER, Oct. 18, 2004, at 62 (detailing the campaign in California for Proposition 71).

113. California Stem Cell Research and Cures Act of 2004, CAL. HEALTH & SAFETY CODE § 125291.30 (West 2008).

114. *See* Fossett, *supra* note 29; *see also* Sarah Webb, *A Patchwork Quilt of Funding*, NATURE REPORTS STEM CELLS, Nov. 1, 2007, http://www.nature.com/stemcells/2007/0711/071101/full/stemcells.2007.110.html.

115. *See* CONN. GEN. STAT. ANN. §§ 19a-32d–19a-32g (West Supp. 2008) (providing public funding in support of embryonic and human adult stem cell research); CONN. GEN. STAT. ANN. § 4-28e(c)(3) (West 2007) (providing that, for the fiscal years 2008 through 2015, the sum of $10 million shall be disbursed from the Tobacco Settlement Fund to the Stem Cell Research Fund).

116. In April 2006, the Governor authorized $5 million to recruit private stem cell companies to move to Wisconsin, and negotiated key licensing incentives from WARF to help recruit new companies. He has also announced a much larger funding program, but it had not been initiated as of 2006. *See* Stayn, *supra* note 111, at 8.

117. The Illinois Governor's Executive Order created the Illinois Regenerative Medicine Institute (IRMI) providing for grants to medical research facilities for adult and embryonic stem cell research. Office of the Governor of Illinois, Exec. Order No. 6 (2005), amended by Exec. Order No. 3 (2006), *available at* http://www.illinois.gov/gov/execorder.cfm?eorder=46. Ten million dollars went to this new program, with grants awarded in April 2006. Press Release, Gov. Blagojevich, Comptroller Hynes Announce $10 Million in State Stem Cell Research Grants, Office of the Governor of Illinois (Apr. 24, 2006), *available at* http://www.idph.state.il.us/public/press06/4.24.06StemCellGrants.htm. In 2006, $5 million were appropriated and allocated to the stem cell program for 2007. Press Release, Gov. Blagojevich Announces Recipients of $5 Million in New State Stem Cell Research Funding, Illinois Regenerative Medicine Institute (Aug. 17, 2006), *available at* http://www.idph.state.il.us/irmi/news_081706.html. In 2007, the Illinois General Assembly enacted the Stem Cell Research and Human Cloning Prohibition Act, which permitted IRMI to conduct research on stem cells from any source. 410 ILL. COMP. STAT. 110/1-50 (2007).

118. Overriding the Governor's veto, Massachusetts legislators created an institute for stem cell research and regenerative medicine at the University of Massachusetts with an appropriation of $1

Jersey,[119] and New York.[120] These programs have brought explicit policy attention to the ethical and political aspects of implementing large-scale stem cell research programs.[121]

These states differ, sometimes only slightly, on three sets of regulatory issues facing the governance of hESC.[122] First, states differ in the regulation of the procurement of the gametes, embryos, and other cells from human donors for the generation of new hESC lines. Putting aside for a moment the potential of the announced discovery of so-called cell reprogramming technologies to change the derivation landscape,[123] new hESC lines need to be derived from human embryos at an early stage of its development called the blastocyst, for which there are three major pathways of donation. The first is the *in vitro* fertilization (IVF) process and the supernumerary embryos created thereby. *In vitro* fertilization involves the extraction of eggs and sperm from potential parents or donors, and the creation of embryos *in vitro* for subsequent transplant into the potential mother's womb. The second source of embryos is from the creation of embryos *in vitro* from egg and sperm specifically for the purpose of deriving new hESC lines. A third source of stem cell lines would involve somatic cell nuclear transfer (SCNT), also known as cloning. Through this method, scientists insert genetic material from an adult cell and inject it into an egg cell, stimulating it to reproduce. An advantage of SCNT is that it may avoid the problem of rejection

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million to be spent on stem cell biology. They also established a center and a "Life Sciences Investment Fund" with $10 million to promote research in stem cell, regenerative medicine, biotechnology, and nanotechnology. Nat'l Conference of State Legislatures, *supra* note 117; 2005 Mass. Acts, Chapter 111L, *available at* http://www.mass.gov/legis/laws/seslaw05/sl050027.htm.

119. In 2005 and 2006, the New Jersey Stem Cell Institute was allocated a total of $23 million in general revenues. Since 2005, grants have been awarded to at least seventeen institutions for research on stem cells from embryos and other sources. In 2007, voters rejected a ballot measure to allow the sale of bonds to fund stem cell research. Nat'l Conference of State Legislatures, *supra* note 117; *see also* State of New Jersey, Comm'n on Sci. & Tech., Stem Cell Research in New Jersey, http://www.state.nj.us/scitech/stemcell (last visited Nov. 13, 2008).

120. New York legislators created a Special Revenue Fund called the "The Empire State Stem Cell Trust" in 2007 "to collect and distribute grants in support of stem cell research" on lines from any source. One hundred million was earmarked for FY 2007-2008 and $500 million was earmarked at $50 million per year for ten years beginning in FY 2008-2009. Applications for the first grant awards were due in January 2008. *See* N.Y. State, A New Stem Cell Research Fund, http://www.ny.gov/governor/ press/lt_stemcell.html (last visited Nov. 13, 2008); N.Y. PUB. HEALTH LAW §§ 265, 265-a-e, 235-f (McKinney 2008), *available at* http://stemcell.ny.gov/about_ nystem_esc_board_statute. html.

121. *See* NRC-IOM GUIDELINES, *supra* note 109; Winickoff, *Bioethics and Stem Cell Banking in California*, *supra* note 28.

122. *See generally* Nat'l Conference of State Legislatures, *supra* note 117; *see also* Stayn, *supra* note 111.

123. *See supra* note 69.

that is common in stem cell transplantation procedures.[124] Individual states differ with regard to the sources of acceptable materials and the methods of procurement, specifically in the terms and provisions for informed consent, payment of donors, and levels of oversight.[125]

Second, many new state regulatory regimes address the derivation of new hESC lines in different ways, due to the open-ended controversies about different derivation techniques.[126] There is agreement that human embryos enjoy some sort of special status, even among those who favor proceeding with hESC research, leading to various kinds of restrictions and oversight. Furthermore, the use of SCNT to derive new hESC lines is especially controversial, raising issues of embryonic manipulation and reproductive cloning, since the embryos produced could in theory become cloned human beings.[127] As a result, individual states differ as to what types of materials can be used, in what ways, and with what kind of oversight.[128]

Third, oversight regimes address different research uses of hESC lines, an area that is currently only minimally regulated under federal research rules in the United States.[129] A number of highly controversial types of research are possible using hESCs. Because of their potential to develop into human nerve and brain cells, hESCs could be used to create animals with a significant number of human cells. These chimeras may be useful for conducting biomedical experiments, but blur the boundary between humans and animals, introducing ethical complexity

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124. *See, e.g.*, NRC-IOM GUIDELINES, *supra* note 109, at 13. Rules around procurement will help establish the processes and contexts through which donation of gametes, embryos, and adult cells may occur, as well as the rights and duties between researcher and donor that the process gives rise to.

125. Susan Stayn, Senior Univ. Counsel, Stanford Univ., Presentation to the Planning Meeting to Establish an Interstate Alliance for Stem Cell Research: Overview of State HESC Research Laws (May 23-24, 2007), *available at* http://www.iascr.org/docs/StateSummaryTable.pdf.

126. This is true across the United States and other nations. For review of current laws, see The Hinxton Group, World Stem Cell Policies, http://www.hinxtongroup.org/wp.html (last visited Nov. 13, 2008).

127. *See* NRC-IOM GUIDELINES, *supra* note 109, at 1-2. Many bioethicists and scientists agree that if the use of this technique is to proceed, it should be regulated.

128. *See* Stayn, *supra* note 111; Stephen Smith, *Officials from Across the Nation Meet To Foster Stem-Cell Research*, BOSTON GLOBE, Oct. 24, 2007, *available at* http://www.boston.com/yourlife/health/blog/2007/10/officials_from.html ("States differ in their interpretation of what constitutes a legal line of stem cells. In some states, such as New York, scientists hunting for treatments for a disease can produce embryos using sperm and eggs donated by families stricken with the ailment. The resulting stem cells can then be used to understand a disease and to look for treatments. But in Massachusetts, state law does not allow the production of embryos for the express purpose of scientific exploration").

129. NRC-IOM GUIDELINES, *supra* note 109, at 52-61.

into questions of human research subject protection and animal experimentation.[130] Furthermore, if the rights of human donors to limit certain research uses are recognized and documented, it will be necessary to enforce these limitations either contractually or through regulatory oversight. States disagree, and may continue to disagree, for instance, on how to handle these issues of chimeras and donor limitation on use.[131]

So far, we have examined only regulatory complexity within the United States. A similar range of differences occurs across nations that have regulatory regimes for stem cell research in place.[132] International variation in regulation across countries exacerbates the complications posed by the patchwork nature of the U.S. regime.

Technological fixes may ease, but not solve, some of this ethical and regulatory complexity. The emergence of a new array of derivation techniques may present different sets of ethical quandaries and disagreements.[133] For instance, recent advances in cell reprogramming[134] may resolve some of the ethical complexities of this research because they may reduce the need to use "spare" embryos or create new ones through SCNT.[135] However, many stem cell researchers still see the need for developing hESC lines.[136] Cell reprogramming

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130. *See* Jamie Shreeve, *The Other Stem-Cell Debate*, N.Y. TIMES MAGAZINE, Apr. 10, 2005, *available at* http://www.nytimes.com/2005/04/10/magazine/10chimera.html. For a discussion of nascent efforts to ban the creation of certain human chimeras, see Christopher Thomas Scott, *Chimeras in the Crosshairs*, 24 NATURE BIOTECH. 487, 487-90 (2006).

131. *See generally* Stayn, *supra* note 111.

132. For a useful synopsis of regulatory differences across nations, see StemGen, http://www.stemgen.org (last visited Nov. 13, 2008) ("StemGen . . . is a research database of international, regional and national normative instruments concerning the socio-ethical and legal aspects of stem cell research and related therapies. It was created as a free tool for the dissemination of information relevant to policy-making, the goal being to make the information accessible to as many people as possible without geographic or cost barriers.").

133. Take for instance the announcement by the biotechnology company, Advanced Cell Technology, that it had "dramatically improved a technique for producing human embryonic stem cells without destroying embryos." Colin Nickerson, *Firm Says It Can Get Stem Cells No Harm to Embryos*, BOSTON GLOBE, Jan. 11, 2008, at A10. This advance assuages some ethical qualms, e.g., the concern with sacrificing the lives of embryos to extract usable hES cells, while reintroducing others, e.g., the ways this technique might pave the way for human reproductive cloning.

134. *See supra* note 69.

135. Gina Kolata, *Scientists Bypass Need for Embryo To Get Stem Cells*, N.Y. TIMES, Nov. 21, 2007, *available at* http://www.nytimes.com/2007/11/21/science/21stem.html.

136. *See* Monya Baker, *From Skin Cell to Stem Cell*, NATURE REPORTS STEM CELLS, June 7, 2007, http://www.nature.com/stemcells/2007/0706/070607/full/stemcells.2007.6.html (stating that "despite the promise, most researchers believe the potential of iPS cells for drug screens or therapies is no reason to abandon work on ES cells"); *see also* Holden, *supra* note 67, at 1603; Hyun et al., *supra* note 96.

to produce pluripotent stem cell lines also raises its own set of ethically vexing questions. For example, can normal cells from any person be used to create viable human germ cells in a Petri dish?[137] As the number of techniques for derivation of lines proliferates, it only increases the needs for further harmonization of regulatory documentation.

The current patchwork of laws, regulations, and ethical rules emerging across nations, individual states, and individual institutions causes repetitive work across institutional SCROs and could stymie scientific collaborations across regulatory jurisdictions.[138]

D. Current Efforts to Address These Problems

Stem cell scientists and policymakers have recognized many of these problems, and there have been some important initiatives attempted within each of these three domains. These efforts should be applauded and then extended in a number of ways. First, none of them goes far enough to solve the problems within its specific domain. Second, since they are largely domain-specific, these existing efforts neglect the important interconnection of problems across domains and thus miss taking an integrative approach that promises to be more effective.[139]

1. Ethics and Regulation

Some of the deepest efforts to date have occurred in the domain of ethics, where regulatory gaps threatened public acceptance of the entire research field. Within the United States, as discussed above, the National Academies published an influential set of guidelines in 2005, with updates in 2007, in order to fill holes in existing regulation and to foster a harmonized federal approach to regulating stem cells.[140] As mentioned above, these guidelines remain voluntary, though they have exerted a significant effect on many institutions conducting stem cell research. This did not, however, prevent the proliferation of differences across

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137. *See* Charis Thompson, *Can Opposition to Research Spur Innovation?*, NATURE REPORTS STEM CELLS, Dec. 13, 2007, http://www.nature.com/stemcells/2007/0712/071213/full/stemcells.2007.128.html; *see also* Robert Lanza, Letter, *Stem Cell Breakthrough: Don't Forget Ethics*, 318 SCIENCE 1865, 1865 (2007).

138. The Hinxton Group, Consensus Statement (Feb. 24, 2006) [hereinafter Hinxton Consensus Statement] *available at* http://www.hinxtongroup.org/docs/Hinxton%202006%20consensus%20document.pdf (stating that "inconsistent and conflicting laws prevent some scientists from engaging in this research and hinder global collaboration"). The Hinxton Group Consensus Statement is described in more detail *infra*.

139. The point will be developed *infra* Section II.A.

140. *See* NRC-IOM GUIDELINES, *supra* note 109.

state jurisdictions. In 2007, in order to begin addressing this problem, a group of state regulators and interested stakeholders came together around the problems caused by the federal approach to stem cell funding and regulation, founding the so-called Interstate Alliance on Stem Cell Research.[141]

At the international level, a number of initiatives seek to facilitate international collaboration and encourage research institutions to cohere around base-level ethical norms and practices. First, in February 2006, the so-called Hinxton Group—an international and interdisciplinary team of "scientists, philosophers, bioethicists, lawyers, clinicians, journal editors and regulators" convening in Hinxton, United Kingdom—issued a consensus statement setting out principles and strategies for promoting the ethical conduct of stem cell research across countries.[142] In an effort to foster international scientific collaboration and ethical scientific conduct in the face of value pluralism, the Hinxton Group outlined general principles for how research in this area ought to proceed given national variations in policy.[143] The statement, however, sets out few specifics.[144]

Second, in December 2006, the International Society for Stem Cell Research (ISSCR) issued more specific recommendations aimed at the international community of stem cell scientists. The ISSCR is the leading international society for stem cell scientists, who engage in yearly scientific meetings that also address matters of policy and regulation.[145] As such, it has become one of the most important international venues for discussing means to promote better international and cross-institutional collaboration on scientific and policy issues. Encompassing the National Academy of Sciences guidelines, as well as regulations promulgated by the California Institute of Regenerative Medicine (CIRM) and the Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom,[146] the ISSCR guidelines were developed over the course of a

141. This group has made important strides in documenting the problem of regulatory discord across the states, seeking to make state rules more transparent, and initiating cross-state conversations. "The goals of IASCR are to (a) identify and increase opportunities for interstate collaboration; (b) identify and decrease obstacles to collaborative research across state lines; and (c) assist states that wish to develop or improve public funding programs in this area." Interstate Alliance on Stem Cell Research, About IASCR, http://www.iascr.org/about.shtml (last visited Nov. 13, 2008).

142. Hinxton Consensus Statement, *supra* note 138, at 1.

143. *Id.*

144. It does assert, *inter alia*, general principles of respect for donors, the duties of beneficence, the need to be "circumspect when regulating science" and "citizens' conduct extraterritorially," and the need for broad consultation in developing regulations. *Id.*

145. *See* International Society for Stem Cell Research, http://www.isscr.org (last visited Nov. 13, 2008).

146. George Q. Daley et al., *The ISSCR Guidelines for Human Embryonic Stem Cell Research*,

year by an international panel of scientists, lawyers, ethicists, and policymakers. Like the National Academy of Sciences, the ISSCR recommends making institutions responsible for ensuring that hESC research under its auspices have been subject to "impartial" and "rigorous" review by Stem Cell Research Oversight Committees.[147] SCRO review, which could occur at local, national, or international levels, ensures compliance with particular guidelines and constraints on types of research, procurement of cell lines, informed consent, cell banking, and provenance.[148]

These efforts at the national and international levels mark the beginning of a long-term project of promoting greater harmonization in regulations, coordinating the ethical review of stem cell lines and materials, and promoting transparency and enforcement of existing regulations. Developing common sets of norms and practices, they help ease some of the problems in the ethical domain, as discussed above. But they hardly go deeply enough. First, all of the efforts mentioned above are voluntary statements. Some jurisdictions, including many U.S. states, continue to lack legally binding rules. At the same time, significant regulatory differences have emerged among jurisdictions that have adopted rules. At present, it is costly and inefficient to assess and analyze whether and how particular cell lines and materials satisfy requirements of different jurisdictions. The individual SCROs that have grown up at major institutions involved in stem cell research currently conduct this sort of analysis. Opportunities for coordination and consolidation in these review functions have not been developed, which allows for redundancy.

In one of the more promising efforts in this area, the ISSCR plans to "curate and maintain a website listing of human stem cell lines that testifies to independent validation of the provenance of the cell lines."[149] The Hinxton Group encourages the creation of such a database.[150] This sort of activity, if it could be expanded to be an international ethical and regulatory clearinghouse, could

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315 SCIENCE 603, 603 (2007). Note, however, that "the ISSCR guidelines diverge subtly from the U.S. NAS guidelines" in a number of ways, being more permissive towards "breeding of animals that might carry human gametes" and recommending exemption from SCRO review of certain in vitro experiments that use established cell lines, such as the teratoma assay." *Id.* at 604.

147. Int'l Soc'y for Stem Cell Research, ISSCR GUIDELINES FOR THE CONDUCT OF HUMAN EMBRYONIC STEM CELL RESEARCH § 8.2 (2006) [hereinafter ISSCR GUIDELINES], *available at* http://www.isscr.org/ guidelines/ISSCRhESCguidelines2006.pdf.

148. *Id.* §§ 10, 11, 11.3, and 12 respectively.

149. The ISSCR Standards Committee is charged with the responsibility of verifying this provenance. *Id.* § 12.4.

150. Hinxton Consensus Statement, *supra* note 138 (stating at 3, "We encourage the creation of a public database for the deposition of statements of ethical conduct and guidance, research protocols, consent forms, information provided to potential human subjects and tissue donors and other related documents that bear on the ethics of stem cell research.").

provide a crucial service for more effective and efficient tracking of stem cell materials across the regulatory patchwork that has emerged. Unfortunately, the ISSCR's ethical database remains underdeveloped, due to a lack of funding and a general lack of interest within the scientific community.

2. Sharing Data and Materials Access

Among stem cell researchers and policymakers, there is broad recognition of the importance of access to scientific data and materials. A number of data and materials sharing guidelines, stem cell banks, and data registries—including the efforts described above to promote the transfer of the WARF cell lines—have begun to address the constraints imposed by these issues.

Scientific conferences are, of course, important channels through which ideas and knowledge flow, and the stem cell community has many such meetings, both national and international in scope. Beyond meetings, however, the research community—through deliberative bodies such as the National Academy of Sciences, ISSCR, and the Hinxton Group—has articulated loftier goals and has developed certain policies around data and materials access. The ISSCR has been the most active of these groups, stressing the importance of "the open exchange of scientific ideas and materials to maximize exploration, to promote innovation and to increase the probability of public benefit through affordable advances."[151] Consistent with this goal, the ISSCR has established clear policies on data sharing for its affiliated academic journal, *Cell Stem Cell*: "One of the terms and conditions of publishing in *Cell Stem Cell* is that authors be willing to distribute any materials and protocols used in the published experiments to qualified researchers for their own use," including "cells, DNA, antibodies, reagents, organisms, and mouse strains or if necessary the relevant ES cells."[152] These must be provided "with minimal restrictions and in a timely manner."[153] Furthermore, authors are also "encouraged to deposit materials used in their studies to the appropriate repositories for distribution to researchers." The ISSCR Guidelines also recommend that institutions grant "unhindered access" to materials and promote nonexclusivity and broad accessibility in their licensing practices, especially for non-commercial research.[154]

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151. ISSCR GUIDELINES, *supra* note 147, §§ 1.4, 7.

152. Cell Stem Cell, Author Guidelines, http://www.cellstemcell.com/misc/page?page =authors (last visited Nov. 13, 2008).

153. *Id.* (also stating that "it is acceptable to request reasonable payment to cover the cost of maintenance and transport of materials" and that "if there are restrictions to the availability of any materials, data, or information, these must be disclosed in the cover letter and the experimental procedures section of the manuscript at the time of submission").

154. ISSCR GUIDELINES, *supra* note 147, § 7.2 ("[I]nstitutions engaged in human stem cell research, whether public or private, academic or otherwise, develop procedures whereby research

Centralized stem cell banks and registries are a tangible way to provide exchange of materials and data across labs, institutions, and political jurisdictions,[155] and these efforts have sprung up both in the United States and elsewhere. In collaboration with WiCell Research, the NIH developed "the National Stem Cell Bank (NSCB)," a repository that distributes the recently liberalized WARF cell lines and other lines approved for federal research funding.[156] In addition to covering only a few cell lines, the bank and its associated NIH Registry have disappointing limitations regarding the provision of useful data: They simply list the federally-approved lines and provide contact information on how to acquire them.[157] The registry does not include information needed to perform follow-up work, nor does it contain provenance or ethical information.[158] Furthermore, the $3 billion California stem cell initiative has not developed banking and materials distribution capacity, despite calls within California for centralizing governance through stem cell banking and even explicit plans to do so.[159]

The lack of good ethics data and provenance data in the NIH Registry turned out to be a critical omission, illustrating the need for more robust cell line databases. A 2008 study of the provenance and consent conditions for all twenty-one government-approved hESC lines found that none of these consent forms meet the standards set out recently by the National Academy of Sciences, and some depart significantly.[160] While it is being debated whether the cell lines are

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scientists are granted, without undue financial constraints or bureaucratic impediment, unhindered access to these research materials for scientifically sound and ethical purposes, as determined under these Guidelines and applicable laws. The ISSCR urges such institutions, when arranging for disposition of IP to commercial entities, to take all possible care to preserve nonexclusive access for the research community, and to promote public benefit as their primary objective. The ISSCR endorses the principle that as a prerequisite for being granted the privilege of engaging in human stem cell research, researchers must agree to make the materials readily accessible to the biomedical research community for non-commercial research.").

155. Indeed, the National Academy of Sciences, Hinxton Group and ISSCR have made strong recommendations to enhance efforts in these areas. *See* ISSCR GUIDELINES, *supra* note 147, § 12.2; NRC-IOM GUIDELINES, *supra* note 109, § 5; Hinxton Consensus Statement, *supra* note 138, § 8.

156. Editorial, *Registries and Banks*, *supra* note 31.

157. *Id.*; *see also* NIH Human Pluripotent Stem Cell Registry, http://stemcells.nih.gov/research/registry (last visited Nov. 13, 2008).

158. Editorial, *Registries and Banks*, *supra* note 31.

159. Winickoff, *Bioethics and Stem Cell Banking in California*, *supra* note 28, at 1094-1105; David Winickoff, The California Public Biorepository and Trust (CPBT): A Governance Model for Ethics and IP of Stem Cell Research (Sept. 27, 2005) (unpublished white paper and written testimony to public hearing of the Ethics and Standards Working Group of the California Institute of Regenerative Medicine in San Francisco) (on file with author).

160. Robert Streiffer, *Informed Consent and Federal Funding for Stem Cell Research*, HASTINGS CENTER REP., May—June 2008, at 42-44.

in violation of ethical guidelines in place at the time of President Bush's 2001 announcement,[161] it is clear—if the report is accurate—that new regulations in certain jurisdictions bar the use of some of these lines. For example, researchers using some of these cell lines in California may actually be in violation of recently enacted ethical regulations, prompting Stanford and other universities to announce that they are re-examining the approval of work using those lines.[162] If these alleged violations are born out, research may be seriously set back because of failure to perform appropriate due diligence and tracking of cell provenance and ethical requirements.

At the international level, both stem cell banks and data registries have emerged that seek to improve materials and data sharing across research communities. The best known and most developed to date is the UK Stem Cell Bank (UKSCB), funded by the Medical Research Council (MRC) and the Biotechnology and Biological Sciences Research Council (BBSRC).[163] Launched in 2002, the UKSCB was recently renewed with a grant of nearly £10 million[164] to establish a permanent repository for all types of human stem cell lines (adult, fetal, and embryonic) with clinical applicability.[165] UKSCB deposited its first line in 2005 and hopes to scale up as a bank and distributor of both U.K. and international cell lines for the global stem cell research community.[166] A basic online database has also emerged along with the UK Stem Cell Bank, although its capacity is only to catalogue the lines in the bank, not to provide substantial technical data.[167]

Small international data registry projects for stem cell lines have emerged, such as the International Stem Cell Forum (ISCF) housed within the International Stem Cell Initiative.[168] However, the most advanced and ambitious registry to

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161. In 2001, President Bush "declared that only lines already in existence could receive federal support." Monya Baker, *Consent Issues Restrict Stem-Cell Use*, NATURE NEWS, July 28, 2008, http://www.nature.com/news/2008/080728/full/454556a.html (last visited Nov. 13, 2008).

162. *Id.*

163. *See* UK Stem Cell Bank, http://www.ukstemcellbank.org.uk (last visited Nov. 13, 2008). For a discussion of UK Stem Cell Bank's governance structure, and potential adaptation to the U.S. situation, see David E. Winickoff, *Bioethics and Stem Cell Banking*, *supra* note 28, at 1095-105.

164. Editorial, *Registries and Banks*, *supra* note 31.

165. UK STEM CELL BANK, DEVELOPMENT OF THE UK STEM CELL BANK PHASE II: PROPOSED PLAN FOR 2006-2010, http://www.ukstemcellbank.org.uk/documents/UKSCB%20Development%20Plan%202006-2010.pdf (last visited Nov. 13, 2008).

166. *Id.* at 5 ("The Bank aims to consolidate its position as the foremost repository of both UK and international stem cell lines in order to provide ethically sourced and well characterized stocks of human stem cells banked with a stringent quality framework.").

167. *See* UK Stem Cell Bank, Catalogue Overview, http://www.ukstemcellbank.org.uk/catalogue.html (last visited Nov. 13, 2008).

168. ISCF was set up in January 2003 with the aim "to bring together nine international funding

date is the European hESC Registry (hESCreg) launched in Berlin in January 2008.[169] Funded by the European Union, hESCreg has explicitly international ambitions and scope, growing out of a European "demand for a collaborative and interdisciplinary platform where researchers, regulators, as well as the general public can access comprehensive information about all human embryonic stem (ES) cell lines available."[170] The registry's mission is "to provide comprehensive information on existing hESC lines, their derivation, molecular characteristics, use and quality, and to act as a platform for coordination and cooperation." The registry makes this information freely accessible to the public "in order to further open-up the field and promote the validation of research findings and the efficient use of existing hESC lines."[171] The project aims to better characterize human ES cells, and to standardize research in the field by linking to other repositories, cell banks, regulatory bodies, and specific research projects.[172]

With these emerging efforts, some data and materials have been moving faster, but there is significant room for improvement. One gap involves deficiencies in the amount and type of data included in database efforts. Although hESCreg and the ISCF registries contain significant technical data, much of the methodological details of stem cell culturing history, genome, and derivation residing in supplemental information websites of journals (and even in the e-mail exchanges between researchers) could still be captured in the emerging efforts to centralize key information.

Furthermore, despite their promise, the current registries and banks remain too thinly funded, uncoordinated, and fragmented.[173] Outside of the United

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agencies that were already united in the belief that bilateral collaboration and information-sharing would accelerate progress and improve global practice in stem cell research." Int'l Stem Cell Forum, Background and Aims, http://www.stemcellforum.org/about_the_iscf/background_&_aims.cfm (last visited Nov. 13, 2008). Although this initiative remains nascent and under-funded, its parent organization, the ISCF, is made up of twenty one prominent funders from around the world. *See* Int'l Stem Cell Forum, Members, http://www.stemcellforum.org/about_the_iscf/members.cfm (last visited Nov. 13, 2008).

169. European Human Embryonic Stem Cell Registry, About hESCreg, http://www.hescreg.eu/typo3/index.php?id=14 (last visited Nov. 13, 2008) ("The European Human Embryonic Stem Cell Registry (hESCreg) is funded as a Specific Support Action under the 'Life Sciences, Genomics, and Biotechnology for Human Health' Priority within the 6th Framework Programme for Research and Technological Development of the European Commission. The Project commenced operations in April 2007 and has an envisaged duration of 3 years.").

170. Editorial, *Registries and Banks*, *supra* note 31 (quoting Joeri Borstlap, joint coordinator of the program).

171. European Human Embryonic Stem Cell Registry, Mission & Objectives, http://www.hescreg.eu/typo3/index.php?id=23 (last visited Nov. 13, 2008).

172. Editorial, *Registries and Banks*, *supra* note 31.

173. *Id.*

Kingdom, funders for banking and databases have not delivered on commitments. For instance, California's CIRM has been in a position, as the leading funder of research in the United States, to actively promote banking and data sharing,[174] but it has yet to make this a priority. As more hESC and iPS cell lines are derived, and requests to access such lines come from across the global research community, it is clear that neither individual labs nor the regional or national stem cell banks can easily distribute the lines. Furthermore, there has been no sustained international effort to coordinate among the ISCF, ISSCR, and hESCreg databases.[175]

Lastly, journal policies are uneven, ranging from *Cell Stem Cell*'s strong policy on sharing to no stipulations on sharing at all,[176] and more harmonization among these policies in the science publishing industry could help the community collectively move towards greater sharing of materials and data. Because the scale and scope of these efforts remain limited, gathering information remains a burdensome activity for many scientists. Given the current capacities for sharing, policy lags far behind the need and opportunities for mutually advantageous collective action.

3. Patents and Innovation

Whereas important initiatives have begun in the areas of ethics and data sharing, few have addressed constraints imposed by patents on innovation. The developments with the WARF patents and cell lines have been important, but these changes affect neither the landscape of patents beyond WARF's holdings, such as the emergent iPS area, nor the bottlenecks anecdotally occurring in the start-up biotechnology sector. As discussed above, these issues are closely linked to the ultimate accessibility of stem cell lines and research tools. Indeed, stem cell banks will only be useful for making materials available insofar as the patenting and licensing issues are addressed. For instance, the UKSCB will not release any lines to researchers until the depositor certifies that the depositor, researchers, and third-party users of the cell lines have agreed to terms regarding IP.[177]

Existing funders of stem cell research have constructed some policy solutions to this problem. For instance, CIRM has stipulated that any CIRM-funded inventions must be licensed to other CIRM grantees for non-commercial

174. *See* Eisenberg & Rai, *supra* note 49, at 1191.

175. *See* Healy et al., *supra* note 73; O'Rourke et al., *supra* note 73. A consensus statement and a common portal to search across these databases are being discussed but have not yet materialized.

176. *See, e.g.*, Piwowar & Chapman, *supra* note 42, at 2.

177. *See* UK Stem Cell Bank, Materials Access Agreement, http://www.ukstemcellbank.org/documents/UKSCB%20Materials%20Access%20Agreement%20-%20(v6%2019-08-08).pdf (last visited Nov. 13, 2008).

research use at reasonable cost.[178] This policy, however, fails to provide for sharing to non-CIRM grantees, making it a rather insular solution to a larger problem and yet another detrimental consequence of the patchwork nature of regulation in the United States. Similar guidance by NIH would have leverage over a much larger number of scientists and institutions. Furthermore, while international bodies like the ISSCR have urged that patent holders use non-exclusive licenses whenever possible in order to promote the greatest public benefit,[179] the group has advanced no specific policies regarding the collaborative management of IP, even within the academic sector. Clearly, further thought in this area is needed.

II. DESIGN ELEMENTS FOR OPENING UP STEM CELL R&D

The discussion will now shift from a descriptive to a prescriptive mode, turning to the question of what might be done to advance solutions to the coordination problems in stem cell research outlined above. Any response to these problems must build upon existing initiatives in each domain, while also looking to creative solutions from other fields. Broadly speaking, we argue that collective action can be a basis for opening up stem cell R&D in the face of multiple compounding constraints. In particular, such opening up would result in a more efficient exchange of data, materials, and tools within the stem cell research community. Such collective action could also advance new applications of regenerative medicine, orient stem cell research toward the most pressing social needs, and promote more accountable ethical oversight of stem cell research. To achieve these goals under the current situation of stem cell R&D, we advance six interrelated design principles for institutional collaboration in stem cell R&D.

A. Integration Across Technical, Proprietary, and Ethical Domains

Discussions in academic and policy circles have focused on the technical, proprietary, and ethical arenas as isolated domains.[180] This ignores their key

178. *See* 17 CAL. CODE REGS. tit. 17, § 100306 (2008) ("Grantee Organization agrees to make its CIRM-funded patented inventions readily accessible on reasonable terms, directly or through a licensee or licensees, to other Grantee Organizations for non-commercial purposes, upon request from a Grantee Organization.").

179. *See* ISSCR GUIDELINES, *supra* note 147, § 7.2 ("The ISSCR urges such institutions [involved in stem cell research], when arranging for disposition of IP to commercial entities, to take all possible care to preserve nonexclusive access for the research community, and to promote public benefit as their primary objective.").

180. Important exceptions include, for example, Vickie Brower, *Human ES Cells: Can You Build a Business Around Them?*, 17 NATURE BIOTECH. 139 (1999); and Kenneth S. Taymor,

interactions. Any decision by a researcher to use an existing technology, tool, or method in the laboratory inevitably begins with consideration of its technical efficacy, but the decision must also factor in whether that technology is owned as IP and whether the contemplated use complies with ethical requirements. Investigators will likely make tradeoffs among the three types of bottlenecks. For example, the selection of a more ethically acceptable method or tool may render the experiment less capable of achieving desired technical results; similarly, the selection of a technology with more freedom to operate may be more constrained by regulation. In fact, all such decisions carry implications in all three domains—technical, IP, and ethical—whether or not the researcher knows it. Furthermore, these decisions will embed technical, ethical, and proprietary characteristics of the tools chosen within the research results, and therefore within subsequent or derivative lines of work. Early choices, then, will impose conditions or limitations on future directions, such as the commercialization of therapies based on that work. In practice, technical expediency often dictates researcher choice, IP considerations are left to legal counsel, and ethics are delegated to a review board. Given such specialization in the R&D decision-making processes, interactions are often overlooked.

Overlooking interaction among the three domains involves both a conceptual and a practical error. The conceptual error is to ignore the profound ways in which these domains are mutually constitutive categories: norms and practices of sharing data and materials, even "scientific practices" enabling technical laboratory work, are simultaneously issues of property (e.g., in what ways are data and materials individual property or joint property?) and ethics (e.g., what constitutes best practice and ethical conduct with respect to the sharing of data sets and materials?). Likewise, too often, issues of property rights in works, data, and inventions are compartmentalized within science policy discussions, and therefore divorced from larger concerns of ethics in science or bioethics. As a result, IP policy is sometimes managed as if it were only a technocratic system that did not implicate important ethical and political questions, such as the distribution of resources, social justice, and the ethos of science. Conversely, IP issues are rarely raised within international bioethics documents, and this is a major shortcoming.[181] Data sharing questions are, at their root, property questions, which are, in turn, ethics questions. To separate these questions is to perform a conceptual purification that prevents optimal solutions.

Yet the overlap is not merely conceptual; it is also practical, as the preceding discussions of each domain in Part I suggested. As the recently encountered

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Christopher Thomas Scott & Henry T. Greely, *The Paths Around Stem Cell Intellectual Property*, 24 NATURE BIOTECH. 411 (2006).

181. For example, the Hinxton Consensus Statement, *supra* note 138, discusses cell banking but barely addresses issues of property in data, materials, and patents.

problems with some of the NIH hESC lines illustrate, ethical accountability can be promoted only to the extent that provenance characteristics and data about cell lines are shared.[182] Consider also the ISSCR's recommendation promoting both cell line banking and clear and accessible MTAs. This is an important aspiration, but MTAs depend entirely on the specific material and IP terms controlled by the depositor. Materials and data access issues are strongly connected to material and IP issues: Together they dictate how smoothly a cell bank will be able to facilitate access. As a consequence, efficient progress of ethically accountable stem cell research will require the consideration of complexities and bottlenecks emanating from all three domains.

In order to illustrate more deeply how these three dimensions of complexity operate together, consider three different stem cell technologies for which degrees of interaction across these domains would vary significantly: 1) a single protein growth factor; 2) a single hESC line; and 3) a multi-component or "platform" technology like a neural differentiation kit.

For a single protein like the fibroblast growth factor,[183] frequently used to propagate undifferentiated stem cells, there are minimal technical constraints in using it in stem cell culture, since its function is simply controlled by its concentration in media and its production utilizes standard recombinant methods. Production of recombinant proteins based on human proteins typically faces minimal regulatory hurdles as it uses standard biotechnology processes to make therapeutics.[184] However, the primary bottleneck in using this molecule in stem cell R&D is the uncertainty over IP claims: It is not necessarily clear whether freedom to operate extends to the use of the fibroblast growth factor to propagate stem cells. This would turn on a detailed analysis of the claims in any patent(s) granted over the fibroblast growth factor. In this example, bottlenecks in the proprietary domain interact minimally with bottlenecks in the technical and ethical domains.

At a higher degree of complexity, the selection of a hESC line for an experimental application requires an assessment not only of the relevant property rights, but also of the cell line's genetic and other technical characteristics. Furthermore, for research materials that are derived from human tissues,

182. *See supra* notes 160-162 and accompanying text.

183. Growth of hESCs has been shown to depend on this protein. *See, e.g.*, Sean C. Bendall et al., *IGF and FGF Cooperatively Establish the Regulatory Stem Cell Niche of Pluripotent Human Cells* In Vitro, 448 NATURE 1015 (2007).

184. Regulatory approval will depend on the exact administration and application of basic fibroblast growth factor, but it is being tested in clinical trials under the name Trafermin for patients with periodontitis. *See* ClinicalTrials.gov, A Phase 2 Clinical Trial of Trafermin in Patients with Marginal Periodontitis in Japan, http://clinicaltrials.gov/ct2/show/NCT00199290 (last visited Nov. 13, 2008).

researchers must take into account significant ethical or regulatory considerations. Obviously, in the United States this begins with the decision of whether to select one of the twenty-one federally-approved hESC lines. But ethical and regulatory analysis must go well beyond this. The consent forms for the donation of embryos or other human tissue used to create cell lines may restrict the scope of the resulting research, creating contractual and ethical constraints on the uses of resulting cell lines. This is precisely what has happened with the WARF cell lines. Carl Gulbrandsen, WARF's Managing Director, has repeatedly defended the strict requirement that WARF cell lines cannot be shared with third parties without an MTA from WARF on *ethical* grounds, namely that restrictions on types of research promised to embryo donors needed to be contractually protected and enforced.[185] As a result, scientists who wish to access these cell lines have to worry not only about infringing IP, but also about recognizing constraints on certain experiments, like implanting the cells into embryos, generating new embryos, or implanting cells into a uterus.[186]

As individual jurisdictions have created enforceable standards on informed consent, payment to donors, and limitations on certain types of experiments, researchers will have to establish the ethical provenance of cell lines they seek to use. For instance, are there assurances on record that the line was developed with the donor's informed consent in ways that are permitted in the scientist's home jurisdiction? The stem cell line with the best technical characteristics (e.g., low passage and clinical grade for implantation studies) may be available only for research use and may have been procured in a manner contrary to a state's provenance guidelines. For instance, the line may have been derived with materials that were paid for in contravention to California's state laws.[187] This situation is far from hypothetical: The recently discovered ethical problems with the provenance of the federally-approved hESC lines illustrate the setbacks researchers face if these conditions are not tracked carefully.[188]

The interwoven complexities facing researchers trying to find a suitable stem cell line do not end there. It is becoming apparent that the personal, medical, and biological characteristics of donors are also relevant to follow-up work with the cells derived from their donations. Donor diversity is relevant not only for basic

185. Wadman, *supra* note 61. Gulbrandsen has also stated in a *Nature Biotechnology* editorial that "WARF has always had to balance the private interests of industry, which first funded hES cell research, with promises made to donors of embryos regarding what research could be performed with them, with ethical, religious and political issues, and both state and federal policies." C. Gulbrandsen, Editorial, *WARF's Licensing Policy for ES Cell Lines*, 25 NATURE BIOTECH. 387, 387 (2007).

186. Wadman, *supra* note 61, at 273.

187. *See* CAL. HEALTH & SAFETY CODE § 125340 (West Supp. 2008).

188. *See generally* Streiffer, *supra* note 160.

scientific work, but also for uses downstream.[189] Sharing the personal genotypic and phenotypic details of material donors across laboratories may give rise to new privacy concerns and thus new responsibilities to obtain consent from donors. It is apparent that the evolving need for richer datasets implicates new ethical questions, a clear example of domain overlap.

The requisite analysis becomes even more cumbersome for a multi-component or "platform" technology like a neural differentiation kit. Figure 2 illustrates the process for obtaining differentiated neural cells from hESCs. In this case, several different component technologies need to work in concert, including an appropriate stem cell line, a vector, and culture media. Each of these components may be owned as IP by a different institution. Use of each may involve compliance with different ethical requirements.[190] Again, in this case, analysis must span all three domains—technical, IP, and ethical—and tradeoffs among the three are likely. The technology platform that is preferred for technical reasons may be encumbered by IP claims over most desired uses; while an alternative technology platform for which there is greater freedom to operate may be ethically proscribed. Thus, in order to find (or design) an enabling platform technology, all three types of bottlenecks must be considered together. Conversely, once platform technologies become packaged and standardized, they tend to lock in the technical, ethical, and proprietary characteristics of their component parts, likely narrowing the range of subsequently available alternatives for researchers.

Overall, the interplay of technical functionality, property rights, and ethics can be costly to navigate and can create situations of uncertainty and risk in pursuing stem cell R&D.[191] First, these costs act as a disincentive to conduct stem cell R&D. This disincentive reduces the overall volume and pace of stem cell R&D. Second, these costs act to skew the mix of stem cell R&D being

189. Jeanne F. Loring, Ctr. for Regenerative Med., Scripps Research Inst., Presentation at Institutional Landscapes in Stem Cell Research and Development Conference: Technical Problems Facing Stem Cell R&D (Feb. 6, 2008) (presenting work on "ethnic" SNP profiles of different hESC lines); *see also* Jeanne F. Loring, Problems and Solutions: Technical Problems Facing Stem Cell R&D, http://stsc.berkeley.edu/Events/2008%20Stem%20Cell%20Speaker%20PDFs/J_LORING.pdf (last visited Nov. 13, 2008) (slides from presentation). Nascent work has investigated whether donor characteristics—such as genomic imprinting—are maintained during culture of hESC lines. *See* Int'l Stem Cell Initiative, *supra* note 72.

190. Some culture components, like animal serum, might be isolated using procedures deemed unethical by proponents of animal rights. For example, fetal bovine serum is harvested from bovine fetuses and is commonly obtained by means of cardiac puncture without anesthesia. Animal welfare committees may argue to minimize animal suffering during such procedures. *See* Megha S. Even, Chad B. Sandusky & Neal D. Barnard, *Serum-Free Hybridoma Culture: Ethical, Scientific and Safety Considerations*, TRENDS BIOTECH., Mar. 2006, at 105.

191. *See* sources cited, *supra* note 74.

conducted, discouraging work in areas with lower expected payoffs (regardless of their potential contributions to human welfare). Third, as suggested above, they can actually narrow the set of ethically viable options available. Having fewer technical options reduces the number of ethical options, which in turn limits opportunities for collective decision-making about the ethical acceptability of technology options.

An *integrated* approach to solving problems across the three domains would increase both the efficiency and efficacy of public policy. Despite potential synergies of working across the three domains, they remained balkanized. Although a scientific data sharing architecture would certainly create efficiencies in the field, by itself it would do nothing to simplify onerous regulatory review at the institutional level, and it could even trigger new forms of regulation—e.g., if personally identifiable information on material donors were included along with cell line information. The communities knowledgeable in stem cell science, IP, and ethics would be better positioned to navigate these obstacles if they could approach them in a more integrated fashion.

B. Balancing Access and Property Through a Protected Commons

While free markets are, in many cases, the best available mechanism for solving complex coordination and resource allocation problems, it has long been recognized that markets do not efficiently provide informational or knowledge-based resources such as new technologies—the very inputs and outputs of R&D.[192] The fundamental conditions necessary for markets to operate efficiently include the clear definition of property rights, access to all relevant information, and perfect competition in both supply and demand. These conditions are not met, almost by definition, for scientific knowledge and early-stage technologies, which, in their raw form as pure information, are classic public goods. In the case of classic public goods, complex coordination problems are typically solved by their public provision within the public domain, where free and open access helps to minimize transaction costs and attendant uncertainties. Yet, while open access provision within the public domain solves some market failures, it introduces others, most notably an erosion of incentives for private investment and the resultant "free rider" problem.[193]

It is also well-known that focused collective action strategies such as cooperatives or land-use associations can provide solutions for the use of open-

192. *See* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Innovation*, *in* NAT'L BUREAU OF ECON. RESEARCH, THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609 (1962).

193. *See, e.g.*, Richard C. Levin, *A New Look at the Patent System*, 76 AM. ECON. REV. 199 (1986).

access natural resources and agricultural lands.[194] Legal scholars have argued that collective strategies to manage IP resources through a "protected commons" may be preferable to putting them in the public domain.[195] Others have suggested that targeted, industry-led, technology-specific "collaborative rights organizations" can be more efficient than government interventions, such as compulsory licenses, in ameliorating holdups or transaction costs endemic to heavily patented technology fields, such as the life sciences.[196] Reichman and Uhlir have argued that properly aligning incentives within a community of researchers through a "contractually reconstructed research commons" could overcome the prisoners' dilemmas so often confronted when sharing technical data and research materials.[197] A well-calibrated protected knowledge commons can, in theory, provide some relief from market failures associated with the provision and exchange of information, research materials, and IP rights.

Just how a protected commons might achieve this goal is best understood by decomposing the protected commons into its two aspects: the commons and its protection. The "commons" aspect of a protected commons regime seeks to regain some of the efficiencies of open access. This operates on what we might consider the upstream end of R&D, bringing together resources that many will need to share and draw upon for their downstream R&D. Likely pieces of such a commons include information about the resource or how to make its component parts interoperable; property rights or permissions to use the resource (or any of its respective components); and, if the resource is not purely informational or intangible, the actual physical components. Gathering these pieces together should minimize the marginal costs of disseminating the information or even the physical components that embody the resource, as well as the costs of engaging in negotiations or transactions to obtain it.

The "protection" aspect of a protected commons involves controlling who can use that common resource in its downstream applications. In particular, to the extent that uses of the resource are separable, its collective owners can regulate those uses separately, such as segmenting the market and charging differentiated prices or writing different contracts over those different uses. Such control can allow for a broader range of objectives to be achieved. While abuse of market

194. Elinor Ostrom, GOVERNING THE COMMONS: THE EVOLUTION OF INSTITUTIONS FOR COLLECTIVE ACTION (1990) (demonstrating that common pool resources in the environmental goods context evince a broad array of formal and informal governance structures that can and do prevent overuse, thus casting doubt on the conclusion that joint ownership necessarily leads to a "tragedy of the commons").

195. *See* Chander & Sunder, *supra* note 14, at 1337.

196. *See* Robert Merges, *supra* note 20, at 183; *see also* Gregory D. Graff & David Zilberman, *An Intellectual Property Clearinghouse for Agricultural Biotechnology*, 19 NATURE BIOTECH. 1179 (2001).

197. *See* Reichman & Uhlir, *supra* note 4, at 416-52.

power cannot be ruled out as an objective, a protected commons can enhance welfare by seeking to preserve investment incentives in those fields of use that are commercially viable, while simultaneously making the resource broadly available for most other uses at essentially zero cost, approximating the efficiencies of the public domain. Indeed, it has been suggested that constructing a protected commons at the interface between the public domain and private commerce, as a hybrid form, can better facilitate interaction between the public and private domains than relying upon either the complete exclusivity of control afforded by property rights or the complete freedom of the public domain alone.[198] A number of such collective action initiatives have emerged in the life sciences among researchers and their institutions within both the public and private sectors in order to coordinate access to data and IP.[199]

1. PIPRA as a Model of a Protected Commons

Models do exist for such a protected commons. One initiative, the Public Intellectual Property Resource for Agriculture (PIPRA), demonstrates well the principles and operation of a protected commons. With headquarters at University of California (U.C.) Davis, PIPRA was established in 2003 by a coalition of a dozen universities and research institutes with funding from the Rockefeller Foundation.[200] Today, the organization is growing rapidly and employs a professional staff of legal analysts and scientists.[201] The goal of PIPRA is to make agricultural biotechnologies more easily available for the development and distribution of "orphan crops"—meaning both subsistence crops developed for humanitarian purposes in the developing world and specialty crops developed for smaller-scale and often regional commercial markets. These goals are supported by analyzing and providing freedom to operate with the key research tools and enabling technologies of agricultural biotechnology.[202]

198. *See* Chander & Sunder, *supra* note 14, at 1331-74; Rai, *supra* note 18.

199. *See supra* text accompanying notes 18-22.

200. Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 SCIENCE 174 (2003); *see also* The Public Intellectual Property Resource for Agriculture, http://www.pipra.org (last visited Nov. 13, 2008).

201. Graff has been affiliated with PIPRA over its entire history and still works with the organization. Much of the material that follows is based on his personal experience with the organization. Some of this information is available on the PIPRA website, *supra* note 200; *see also* Alan B. Bennett et al., *Intellectual Property in Agricultural Biotechnology: Strategies for Open Access*, *in* PLANT BIOTECHNOLOGY AND GENETICS: PRINCIPLES, TECHNIQUES, AND APPLICATIONS 325 (C. Neal Stewart, Jr. ed., 2008).

202. For a short description of PIPRA's mission and core activities, see The Pub. Intellectual Prop. Res. for Agric., About Us, http://www.pipra.org/en/about.en.html (last visited Nov. 13, 2008).

PIPRA has grown into a collaboration of roughly fifty public and private nonprofit research institutions and universities that conduct agricultural research.[203] Most member institutions are U.S.-based, but there are members in Canada, Italy, Tanzania, the Philippines, Peru, Chile, Mexico, Vietnam, and Taiwan, with most of the recent growth in membership coming from institutions outside the United States. When joining PIPRA, an institution signs a Memorandum of Understanding (MOU) whereby it agrees to cooperate with other members of the collective on a number of issues.[204] First, the institutions agree to work together to develop guidelines for licensing standards that will encourage product development for the broader public benefit, such as retaining rights for research use and for humanitarian use of licensed technologies.[205] The institutions also agree to contribute non-confidential information to a common database detailing which agricultural technologies in their portfolios are still available for licensing and which have become fully encumbered. Finally the institutions agree simply to explore possibilities for bundling or pooling technologies.

One of the key functions of PIPRA is to reduce uncertainty around the IP status of commonly used technologies, identifying the extent to which there may be freedom to operate or how it might be negotiated. PIPRA has launched its public database in collaboration with PatentLens, a nonprofit patent data initiative that provides web-based patent data search and patent landscape analysis.[206] The PIPRA patent database contains the agricultural portion of the patent portfolio held by PIPRA members and gives a clear picture of the availability of agricultural technologies developed across the full set of PIPRA institutions. The database contains, in addition to patent text, patent status information (such as whether it is in application, in force, or expired), and licensing status (such as whether it is available for license or sublicense, licensed exclusively, licensed non-exclusively, or licensed in all or some fields).

Beyond providing a patent database, PIPRA conducts analysis to advance common goals of researchers within its member institutions. First, PIPRA

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203. According to its website, "PIPRA membership is open to any university, public agency, or nonprofit research institution actively engaged in agricultural research." *Id.*

204. *See* The Public Intellectual Property Resource for Agriculture, *supra* note 200.

205. Once developed, these standard licensing terms are voluntarily adopted by PIPRA member institutions and, as with any boilerplate language, are modified and adapted to specific situations. The fact that the standard licensing terms have been thoroughly vetted and standardized, however, makes them more broadly accepted by those in industry negotiating technology licenses with PIPRA member institutions. *See* Ashley J. Stevens & April E. Effort, *Using Academic License Agreements To Promote Global Social Responsibility*, 43 LES NOUVELLES: J. LICENSING EXECUTIVES SOC'Y 85, 89 (2008).

206. *See* Patent Lens, http://www.patentlens.net (last visited Nov. 13, 2008); Pub. Intellectual Prop. Res. for Agric., PIPRA Patent Search, http://search.pipra.org (last visited Nov. 13, 2008).

conducts preliminary searches of patent and non-patent prior art to support freedom to operate analyses of important technologies, looking at the question of global ownership.[207] The analyst team at PIPRA identifies relevant patents and licensing information, and it makes preliminary validity assessments. The end result is a set of recommendations that public sector researchers can consider when deciding how to proceed with research or commercialization. These include suggestions on strategies to "invent around" or to acquire sublicenses to blocking technologies. A number of law firms support PIPRA in this public service by conducting freedom to operate analyses on a pro bono basis.[208] Second, PIPRA maps IP across broad sets of technology. These "patent landscapes" can vary in degree of detail but generally do not go into the same level of detail as a freedom to operate analysis. Rather, a patent landscape of a broad set of technologies can provide a starting point for freedom to operate research on a narrower subset of technologies or support research on industry trends and policy shifts that may affect or be affected by IP in agriculture.[209]

Based upon its database resources and IP analysis, PIPRA is developing enabling technologies for plant biotechnology. The first project undertaken involves a vector for the insertion of DNA into a range of plant cells, an important crop development tool in agricultural biotechnology. Currently, IP on this vector has effectively blocked its commercial use outside of the several major corporations that have integrated dominant patent portfolios in plant biotechnology, clamping down innovative activity in this space.[210] In order to avoid this bottleneck, PIPRA is attempting to develop a novel transformation vector in the lab[211] using technologies for which freedom to operate has been established, whether because they are in the public domain[212] or owned by

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207. Gillian M. Fenton, Cecilia Chi-Ham & Sara Boettiger, *Freedom to Operate: The Law Firm's Approach and Role*, *in* 2 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 879 (Anatole Krattiger et al. eds., 2007), *available at* http://www.iphandbook.org/handbook/chPDFs/ch14/ipHandbookCh%2014%2004%20Fenton-Chi-Ham-Boettiger%20FTO%20and%20Law%20Firm%20Roles.pdf.

208. Some of the legal affiliates are listed on the PIPRA website. *See* The Public Intellectual Property Resource for Agriculture, *supra* note 200. PIPRA also engages pro bono services through the Public Interest Intellectual Property Advisors (PIIPA) network. *See* Public Interest Intellectual Property Advisors, http://www.PIIPA.org (last visited Nov. 13, 2008).

209. *See, e.g.*, Bergman & Graff, *Global Stem Cell Patent Landscape*, *supra* note 28; Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECH. 989 (2003).

210. Graff et al., *supra* note 209.

211. *See* Alan B. Bennett et al., *Enabling Technologies for Grape Transformation*, *in* PIERCE'S DISEASE RESEARCH SYMPOSIUM PROCEEDINGS 239, 240 (2007), *available at* http://pd.pipra.org/Proceedings/2007/2007_249-252.pdf.

212. *See* Sara Boettiger & Cecilia Chi-Ham, *Defensive Publishing and the Public Domain*, *in* 1

PIPRA member institutions and available for license. In the end, roughly six of the fifty PIPRA members will be contributing technologies to the vector system and will do so under a separate and more complex IP agreement than the MOU establishing PIPRA membership.[213] PIPRA is developing an out-licensing model for the vector whereby the bundle of technologies that comprise the vector can be made widely available under a single non-exclusive license—in effect a patent pool—but with separate terms for research, humanitarian, and commercial uses.[214] Much effort has gone into discussions and negotiations with the technology owners, all of which are PIPRA member institutions, to find a balance that preserves commercial interests while carving out space for public research and humanitarian uses.[215] If the project is successful, vectors will be distributed free of charge within the public sector for research and humanitarian use. Private companies will pay a royalty to use the vectors commercially. The royalties will help to cross-subsidize the administration of the patent pool for research and humanitarian uses. Any remaining royalties will be distributed among the owners that made their technologies available for use in the vector. The project requires close collaboration between researchers in the lab, PIPRA staff performing the IP searches, and supporting law firms doing the freedom to operate analysis. This degree of IP "self awareness" guiding the research design is uncommon, but is gaining momentum in the public sector.[216]

What may be our most nuanced observation of the PIPRA model is the multiple cascading or concentric protected commons that have emerged around

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INTELLECTUAL PROPERTY MANAGEMENT, *supra* note 207, at 879, 889, *available at* http://www.iphandbook.org/handbook/ch10/p01.

213. Henry Lowendorf, Presentation at the 2008 Annual Meeting of the Association of University Technology Managers: PIPRA Vector Licensing Strategy (Feb. 29, 2008).

214. *See* Gregory D. Graff et al., *Intellectual Property Clearinghouses as an Institutional Response to the Privatization of Innovation in Agriculture*, 3 AFRICAN TECH. DEV. F. J. 11, 14 (2006), *available at* http://www.atdforum.org/IMG/pdf/ATDF_Journal_October_2006_V3_I3.pdf; Amy Yancey & C. Neal Stewart, Jr., *Are University Researchers at Risk for Patent Infringement?*, 25 NATURE BIOTECH. 1225 (2007).

215. It is important to point out that PIPRA does not have ambitions to in-license technologies and offer sublicenses. Rather, as a collective of public sector institutions that routinely out-license their own agricultural technologies, PIPRA's role is to identify anti-commons issues and then set up and help manage the complex licensing arrangement between the technology owners. Specific arrangements are likely to differ markedly depending on the nature of the particular technology involved, the set of owners, and its commercial potential.

216. Anatole Krattiger, *Freedom to Operate, Public Sector Research, and Product-Development Partnerships: Strategies and Risk-Management Options*, *in* 2 INTELLECTUAL PROPERTY MANAGEMENT, *supra* note 207, at 1317, 1320-26, *available at* http://www.iphandbook.org/handbook/chPDFs/ch14/ipHandbook-Ch%2014%2001%20Krattiger%20FTO%20and%20Public%20Sector%20Strategy.pdf.

the initiative. First, PIPRA's MOU requirement creates a boundary that, however faint in legal terms, helps define a community with common interests. The act of signing the MOU triggers an internal dialogue at each institution, wherein the officers and researchers of that institution must at least consider and endorse the principles of collective action espoused by the PIPRA community. The next definitive collective act is that of contributing IP status data to the PIPRA database, which requires some commitment of time, resources, and information. This act creates a common resource. A third level of common resource emerges from the many freedom to operate and patent landscape analyses that PIPRA conducts: a rapidly accumulating body of knowledge and expertise about the IP landscape specific to the field of plant biotechnology. The raw freedom to operate data informing this body of knowledge is indeed a protected resource: Freedom to operate opinions are not published, in part to protect the contributing pro bono attorneys' opinions from public disclosure and associated liabilities, but also to maintain some degree of strategic benefit on behalf of the public institutions that make up PIPRA. This common knowledge resource is made available to PIPRA members in three main forms: first, through technical advice and freedom to operate recommendations made directly to scientists and technology transfer officers; second, through published studies and IP landscapes; third and perhaps most importantly, through the technical choices designed into the enabling technology platform licensed under a patent pool. That specific technology platform, which requires IP permissions granted under a single license with different terms and royalties for different fields of use, is the fourth and highest level of protected commons achieved by PIPRA.

2. Lessons from PIPRA for Stem Cell Research

The model for bundling or pooling IP observed in PIPRA's transformation vector project—to be licensed for a wide range of commercial and non-commercial uses—may well be useful in stem cell research and other areas of the life sciences. Indeed, patent pooling has been proposed for the field of stem cells to consolidate IP and simplify the process for obtaining freedom to operate with the most widely used research tools and methods.[217] However, drawing lessons from PIPRA for the opening of stem cell R&D requires attention to those issues and constraints confronting stem cell R&D that are distinct from those in plant biotechnology.

For a cascading set of protected commons to be useful, it will need to unfold differently. For instance, the set of member institutions involved in a stem cell

217. Bergman & Graff, *Global Stem Cell Patent Landscape*, *supra* note 28; Ted J. Ebersole, Robert W. Esmond & Robert A. Schwartzman, Stem Cells–Patent Pools to the Rescue? (June 2005) (unpublished manuscript, *available at* http://64.237.99.107/media/pnc/8/media.668.pdf).

initiative may need to encompass biotech companies as well as publicly funded research institutions, given the central role that companies have played in the development of this technology. Furthermore, for stem cell R&D, the design of a common data resource may need to encompass more than just IP data, as the PIPRA data resource does. Given the intersections of the domains discussed above, such a resource ought to integrate technical characterization, ethical provenance, and regulatory compliance data. To the extent that multiple types of data are included, the protections maintained around that data commons may need to be stronger and may even need to include differentiated levels of access for different kinds of users and uses.

Finally, while potential commercial payoffs from stem cell therapies are difficult to establish at this early stage, high expectation held by researchers or institutions may make them reluctant to take any actions that they might perceive as relinquishing control over a valuable technology. Yet, on the other hand, the expectation of high payoffs may itself invoke the very value of creating common resources. High expectations of commercial payoffs may also, conversely, increase the need for reliable strategies that would enable non-commercial, small market, or generic applications of the technology.[218]

C. Push from Funders

In the classic collective action problem, a diverse set of actors may share common interests that can only be achieved through collective action, yet no one individual actor's incentives are sufficient to overcome the inertia of inaction. Mobilization requires leadership in the form of coordination and making fixed initial investments. This certainly seems to be the case for addressing the problems facing stem cell R&D. Sufficient conditions for collaboration have not yet developed in any one of the three domains discussed, nor have they developed across domains. Under such circumstances, it will be necessary to motivate potential actors through the use of various carrots and sticks.

Here we can draw on the experience of successful collaborations in the life sciences for ideas. The examples of PIPRA and the Human Genome Project, discussed below, suggest that a push from funders may be critical. Forward-looking project funders can help motivate diverse institutions and can help establish the architectures that enable collaboration. For PIPRA, the initial push came from the willingness of the Rockefeller Foundation to convene meetings of key players in 2000 and 2001 and make grants that funded the initial personnel for the activities described above. The Rockefeller Foundation, with its long

218. *See* Stevens & Effort, *supra* note 205 (suggesting a licensing approach with differentiated prices or terms in order to simultaneously serve both the commercial and the social or humanitarian goals of university technology commercialization).

history of funding research in crop genetic improvement for agriculture in low-income countries, provided not only financial leadership, but also clear moral leadership around commonly-held humanitarian goals. These actions proved sufficient to mobilize the original coalition of universities and research institutes to engage in collective action that generated benefits well beyond the scope of the Rockefeller Foundation's initial goals.

The Human Genome Project and its follow-on projects exemplify how large funders of public science can drive international collaborative research efforts to create common data resources for widespread use.[219] From the mid-1990s, both the Wellcome Trust in the United Kingdom and the NIH in the United States supported data sharing of the human genome sequence as it was generated. The Wellcome Trust provided the critical leadership in this regard, sponsoring a meeting of international scientists and funders in 1996 that gave rise to the "Bermuda Principles."[220] These principles state that funded centers generating the human genome sequence should make that information freely available in order to encourage its broad use in research and maximize benefits to society.[221] The Bermuda Principles also state that primary genomic sequence information should be released "as soon as possible" and that assemblies greater than one kilobase should be released on a daily basis.[222]

Public funders have acted decisively to implement the Bermuda Principles and other data sharing initiatives within genomics. For instance, the NIH made its commitments to the Bermuda Principles clear in its request for proposals for large-scale sequencing centers, using its funding power to receive assurances from grantees that they would act in accordance with the Bermuda Principles.[223]

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219. For detailed accounts of how this was accomplished, see Eisenberg & Nelson, *supra* note 16, at 94-99; see also Robert Cook-Deegan, *The Science Commons in Health Research: Structure, Function, and Value?*, 32 J. TECH. TRANSFER 133, 136-45, 149-52 (2007).

220. WELLCOME TRUST, SHARING DATA FROM LARGE-SCALE BIOLOGICAL RESEARCH PROJECTS: A SYSTEM OF TRIPARTITE RESPONSIBILITY (2003), *available at* http://www.genome.gov/Pages/Research/ WellcomeReport0303.pdf; Human Genome Project Information, Policies on Release of Human Genomic Sequence Data, Summary of Principles Agreed at the First International Strategy Meeting on Human Genome Sequencing (Bermuda, Feb. 25-28, 1996), http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml#1 (last visited Nov. 13, 2008) [hereinafter Bermuda Principles].

221. Bermuda Principles, *supra* note 220.

222. *Id.*

223. *The Human Genome Project: How Private Sector Developments Affect the Government Program: Hearing Before the Subcomm. on Energy and Environment of the H. Comm. on Science*, 105th Cong. 21 (1998) (testimony of Francis S. Collins, Dir., Nat'l Human Genome Research Inst.), *available at* http://www.hhs.gov/asl/testify/ t980617a.html; *see also* Eisenberg & Nelson, *supra* note 16, at 97-98 (stating that "[t]he public sponsors of the Human Genome Project stressed the importance of prompt and unrestricted access to the sequence, which they ensured by requiring

Free access to the genome became a touchstone across the public genomics community, thereby prompting pre-publication disclosure policies and the acceleration of public funding to complete the sequence before private competitors appropriated it as a private resource.[224] Furthermore, the Wellcome Trust and NIH used their funding power to promote a public consortium on Single Nucleotide Polymorphisms (SNPs), though it was ultimately the private sector that determined it was in their common interests to form a public database of SNPs called the "SNP Consortium."[225] The NIH houses an important SNP database,[226] and sharing within the International Haplotype Map project has also been driven by funder involvement.[227]

Complementing this important role of funders, journal publication policies have also played a key role in promoting open access to genome data, especially with regard to the private sector competitors of the public genome projects. Craig Venter and his company Celera acknowledged the importance of free access in the form of quarterly data release,[228] but he later repudiated this idea.[229] As Eisenberg and Nelson describe it, "[a]lthough Celera's promised quarterly data releases never occurred, Celera agreed to provide limited access to its data free of charge on its own web site as a condition of publication in *Science*, subject to restrictions that preserved the market for its proprietary products."[230]

The experience with genomics carries important design lessons for opening up stem cell R&D. Because of the competitive nature of laboratory work at the cutting edge of a potentially lucrative field, it is likely that only public funders will have sufficient clout to mobilize players to overcome the reluctance or inertia of the classic collective action problem. Funders are well positioned not only to construct data sharing architectures, but also to enforce them through the power of the purse and moral suasion.[231] As a collaborative architecture comes

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grantees to deposit new sequence data in the publicly accessible Genbank database within twenty-four hours").

224. Eisenberg & Nelson, *supra* note 16, at 96-98.

225. Cook-Deegan, *supra* note 219, at 151-52.

226. *See* NCBI, Entrez Single Nucleotide Polymorphism, http://www.ncbi.nlm.nih.gov/sites/entrez?db=snp (last visited Nov. 13, 2008).

227. *See* International HapMap Project, http://www.hapmap.org/index.html (last visited Nov. 13, 2008); *see also* Eisenberg & Rai, *supra* note 49, at 1191 (noting that "[w]ithin genomics, public research sponsors like NIH and the U.K.'s Wellcome Trust have applied normative pressure to achieve widespread data dissemination").

228. J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304, 1306 (2001).

229. Cook-Deegan, *supra* note 219, at 141.

230. Eisenberg & Nelson, *supra* note 16, at 98.

231. *See* Reichman & Uhlir, *supra* note 4, at 332 (arguing that government funding agencies "are in a position to reinforce the underlying norms of science by suitable contractual provisions

into being, funding agencies could make data contribution and participation a contractual obligation of grantees, in order to enhance or at least maintain the public value generated by their research grants.

The lack of U.S. federal funding and leadership on hESC research has meant that the field, at least in the United States, has lacked a clear leader with a coordinating mandate. Even the simple collection of technical information in scientific research has arguably been under-funded.[232] Yet, within the United States, it is precisely the major funding agencies, such as CIRM or the NIH,[233] that have important roles to play in supporting and enhancing a protected knowledge commons in stem cell research.

D. Use of a Contractual Legal Regime

Although we imagine the role of public funders such as government agencies and legislatures to be quite important in providing the impetus for promoting sharing and in coordinating the domains of ethics and patents, we do not believe that such solutions should as a general matter be driven by statutory change, whether in data protection law, patent law, or reform of the Bayh-Dole Act. Rather, a regime of liability rules developed through contracts ought to drive the solutions in stem cell research. Such a regime would entail both funding agreements between public funders and research institutions, and commitments among major research institutions as manifested in the PIPRA initiative.[234]

A first rationale underlying this preference for a contractual regime is our observation that effecting meaningful change in existing laws and regulations can be costly and time-consuming, particularly given the degree to which the current system represents a stalemate between competing interests that have chosen to use stem cells as a symbolic issue in larger cultural battles. Also, statutory changes are country-specific, and while positive changes in any individual jurisdiction are welcome, they are unlikely to be emulated in all other jurisdictions important to the global stem cell research community. Instead, a

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that regulate access to data before and after publication of the research results").

232. *See* Stephen M. Maurer & Suzanne Scotchmer, *Database Protection: Is It Broken and Should We Fix It?*, 284 SCIENCE 1129 (1999); Stephen M. Maurer, Richard B. Firestone & Charles R. Scriver, *Science's Neglected Legacy*, 405 NATURE 117 (2000).

233. It should be noted that NIH earmarked an estimated $42 million for work on hES lines for 2008 and $203 million for human non-embryonic, including adult, stem cell work. *See* Nat'l Insts. of Health, Estimates of Funding for Various Diseases, Conditions, Research Areas, http://www.nih.gov/news/fundingresearchareas.htm (last visited Nov. 13, 2008). It is likely, however, that federal support for hESC research will dramatically increase with the new administration in January 2009, although this is not reflected in the current official NIH estimates.

234. The classic description of such contractually-constructed organizations of property rights is Merges, *supra* note 90.

contractual regime has the flexibility and adaptability to coordinate action among researchers across multiple national jurisdictions. Developing a contractual regime depends on persuading only those institutions with a stake in stem cell R&D to agree and act, not legislatures, courts, or by extension all of the interest groups within society prevailing on those deliberative bodies.

Second, it is not necessarily clear which general legislative changes are warranted to achieve the goals of greater efficiency and equity in R&D. Even if an ideal statutory regime were to be achieved, it would certainly not eliminate all complexity or coordination problems, particularly given the rapid pace of technological change in the field. While legislative solutions might improve conditions around new discoveries going forward, it is not clear how or whether they would be able to alter the established legacy with respect to existing IP or the provenance of stem cell lines already harvested. Yet, at the same time, we can also imagine that certain statutory changes could be entirely consistent with and complementary to the contractual approach. In fact, a contractually constructed consortium that provides even some of the functions we have proposed could supply policymakers with both the integrative perspective and the analytical data needed to design and implement welfare improving reforms.

Third, we recognize that policies specific to stem cells perhaps should not (or could not) drive science policy in general. While it may very well be that changes in background property rules would be important for advancing national science and technology policy more broadly,[235] such a conclusion would require analysis that is beyond the purview of this article.

Fourth and finally, a contractual regime may be more flexible and adaptive to the ever-changing technical, IP, and regulatory environments. And even if, in the end, the policy community achieves an ideal statutory reform eliminating market failures in the stem cell R&D environment, it could be relatively simple and costless to dissolve a contractual regime and move on to new problems.

E. An International Scope

Because the problems outlined above are international in character, the international level is the proper level for political action. As the Hinxton group says, both "intra- and international scientific collaboration are vital to the success and advancement of science."[236] Because research groups are distributed across the globe, there is a need to promote data and materials sharing globally. Patents

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235. For commentary on the larger need to rethink the Bayh-Dole Act, see, for example, Boetinger & Bennett, *supra* note 8; David Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh–Dole Act of 1980*, 30 RES. POL'Y 99 (2001); and Stevens & Effort, *supra* note 218.

236. Hinxton Consensus Statement, *supra* note 138, at 1.

are filed in jurisdictions all over the world, and the complexities of ethical regulation are compounded on the global scale. Markets for patents and cell lines are global, and the proper tracking of ethical compliance will require broad cooperation in the provision of provenance information and documentation of ethical compliance.

For all of these reasons, we imagine that solutions for the problems discussed above would be best addressed at the international level. While efforts to harmonize regulations across the United States are very useful, they do not go far enough. Efforts to establish a database to document the regulatory patchwork and the ethical validation of materials should be global in scope in order to address the international nature of science and the market in research materials.[237]

F. Self-Reflexivity and Multivalent Evaluation

Stem cell R&D promises to be a complex, pervasive technology in many areas of health care.[238] Because modern biotechnologies deeply implicate many dimensions of human life and values, societies across the world have pushed for more transparent, accountable, and diverse evaluations of costs and benefits.[239] We imagine that any viable solution to alleviate R&D constraints on stem cell R&D, such as a contractually constructed commons described in Section D above, will require built-in systematic mechanisms to periodically evaluate its course. Mechanisms for "multivalent" evaluation should include participation from interest groups and individuals with different values and goals. Such methods can help to systematically reevaluate the distributive consequences of stem cell R&D as it unfolds across global markets and societies, to enhance civic deliberation, to incorporate ordinary citizens as active subjects in an expert discourse, and even to reframe regulatory and social policies.[240]

A contractually-constructed commons will have to distribute decision-making power among its various participants who contribute inventions or resources to be utilized within the protected commons. The power held by each participant will likely fluctuate as new inventions and resources arise or change in value. Further, new entrants into stem cell R&D may embrace goals different from those of the incumbents. All of these factors present challenges for just

237. *See* David Magnus & Mildred K. Cho, *Issues in Oocyte Donation for Stem Cell Research*, 308 SCIENCE 1747 (2005) (arguing the need to address the ethical and regulatory complexities involved in the international transmission of stem cell materials).

238. *See* REGENERATIVE MEDICINE, *supra* note 23.

239. *See* SHEILA JASANOFF, DESIGNS ON NATURE (2006).

240. *See generally* Sheila Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 MINERVA 223, 223 (2003) (arguing that policymakers need to utilize democratic, participatory strategies for critically evaluating and assessing "the unknown and the uncertain" risks posed by modern technologies).

governance of the contractual arrangements as conditions change.

Consider what kinds of periodic, multivalent evaluation mechanisms and methods can be developed. Social institutions often incorporate self-reflective elements to critically examine and guide the course of their development. For example, the scientific review board in corporate settings examines scientific progress of the company's projects. Further, if the law as a whole is viewed as a social institution, the appeal process could be considered a reflexive mechanism. Each step in the step-wise unfolding of the contractual regime could be used as a reflexive moment.[241]

Renewed calls for greater transparency and public participation in the governance of science have been particularly strident in the life sciences.[242] Structures to examine the relationship between stem cell R&D and human health are needed to respond to these calls for the democratization of R&D. Correspondingly, patient advocates, taxpayer groups, and foundations should be formally integrated into R&D decision-making through reflexive measures. While the effectiveness of particular measures like citizen juries and consensus conferences are the subject of current research,[243] forming an intellectual environment in which outsiders are encouraged to share their knowledge would likely increase the assurance of quality and reliability in commons-building projects undertaken and the types of R&D they enable.

III. INSTITUTIONAL COLLABORATION FOR STEM CELL RESEARCH AND DEVELOPMENT: A MULTI-STAGE ROADMAP

The current scientific, social, economic, and legal institutions within each of the three domains are not adapted to the needs of this fast-moving, complex field of research. Norms around data and material sharing remain aspirational, with few enforcement mechanisms. The landscape of existing data registries and cell banks remains fragmented and underdeveloped. In their licensing transactions, individual universities and research institutions must balance collective goals of openness against individual objectives of maximizing revenue. Where innovation is complex and cumulative, the resulting system of bilaterally negotiated technology licenses is not likely to maximize public welfare. Furthermore, relying on decentralized research oversight is unlikely to address adequately the ethical issues specific to stem cells, including the need for transparent and

241. Of course, additional mechanisms at longer or short frequencies can evaluate the collaborative for different purposes of institutional reorientation and learning.

242. *See* Jasanoff, *supra* note 240, at 235-38.

243. In health care, see, for example, Julia Abelson et al., *Deliberations About Deliberative Methods: Issues in the Design and Evaluation of Public Participation Processes*, 57 SOC. SCI. & MED. 239 (2003).

efficient validation of stem cell materials as they move across jurisdictions. We argue that targeted collective action among those institutions actively engaged in stem cell research that takes an integrated approach across the technical, proprietary, and regulatory domains could advance a number of important policy goals.

Building on the design principles described in the preceding Section, we propose a template for undertaking collective action, outlined in a progression of three stages. In the first stage, an international coalition of research institutions and funders could establish a collaborative data architecture for the collection, standardization, and organization of non-confidential information. This information should include details of the technical characterizations, the IP status, and the ethical provenance of stem cell materials and research tools. Born out of existing efforts, this architecture would promote information sharing across research labs, institutions, and jurisdictions. Where previous efforts have foundered, large funding institutions could drive such an initiative by requiring grantees to upload data according to mutually determined norms. Such a commitment and implementation mechanism from funders would separate this proposal from past efforts that have fallen short.

In the second stage, the consortium members would identify high-priority technical, proprietary, or ethical bottlenecks. This stage would develop a centralized analysis of bottlenecks in the field and options for overcoming them, utilizing data collected in the first stage. In the third stage, collaborating institutions could deliberate, design, and deliver solutions that would break through or work around the selected bottlenecks. Specific products from stage three might include coordinated ethical reviews and pools of IP.

A. Building an International Collaborative Data Architecture

The first step toward developing solutions to the problems discussed above would be the development of an international consortium of funding institutions and research institutions to lay the normative and political groundwork for a database architecture that goes beyond what has been accomplished to date. Disease groups and stem cell advocacy organizations could play a major role here, as the moral impetus should come, in part, from those groups whose constituencies depend critically upon global public goods.[244] But, it should also rely upon the professional self-interest of researchers to gain access to better data resources and thereby enhance their productivity and chances of scientific

244. It was just this sort of initiating action of a few leading institutions that enabled the PIPRA project to take root against collective action obstacles and disincentives. *See supra* note 200 and accompanying text.

success.[245] The lack of success to date in this arena suggests that generating and sustaining the support and interest for such an initiative will require new carrots and sticks from scientific funders. Furthermore, a successful architecture would necessarily include information reaching across the technical, proprietary, and ethical domains.

1. Carrots and Sticks to Promote Research Sharing

Such a consortium, which could grow out of a high-level meeting similar to the summit at which the Bermuda Principles were adopted for the genomics field, would articulate collective norms for the sharing of cell line characterization data, IP data, and ethical provenance data for major stem cell researchers around the world. The challenges for constructing and maintaining a useful international data architecture are significant. A simple articulation of norms would not go far enough: as discussed above, groups like the ISSCR and the Hinxton Group have already called for enhanced materials and data sharing, without robust results. Past experience here underscores the need for a stronger "push" for data sharing from institutional funders.

Accordingly, success will require common approaches to implementing such a data sharing policy across the major global funders of stem cell research. In short, governmental and non-governmental funding agencies alike—from the NIH, CIRM, and Wellcome Trust, to Howard Hughes and disease organizations—could create carrots for data and materials sharing using the mechanism developed in the Human Genome Project, namely through stipulations in Requests for Proposals (RFPs). These RFPs should articulate that the funding agencies have committed to the common principles articulated, and require specific data and materials sharing plans from applicants that would feed into the commonly developed data architecture and associated cell repositories. These plans should be a crucial aspect of proposals under review. Furthermore, continuation of funding should be contingent upon demonstrating that promised sharing activities have been carried out expeditiously.

Dialogue among the member institutions of the coalition and their primary research funders would be necessary to establish a workable data sharing architecture, with realistic incentives and constraints for contributing and accessing data. Good models exist for the development of funder-supported platforms for data sharing from distributed laboratories: NIH has already supported two significant examples in the Biomedical Informatics Research Network (BIRN)[246] and the cancer Biomedical Informatics Grid™ (caBIG™).[247]

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245. *See* Reichman & Uhlir, *supra* note 4, at 442 (discussing the need for commitment by universities to overcome impediments to the construction of an "e-commons" for scientific data).

246. *See* Biomedical Informatics Research Network, http://www.nbirn.net (last visited Nov. 14,

Past experiences should be leveraged. The work of the ISSCR and the Hinxton Group could be a launching point, as those groups have already articulated norms around data sharing, but these efforts lack mechanisms for further implementation. The productive activities of the European Stem Cell Registry and/or the International Stem Cell Forum could provide the physical and informational architecture of such a database, though having the norms and commitments in place would help these projects become better funded and more comprehensive. Other templates that could be incorporated into the architecture can be found in "data commons" approaches.[248] Key elements for such approaches include a commitment to broad dissemination of data for research use and an implementation of software tools to facilitate meta-analysis of the data.

2. Contents of the Collaborative Data Architecture

What would such a collaborative data architecture contain, and how would it go beyond existing efforts? Broadly, this effort would explicitly attempt to alleviate the search costs and information asymmetries described in Part I.

Ideally, researchers, technology transfer directors, and SCRO directors ought to determine the specific technical content of the collaborative data architecture in a dynamic and evolving process. However, certain features will obviously add great value. The scientific community has characterized a variety of stem cell technologies central to stem cell R&D and the data needs associated with them.[249] At the core of the field are, of course, specific *stem cell lines* established from human research subjects. The suppliers of the stem cell lines could provide

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2008).

247. *See* Nat'l Cancer Inst., Cancer Biomedical Informatics Grid™, https://cabig.nci.nih.gov (last visited Nov. 13, 2008).

248. For a detailed proposal for an inter-university project to protect the scientific data commons, and the logic of public good creation as well as university self interest underlying it, see Reichman & Uhlir, *supra* note 4, at 429 ("[U]niversities and nonprofit research institutions that depend on the sharing ethos, together with the government science funding agencies, should consider stipulating to suitable 'treaties' and other contractual arrangements to ensure unimpeded access to commonly needed raw materials in a public or quasi-public space. From this perspective, one can envision the accumulation of shared scientific data as a community asset held in a contractually reconstructed research commons to which all researchers have access for purposes of public scientific pursuits.") (internal citations omitted).

249. Notable examples include the ISSCR Standards Committee and the International Stem Cell Forum characterization project. *See* Peter W. Andrews et al., *The International Stem Cell Initiative: Toward Benchmarks for Human Embryonic Stem Cell Research*, 23 NATURE BIOTECH. 7 (2005); Jeanne F. Loring & Mahendra S. Rao, *Establishing Standards for the Characterization of Human Embryonic Stem Cell Lines*, 24 STEM CELLS 1 (2006) (outlining a plan to identify a set of standard methods for characterizing cell lines).

anonymized genetic and other cell biology characterizations, while scientists at member institutions could provide details about other technical characteristics, such as clinical grade, karyotype, immunohistochemical markers, sex of donor, pluripotency measures, availability of a single nucleotide polymorphism (SNP) profile, or infectious agent tests. Since scientists tend to choose a stem cell line based not only on the line's technical characteristics but also on its ability to interface with other stem cell technologies, it will be helpful to list compatibility with other associated technologies.[250] Figure 3 shows the proposed expansion of the informational content. The details within each category will necessarily evolve and expand over time as stem cell biology and characterization increases in sophistication.

The heart of the IP information gathered would consist of a detailed listing of all patents associated with stem cell lines and technologies that are owned by the members of the coalition. This would include non-confidential information about the licensing status of each patent, indicating the availability of that technology for research, non-commercial (i.e., public health), and commercial uses.[251]

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250. Other associated characteristics of stem cell materials and technologies can be divided into five primary categories, including *derivation*, *growth*, *characterization*, *differentiation*, and *delivery*. Characterization assays are highly useful for establishing the degree of heterogeneity that may arise because of different genotype, isolation and culture protocol, or long-term adaptation to culture. Stem cell scientists currently expect the details of each derivation method to be important for the subsequent properties of the stem cell line, and the effects of many derivation details have yet to be researched fully. Growth factors and culture materials are propagation technologies that address the question of how to grow and maintain stem cells effectively. The last two categories of *differentiation* and *delivery* address more downstream uses of stem cells. *See supra* fig.2. Differentiation, or maturation, of a stem cell line into a particular cell lineage is an inherent property of stem cells that is typically exploited by researchers. Differentiation technologies include factors and culture materials that in many respects recapitulate natural development in a cell culture or exploit novel pharmacological compounds. Finally, the celebrated use of stem cells themselves or their progeny at a site of disease or injury necessarily involves cell delivery technologies. For injected or implanted cells to function effectively at the site of disease or injury, researchers use an array of delivery technologies to maximize cell survival and integration with the host.

251. Basic data on published patents and patent applications can be obtained directly from the USPTO or any of a number of patent data providers such as Thomson Innovation. *See* Thomson Innovation, http://www.thomsoninnovation.com (last visited Nov. 13, 2008). The patent data can be further customized by analysts or programmers employed by the coalition to make the listings more useful to stem cell researchers, such as assembling related patents claiming parts of the same technology into "technology clusters" and associating the technologies claimed in patents with publications in the research literature. In addition, the non-confidential information about the licensing status of each patent provided by participating institutions can indicate the availability for licensing of each of their stem cell patents—even if merely identifying each patent as "exclusive

Technology Category	*Informational Domains*		
	Technical	IP	Ethical
Stem cell lines			
Derivation			
Growth			
Characterization			
Differentiation			
Delivery			

Focus of current database efforts

Proposed expansion of focus

FIGURE 3. Domains of Information Collection
Stem cell technology data needs to cover multiple technologies and domains of information. This schematic indicates where current data-centralizing efforts in the stem cell research community are focused: on technical information about stem cell lines. We propose expanding such data centralizing efforts to include more stem cell technologies and more types of information.

Lastly, this information resource would bring together information detailing the provenance and oversight associated with particular stem cell lines and related research material. National or regional regulations[252] pertinent to particular technologies would be listed on a country-by-country or state-by-state jurisdictional basis. For any given cell line, potential users would want to know the jurisdiction in which stem cells were derived, regulation of gamete or embryo procurement, derivation details, and whether the line has various types of "ethical approval" by oversight committees and other stem cell repositories. Furthermore, users would want to know whether particular cell lines satisfy the law in these

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license available for all fields of use," "non-exclusive license available for all fields of use," "license available for limited fields of use," or "license unavailable." Basic terms of availability for research use under MTA could be indicated, and contact information for obtaining materials and necessary documentation could be provided. Scientists might even post additional terms of exchange, such as co-authorship requirements, which they may choose to place on the distribution of a particular cell line or a technology for research purposes. The compilation of information on coalition members' IP and its availability for research or for licensing can be quite useful for those analyzing the IP implications of combining specific technologies. Taken together, such information might be considered an IP analog to a "universal listing" of real estate within a given metropolitan area.

252. *See supra* Section I.C; *see also, e.g.*, Rosario M. Isasi et al., *Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa*, 32 J.L. MED. & ETHICS 626-40 (2004).

different jurisdictions, and how the different voluntary guidelines recently adopted by the National Academy of Sciences[253] and by the ISSCR may apply to that line.[254]

3. Promotion of Materials Sharing and Stem Cell Banks

The collaborative data architecture could also help promote materials sharing within the research community. More technical characterization data on stem cell materials would enable their usage in more research projects that would increase the overall flow of materials in the community. Uncertainty about use of stem cell materials would be reduced, as key proprietary and ethical information would be made transparent. Stem cell banks are expected to be key participants in the development of the initial architecture, and better integration of data about their lines would likely increase usage of those lines. Overall, it will not be necessary to build more physical repositories of stem cell materials to increase the circulation of stem cell materials, but the data and the data architecture itself should function to leverage existing physical capacity for material production and distribution.

In the end, a collaborative data resource would couple well with current plans to network stem cell banks, such as the International Stem Cell Banking Initiative.[255] Bank participation would be a convenient way to gather high quality data on existing cell lines. Further, a collaborative data resource could also provide banks with a powerful and convenient way to manage their own information on their lines. In turn, banks would have a key role in producing and disseminating data on new cell lines, as funding mandates push labs to bank cells in public collections more quickly and reliably. Lastly, the banks could help coordinate international standards on issues relating to the cell line characterization and clinical applications of stem cells. Together, compatible architectures for data and cell line management have strong potential to open up stem cell research.

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253. NRC-IOM GUIDELINES, *supra* note 109.

254. Daley et al., *supra* note 146. Salient aspects of the informed consent procedure for any material from human subjects would be listed, as well as whether there were any stipulations on the use of cell lines. These usage constraints might arise at the time the stem cell lines were derived as a result of member institutional review, or as a result of conditions imposed by embryo and gamete donors. Data would be assembled from regulatory bodies, advisory boards, stem cell repositories, and the member institutional oversight committees.

255. *See* Int'l Stem Cell Forum, ISCBI Scoping Plans, http://www.stemcellforum.org/forum_initiatives/international_stem_cell_banking_initiative/iscbi_scoping_plans.cfm (last visited Nov. 13, 2008).

4. How Open?

Post-publication technical data, patent data, and published regulatory data from academic institutions are public. As such, these large sections of data within the common architecture should be broadly available. As seen in the genomics experience, technical data have variable commercial potential with portions of potential interest to industry. Therefore, those sections of the database may be protected and reserved for use among members, according to agreed-upon protocols. Such sections could encourage the deposit of pre-publication technical data by researchers within particular subfields. Such protections are likely to change over time, but the overarching mission of disseminating technical data should prevail for data that lack strong rationale for protection. The consortium could also provide its members with software tools for data analysis.

B. Conducting Analysis of Key Constraints

Developing a database architecture with the appropriate incentives to share data and materials would enable much greater data exchange and ethical transparency in the conduct of the research. Nevertheless, without further agreement among research institutions to improve the exchange and use of biological materials and other proprietary tools, the gains from a public data resource for stem cells will be limited. Here the PIPRA example is especially useful, illustrating how nonprofit institutions could pool resources to overcome some of the remaining bottlenecks in the field. Thus, as the data architecture is constructed, the consortium of institutions could initiate a series of other tasks that provide mutual advantages to the participants, moving the initiative from just an information clearinghouse to more of a user association.[256] This would initiate and enable the second stage of activities.

Following the needs of the stem cell research community, the second stage of key functions would be analytical, much as it was for PIPRA in the plant biotechnology research community. For widely-used cell lines, technologies, or methods, many researchers will approach the collaborative data architecture or its curators with similar concerns and questions, with many of them separately engaging in similar queries or analyses of their technical, IP, and ethical status. Conducting authoritative analyses of the most widely used cell lines and technologies and providing them to the coalition membership would create large efficiency gains for the research community.

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256. Steven Wolf et al., *Institutional Relations in Agricultural Information Systems*, *in* KNOWLEDGE GENERATION AND TECHNICAL CHANGE: INSTITUTIONAL INNOVATION IN AGRICULTURE 233 (Steven A. Wolf & David Zilberman eds., 2001) (discussing various institutional arrangements for data provision across the academic and private sector in agriculture).

It is likely that in the discussion over what information to include or require in the database, coalition members will begin to identify and prioritize a set of key bottlenecks in stem cell R&D, areas where access to data and materials is particularly complicated by failure to arrive at technical, IP, or ethical terms of use. For those bottlenecks, the coalition could conduct or commission analyses that characterize the salient technical, IP, and ethical dimensions. Just as in the PIPRA example, law firms or even law school clinics could help perform such analysis on a pro bono basis. Understanding which IP claims apply to a given technology for use under a given set of circumstances is not always a simple matter.[257] These analysts could conduct such general assessments of how IP conditions are likely to affect freedom to operate within typical commercial scenarios.

For any given research tool, cell line, or technology, it will be useful to develop a more centralized analysis and validation of the real, potential and imaginable ethical issues. As discussed above, much of the burden of negotiating the patchwork of regulations has come to rest not on states or their governments, but on scientists and review committees at the level of individual research institutions.[258] At this tier, SCRO review itself would not necessarily be centralized. Rather, as illustrated in Figure 4, commonly used materials could be certified and validated centrally in ways that would save time for SCROs. Centralized ethics discussions would feed back into the individual research institutions themselves, such that expertise on local SCROs could be enhanced, enriched, and coordinated. This stage of work would entail ethical and regulatory analysis to identify bottlenecks and lay the groundwork for designing the least controversial research tools and materials.

Although these analyses initially may be conducted by scientists for technical complexity, IP lawyers for proprietary complexity, and ethicists for regulatory and ethical analysis, it will be imperative for the coalition to bring these three analyses together. Reports synthesizing these analyses will be valuable for describing the interaction of technical, IP, and ethical constraints that characterize the climate for stem cell R&D.[259]

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257. IP constraints on stem cell lines and associated technologies can include both patents and contractual obligations created by the signing of MTAs and other agreements. Determination of the IP environment typically requires detailed analysis by technically trained patent attorneys who then render an opinion on their client's freedom to operate with the given technology for that specified use. In general, however, it is still possible to survey the IP landscape around a technology and develop a reasonably well informed understanding of what IP rights are likely to circumscribe what kinds of uses.

258. This is one of the main reasons we pitch our policy solution at the level of the research institution, as explained *infra* Part II.

259. *See supra* Section II.A.

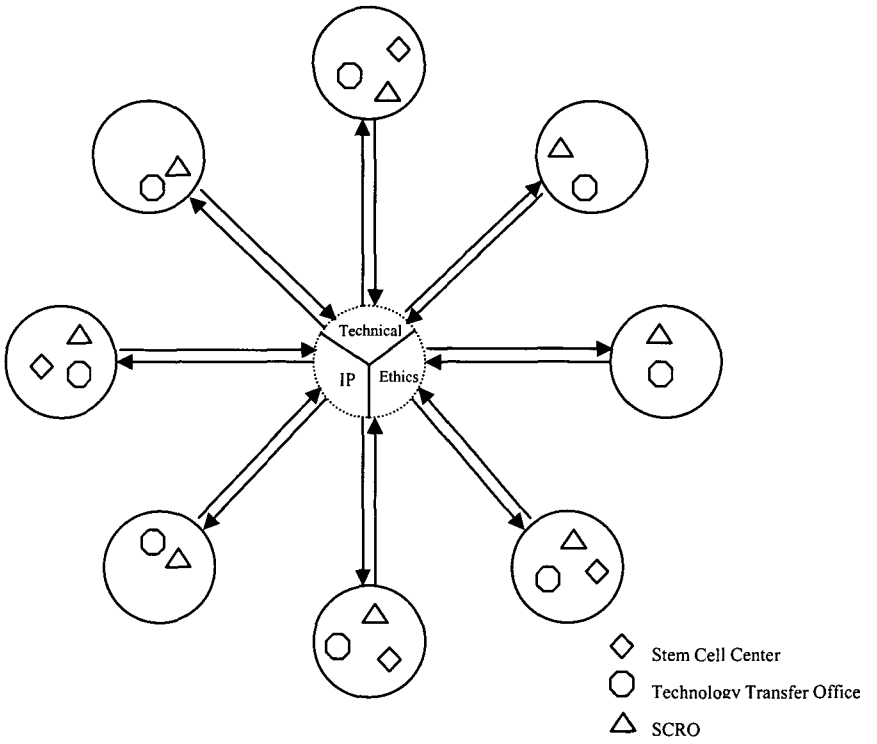

FIGURE 4. The Stem Cell Coalition as a Coordinating Hub for Member Institutions' Decision-Makers
Each member of the coalition has an internal SCRO providing internal policies and guidance on the ethics of stem cell research and a technology transfer office managing IP owned by the institution. In addition, each member institution's stem cell initiatives or center could directly communicate with the coalition. Alternatively, scientists may use existing national and global professional stem cell organizations to build relationships with the coalition. Without effective consultation and coordination across institutions, each of these campus-level offices makes decisions based upon its own limited information. The coalition provides a central forum for the responsible university officers to consult with one another, exchange information, benefit from commonly supported analyses, and provide input on the design of common technology platforms and standards.

C. Pooling, Cross-Licensing, and Other Solutions

These analyses could illuminate important opportunities to develop solutions to common problems experienced by stem cell research institutions, labs, and start-up companies. Drawing explicitly upon the PIPRA model, the consortium could develop a protected common resource through cross-licensing and even patent pooling approaches to advance the dissemination and use of research tools to alleviate IP bottlenecks identified in the analyses of Section B above. Since these workarounds might become standard platform technologies incorporated

into a broad array of further R&D efforts, careful planning and discussion should guide the design of these tools. The tools should embody ethical choices that make the resulting technology as widely acceptable and broadly compliant as possible. Furthermore, the consortium members could pool resources and consolidate efforts in the ethical domain; this would allow SCROs to share reviews and files for commonly used technologies, improving efficiency and lowering barriers to entry.

After analyzing the common bottlenecks arising from technical, IP, and ethical/regulatory considerations and the interactions among the three, it would be feasible for the consortium to design new technology platforms or research tools that work around the most important bottlenecks. The coalition could design and build an enabling research tool by aggregating technology components into a bundle that best meets technical, IP, and ethical parameters for a wide range of the foreseeable applications of that tool—for example, a package consisting of an appropriate cell line, a vector, and a culture medium that enables researchers to obtain neural cells from embryonic stem cells. Furthermore, the coalition would serve as a natural venue—analogous in many ways to a standards-setting body—to deliberate about the content of the research tools, including technical input on preferred standards, legal input on who owns the IP and whether it is available for licensing, and expert analyses of ethical questions. A cohesive assembly of stem cell technologies would combine a complex platform of mutually complementary components, with each component enhancing the others' value or utility.[260]

Designing a technology bundle that succeeds in freeing up the R&D environment would be the top priority for the consortium at this phase. But a number of other principles would be important for the design of such a bundle. The components should work well together and be well characterized technically, making them ready for adoption in the laboratory. The choice of technological components for inclusion in a bundle should partially turn upon their public domain or proprietary status. Those components that are not in the public domain would need to be included under pre-negotiated terms within a patent pool and licensed collectively to users.[261] Component technologies that reside in the public

260. Often, steps spanning the range of derivation, propagation, characterization, differentiation, and delivery technologies are dependent on each other and encompass a full tool set for research into potential medical applications. For such an enabling research tool assembly, at least one interoperable technology component from each of the categories of derivation, propagation, differentiation, and delivery would be included. In other cases, a suite of technologies from within a single category (perhaps a suite of factors for inducing cellular differentiation along a major developmental pathway) might be needed in concert for many research applications. In these cases, the design of that particular enabling research tool bundle would include that set of interdependent components.

261. Where the patent landscape is fragmented across many actors, patent pools can create

domain would be favored for inclusion, as they carry the fewest property restrictions.[262] Component technologies owned by coalition members would have an advantage, both because the terms of availability would already be known based on the information gathered for the database, and because the members of the coalition would already be informed and engaged in the overall process.[263] Occasionally, component technologies owned by outside parties (non-coalition members) may be deemed essential for either technical or ethical reasons. The owner or exclusive licensee of those technologies could then be approached and invited to participate in the exercise by licensing the use of their technology as part of the enabling research tool platform.[264]

Overall, the process for creating each research tool bundle will require substantial bilateral and multilateral negotiations. Inclusion of certain crucial technologies will need to be gained through the use of carefully crafted licenses, allowing the owners to retain control in specified fields of use while still including the core technology in the bundle. Developing a patent pool will require, and build upon, intensive analysis of freedom to operate with each of the individual components and combinations of components.[265] Though the process

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substantial efficiencies because they coordinate and amalgamate multiple patents for the purpose of joint licensing. *See* Merges, *supra* note 90 (defining patent pools and describing their rationale as a general matter); Shapiro, *supra* note 89 (same).

262. *See* Boettiger & Chi-Ham, *supra* note 212, at 889. It must be noted, however, that determining a technology's residence in the public domain is not always straightforward. The public domain can be circumscribed by claims on specific improvements to a public domain technology, claims on the use of that technology in particular combination with proprietary technologies, and claim on use within particular processes. Further complications arise depending upon the choice of countries in which the patentee chose to file: the technology may in fact reside in the public domain within some countries while being patented in others. In other words, technical and legal complexities can interact to diminish the certainties of the public domain as an institution for the transaction of and access to knowledge.

263. University-owned technologies are often unlicensed in all or in some fields of use. Those technologies for which all fields of use are already exclusively licensed would naturally not be available for inclusion in a collective licensing arrangement, although even this situation does not preclude seeking a sublicense from the licensee.

264. Incentives for their participation would include the prospect of licensing revenues gained via participation in a patent pool as well as good will or reputation effects from participation. These latter motives may not be insignificant motives for smaller biotech firms.

265. This freedom to operate analysis would likely continue in parallel with negotiations, as there are likely to be numerous tradeoffs in the choices of technologies and the feasible terms of license and MTAs for various candidate technologies being considered for inclusion in the patent pool. The basic construction of the patent pool would involve non-exclusive licenses over each of the tool components that include rights to execute royalty-free transfers (e.g., MTAs) for research uses or a royalty- or fee-bearing license for commercial uses under pre-negotiated non-exclusive terms.

will require an evaluation of antitrust issues arising from the development of patent pools through such a consortium, these are likely to pass regulatory muster so long as they are intended to promote, not hinder, competition by enabling the broad distribution of research tools.[266]

Finally, the coalition could provide a powerful mechanism to streamline negotiations, approvals, and procurement procedures for enabling research tools. The primary IP concerns in distributing enabling research tools include managing the execution and monitoring of MTAs and license agreements with the users, collecting and disbursing royalty or fee shares back to the technology owners, and participating in enforcement actions against those using the research tools without the proper permissions. Suppliers of stem cell technologies can work with the coalition to provide standardized forms and methods of distribution of cell lines, biological materials, and other materials. For particular technologies that could benefit from such distribution, coordinated dissemination of enabling research tools would reduce transaction costs and put the "right" tools in researchers' hands. For example, suppliers of characterization technologies are increasingly offering stem cell kits.[267] However, these kits seldom include the cell lines themselves or the other propagation, differentiation, and delivery technologies. If the coalition indicates a clear demand for stem cell kits that encompass all technologies, i.e., enabling research tools, then the supply side could work together to provide such integrated kits.

Lastly, the coalition could provide a novel means of including and enforcing ethical standards for stem cell technologies. Technology bundles and platforms could embody ethical and normative goals.[268] Bundles of technologies that are

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266. Using pooling arrangements across nonprofit research institutions to promote dissemination of research tools is likely to be deemed "procompetitive," and thus is unlikely to attract regulatory scrutiny. *See* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (1995) (stating that "[b]y promoting the dissemination of technology, cross-licensing and pooling arrangements are often procompetitive" but that "[c]ross-licensing and pooling arrangements can have anticompetitive effects . . . [and] may be deemed unlawful if they do not contribute to an efficiency-enhancing integration of economic activity among the participants").

267. For example, the ES Cell Marker Sample Kit (SCR002) is being offered by Millipore (Bedford, MA). Millpore, Kits for Pluripotent Stem Cell Research, http://www.millipore.com/cellbiology/cb3/pluripotentkits (last visited Nov. 13, 2008). The StemPro hESC SFM kit is offered by Invitrogen (Carlsbad, CA). Invitrogen, STEMPRO® hESC SFM - Human Embryonic Stem Cell Culture Medium, http://www.invitrogen.com/site/us/en/home/Products-and-Services/Applications/Cell-Culture/Stem-Cell-Research/Stem-Cell-Research-Misc/stempro_hesc_sfm.htm (last visited Nov. 13, 2008).

268. Decades of research in the social studies of technology have demonstrated the ways in which technological artifacts embed human choices, which in turn are shaped both by material conditions and ethical, social, legal, and economic considerations. For classic works in the field,

built using best practices—or what we might call "best ethics"—that satisfy most or all extant guidelines could be developed, such that the resulting research materials and tools actually embody ethical choices and considerations. Ready availability of a technology could establish a practical or feasible ethical option, against which other technologies would thus have to measure up. For example, perhaps the stem cell lines designed and promoted by the coalition could be derived from "spare" embryos or reprogrammed somatic cells rather than SCNT, promoting technical options that are, broadly speaking, less ethically controversial across multiple cultures.[269]

Member institutions of the coalition, in consultation with other key players, could deliberate upon what standards should be implemented. If university partners could be drawn from states across the United States, as well as countries across the globe, this process might have a better chance of achieving a sort of global normative authority. Clearly, the coalition should avoid controversial technologies, such as chimerical entities, in order to minimize political controversy.

This would also be a natural stage in which to invite outside actors and stakeholders into the process in order to achieve a broader and "multivalent" evaluation process, to help guide the consortium towards outputs and activities with broad public benefit and acceptance. We anticipate that such a forum for deliberation and design would have broad political appeal. For instance, even those opposing the destruction of embryos for the creation of new hESC lines might embrace as a pragmatic option the project of distributing more widely the existing lines or lines created by the new technique of cell reprogramming[270] so that fewer embryos would be destroyed for research purposes. In addition to promoting ethical transparency, explicitly embracing the role of values to guide stem cell tool design would, literally, build ethics into the materials of research.

IV. DISCUSSION: INCENTIVE ANALYSIS OF KEY ACTORS

Bringing together a diverse set of institutional actors at the international level across multiple domains requires a clear alignment of interests of the various parties. In stem cell R&D, different kinds of actors control the information, materials, and IP at issue. Data are often generated and controlled at the level of the individual laboratory. Materials may be controlled by a

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see Langdon Winner, *Do Artifacts Have Politics?*, 109 DAEDALUS 121 (1980). *See generally* THE SOCIAL CONSTRUCTION OF TECHNOLOGICAL SYSTEMS (Wiebe E. Bijker, Thomas P. Hughes & Trevor T. Pinch eds., 1987); SHAPING TECHNOLOGY/BUILDING SOCIETY: STUDIES IN SOCIOTECHNICAL CHANGE (Wiebe E. Bijker & John Law eds., 1992).

269. *See* Hinxton Group, *supra* note 126.

270. *See supra* note 69.

combination of the laboratory and university technology transfer personnel. Provenance and other ethical assurance data are usually controlled at the level of the individual SCRO, while patents are usually controlled by the research institution and managed by the technology transfer office. Here, we offer an analysis of how these interests converge around the development of common research resources.[271]

A. Perspective of Research Funders

The development of a robust collective action mechanism to enable stem cell research would require that large funders of public science, particularly the NIH, the Wellcome Trust, and CIRM, view such an effort as important to their institutional goals and policies. Some public funders seem more concerned than others that sharing data and research resources might affect commercialization or even the pace of basic research. CIRM, for one, has not been as active as it might have been on issues of data and materials sharing, in part because the California initiative was conceived not only as a health research initiative, but also as an economic stimulus package.[272] Nevertheless, in communication with patient advocacy groups, companies, and university researchers, funders would likely find that making certain kinds of data and materials more accessible would help advance common goals.

Indeed, most of the large funding institutions already have general policies in place regarding the sharing of data, materials, and research tools produced through its funding. For instance, in 1999, in response to problems of access, the NIH issued an important set of guidelines on the dissemination of research tools.[273] Although these guidelines are not binding, they articulate strong norms of dissemination and minimally burdensome MTAs.[274] Furthermore, NIH began to use its funding power to require more active forms of data sharing in all of its program areas. Starting in October 2003, investigators seeking $500,000 or more in NIH grants in any single year were expected to include a plan for data sharing

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271. We have made a conscious choice to limit the discussion that follows to key actors likely to control the information, materials, and IP at issue. We do not mean to suggest that patient advocacy groups, other citizen groups, and end-users are not key actors in this policy field, though we do not discuss them in this Section. To the contrary, these are precisely some of the groups that should be involved at various stages of the consortium. Hopefully we have already argued persuasively why such groups would benefit from the outlined mechanisms to open up stem cell research and development.

272. *See* Richard J. Gilbert, *Dollars for Genes: Revenue Generation by the California Institute for Regenerative Medicine*, 21 BERKELEY TECH. L.J. 1107, 1107-09 (2006).

273. NIH Principles and Guidelines, *supra* note 52.

274. *Id.* at 72,092-96.

or justify why data sharing was not possible.[275] This NIH Statement on Sharing Research Data states that "data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health," and endorses "the sharing of final research data to serve these and other important scientific goals."[276] As discussed above, the Wellcome Trust has been heavily involved in helping foster the research commons in genomics and other areas as a means of advancing its larger health mission. In its own policy on data sharing, the Wellcome Trust states that it attempts to ensure sharing in ways that maximize public benefit, and that "the benefits gained from research data will be maximized when they are made widely available to the research community as soon as feasible, so that they can be verified, built upon and used to advance knowledge."[277] These stated policies, along with important actions taken in other fields of biomedical research, suggest that funders are motivated to push policy in the ways we advocate.

B. Perspective of Individual Research Labs

Strong incentives to engage in the collaborative activities described above already exist for individual labs and researchers, as evidenced by ample participation in scientific publishing, conferences, and nascent databases. However, to the extent that increased levels of data and materials sharing are required, as argued in Part I, there are strong reasons that the scientific community should support this goal and rally towards a greater degree of collaboration. First, data and materials sharing is a traditional practice within science that has been responsible for scientific advance. At a minimum, labs have a common interest in sharing materials and data to replicate experiments. Second, as part of the stem cell community that lobbies for funding, stem cell researchers around the globe also have a common interest in delivering on promises that the field will produce new therapies. Third, labs must use materials and procedures that satisfy their institutional review boards, and the proposed data architecture would allow labs to avoid ethically questionable materials. Lastly, the data resource could provide a trusted standard that would help labs avoid spending time and resources to characterize stem cell materials and instead focus on conducting their primary research.

Yet to overcome the collective action dilemma within the research community, funders and journals would need to break the inertia. Greater sharing of data and materials, especially pre-publication data, may be unrealistic in the

275. Nat'l Insts. of Health, Final NIH Statement on Sharing Research Data (Feb. 26, 2003), NOT-OD-03-032, http://grants.nih.gov/grants/guide/notice-files/not-od-03-032.html.

276. *Id.*

277. *See* Wellcome Trust, Policy on Data Management and Sharing, http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX035043.htm (last visited Nov. 13, 2008).

absence of sufficient incentives for scientists. Since academic researchers who are primarily interested in advancing their careers seek, first and foremost, to publish, much could be accomplished by raising the standards for data sharing across the range of scientific journals in the field. Indeed, many journals have missions of promoting access to knowledge. In addition, journals may find that a collaborative data architecture could help them organize the increasing amounts of supplemental information that is submitted with publications. If more rigorous journal policies could be combined with stricter sharing requirements of funders, scientific labs would likely cooperate.

C. Perspective of Universities

Research universities could be expected to participate at an institutional level in efforts to foster greater coordination in the stem cell area both as a matter of common interest (i.e., for the common good based on the public service mission of such institutions) and enlightened self-interest.[278] Even as universities increasingly look to the power of exclusive control to generate private investment and revenue, institutional missions and traditional scientific norms support an ethic of sharing and collaboration.[279] Indeed, universities share a common mandate to produce public benefits and to disseminate knowledge and information.[280] It is true that this mandate must be balanced with the goals of raising revenue through commercial research sponsorship and licensing, as well as stimulating local economic development, but universities have special duties that call for finding better ways to get biomedical information and inventions into wider use.[281]

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278. See *supra* note 248.

279. Rai & Eisenberg, *Bayh Dole Progress*, *supra* note 3, at 289-91; *see also* Reichman & Uhlir, *supra* note 4, at 370-71, 428, 440 (noting the increasing tension between the mandate to share data and databases based on the educational mission of universities and the traditional ethos of science, and the new push to commercialize scientific assets under the logic of Bayh-Dole).

280. *See, e.g.*, Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L. J. 1031, 1084-85 (2005) (developing the argument for an open licensing approach to universities' biomedical innovations by emphasizing that "[u]niversities' core institutional principles include the production and dissemination of knowledge, as well as a related and more general dedication to improving human welfare"); Amy Kapczynski et al., *Global Health and University Patents*, 301 SCIENCE 1629, 1629 (2003).

281. *See, e.g.*, IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY (2007), http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf (important consensus document developed by twelve leading research universities in the United States stating that "[u]niversities have a social compact with society. As educational and research institutions, it is our responsibility to generate and transmit knowledge, both to our students and the wider society. We have a specific and central role in helping to advance knowledge in many fields

Furthermore, this policy has the potential to advance the self-interests of individual universities, even narrowly construed: A collaborative environment promises direct savings and gains for universities and other nonprofit research institutions, both in the area of ethical review and in the area of IP. Figure 4 represents a hub-and-spokes model of institutional functions around technology transfer, ethical review, and the administration of stem cell centers. Centralizing certain ethical, regulatory, and technical functions could save universities time and money, promote the use of their stem cell inventions, and reduce the risks to which institutions are inevitably exposed when making controversial decisions alone.

In the domains of ethics and IP, the research institution itself bears primary legal responsibility. As discussed above, government and non-government actors at the state level have initiated productive discussions aimed at harmonizing state regulations,[282] but the burden of assuring compliance of research with the patchwork of rules remains squarely on the shoulders of individual research institutions and their SCROs. Coordinating or even just cross-referencing ethical oversight functions among the institutions within the coalition could prevent each institution's SCRO from unnecessarily repeating complex regulatory analyses. Further, as the PIPRA model shows, there are opportunities for mutual gain through inter-institutional coordination of licensing that reduces uncertainties and transaction costs, thereby increasing the general flow of licensing and new firm formation.[283] Surveys of stem cell research activities and patenting suggest that research universities hold some of the biggest patent portfolios in the field of regenerative medicine and thus have the most to gain in royalties from improvements in the overall rate of R&D.[284]

The proposition for a technology owner to include technology in a patent pool is, of course, a much later consideration than the initial invitation to join a coalition devoted to IP problem solving. Reasonable circumstances may preclude member institutions from allowing a particular technology to be considered in the design of an enabling research tool. Owners may also reasonably want to retain some degree of control over improvements to their technology. However, under the prevailing conditions of stem cell R&D, there may in fact be considerable enthusiasm on the part of owners to participate in a patent pool. Just as there are benefits to having one's technology included in an industry standard patent pool, such as MPEG or DVD, participation in a coalition-designed research tool may

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and to manage the deployment of resulting innovations for the public benefit. In no field is the importance of doing so clearer than it is in medicine").

282. *See supra* note 141 and accompanying text.

283. *See* Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 SCIENCE 174, 175 (2003); *see also supra* Subsection III.B.1 (discussing PIPRA).

284. *See* BERGMAN & GRAFF, *supra* note 28, at 5.

be a good route toward achieving the licensing and utilization of a patented technology.[285]

Finally, on the issue of using IP protected materials in conducting university research, the Federal Circuit's 2002 *Madey v. Duke University* decision denied academic researchers recourse to the common law experimental use exemption to patent law.[286] It seems that this decision has yet to disrupt the common practice among university researchers of disregarding the patent landscape, but this may change as infringement suits are brought against academic researchers.[287] Furthermore, stem cell scientists already need to license commercially provided research tools. Rendering research tools less expensive would lower the marginal costs of initiating R&D and in turn enable more research within the university sector.[288] The generation at the university level of forward-looking solutions to data sharing issues and patent thickets may be essential to the future health of university science.

D. Perspective of Companies

Companies in the private sector are major players in stem cell R&D, but they are by no means homogeneous in purpose or size. Major classes of companies in

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285. *See* Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case of Patent Pools*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 123 (Rochelle C. Dreyfuss, Diane L. Zimmerman & Harry First eds., 2001).

286. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) (refusing to excuse research work at Duke from patent infringement claims despite its non-commercial nature).

287. *See* WALSH, CHO & COHEN, *supra* note 53, at 27-28 (finding that "22% of our academic respondents were notified by their institutions to be careful with respect to patents on research inputs, up from 15% of our respondents who recalled receiving such a notice five years ago," but that "there was little difference in the behavior of those academics who had received such notification"); *see also* REAPING THE BENEFITS, *supra* note 10, at 122; Yancey & Stewart *supra* note 214, at 1225 ("Academic researchers have regularly ignored patents on key technologies as a strategy to maneuver around patent thickets and freedom-to-operate issues, but they may be at risk more than they realize.").

288. For some time, sociologists of technology have dispelled the notion that innovation occurs within a linear model in which there is a unidirectional flow from basic research to applied technologies and therapies. *See, e.g.*, UNIVERSITIES AND THE GLOBAL KNOWLEDGE ECONOMY: A TRIPLE HELIX OF UNIVERSITY–INDUSTRY–GOVERNMENT RELATIONS (Henry Etzkowitz & Loet Leydesdorff eds., 1997); Benoît Godin, *The Linear Model of Innovation: The Historical Construction of an Analytical Framework* (Project on the History and Sociology of S&T Statistics, Working Paper No. 30, 2005), *available at* http://www.csiic.ca/PDF/Godin_30.pdf. Research tools are innovations that feed back into the stream of basic knowledge production, introducing complexities when they are attached to onerous licensing provisions and material transfer agreements.

the stem cell R&D landscape include start-up biotech firms, large pharmaceutical firms, and specialty research tool or technology platform vendors. Even without active participation, we anticipate that private sector companies will benefit from some of these efforts, as common resources could help advance commercial research, potentially reducing in-house R&D costs. Companies, particularly in the start-up space, may benefit immensely from the availability of licensing pooled technologies. Specialty research tool companies may benefit if commonly available datasets or tools combine well with or increase the value of the technologies they provide.

It is quite likely that some companies will want to be more active partners in the data collaborative, as firms are increasingly interested in sharing pre-competitive data.[289] In stem cell R&D, the institutional boundaries that once demarcated basic research from technological development are increasingly porous, as academic research finds application in industry.[290] For example, the Stem Cell Community database encouraging academic research data deposit has been supported by three companies—Chemicon, Illumina, and Invitrogen.[291] A number of important examples of partnerships on data sharing across the public-private divide have developed in genomics, including the SNP Consortium and the Merck Gene Index project, where Merck and Washington University publicly released thousands of expressed human gene sequences.[292] More firms may want to join the collaboration if some sections of the database could be protected for industrial purposes for limited periods of time before public release.

CONCLUSION

Striking the proper balance between openness and restraint in biomedical research and innovation is becoming a crucial policy issue in health policy, law, and bioethics. Innovative mechanisms of open and collaborative research have emerged in some life science fields, but not in the burgeoning area of stem cell research. The productive advance of R&D in the field of stem cells faces a number of challenges that neither markets nor the public domain—nor the complex interplay of the two that characterizes the world of R&D today—have been able to solve. In the previous two Parts, we outlined a cascading multi-stage model that goes beyond traditional approaches to solving complex coordination problems and defines a new forum and set of processes for the coordinated management of data and materials, licensing and technology transfer, and ethical

289. *See* Merges, *supra* note 20.

290. *See* Eisenberg & Nelson, *supra* note 16.

291. *See* Personal Communication with Jeanne Loring, Prof. of Chemical Physiology, The Scripps Research Inst. (Jan.—July 2008).

292. *See* Cook-Deegan, *supra* note 219, at 150-52.

oversight and regulation. In doing so, this proposal responds to some of the systemic debates over the role of research institutions in maintaining the "science commons."

A key point of departure of this proposal from existing efforts in stem cell research, and in other fields, is the explicit recognition of the need to work in an integrated way across the problem domains with data sharing, patents, and ethics. Conceptually and practically these problem domains, as well as best-solution sets, are interwoven. An integrated approach in the design phase would better advance platform technologies that may be less ethically controversial and more broadly enabling. (For example, the first propagation technologies to grow hESCs required irradiating mouse embryonic fibroblasts, but relatively few institutions had the physical infrastructure to do so.) As designers construct technology platforms to minimize proprietary constraints, they may advance other collective goals such as avoiding ethical conflicts and enabling more users.[293] We hope that a greater awareness of how values can inform the material architecture of stem cell research might attract a diverse and informed range of actors and stakeholders into the design process.

This integrative approach could promote greater entrepreneurship in stem cell research and also create positive distributional effects. Proprietary hurdles impeding stem cell research can dissuade firms from entering the field in the first place. By bringing down expected costs of doing adaptive or translational research and development, it is easier for all companies, large and small, to investigate a broader range of products benefiting a wider range of markets. The development of products intended for smaller scale markets expands the universe of potential applications, allowing more companies to fill more niches, including underserved patient populations and neglected diseases. Overall, the reduction of costs and integration of values entailed in this proposal could expand stem cell research beyond exploring only potential blockbusters and direct it towards a fuller constellation of potential stem cell therapies.

293. There is a consensus within the sociology of technology that design aspects of technologies can enable or restrict access to particular segments of society. *See* Winner, *supra* note 268.

NOTE

"Till Naught but Ash Is Left To See":[1] Statewide Smoking Bans, Ballot Initiatives, and the Public Sphere

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* B.A., History, Colgate University. J.D. Candidate, Yale Law School. This Note is deeply indebted to the yeomanly work of Nick Pedersen and his assistance in compiling the survey of laws in Part I and Appendix A. My gratitude goes to Theodore Ruger for encouragement and criticism, and to Vikram Fielding-Singh for his meticulous editing. Justin Henderson, Michael Trow, J.W. Victor, Brandon McKenzie, and Matt Wisnieff assisted in tracking down a number of elusive sources, and thanks are also due to Bill Raffaele, Joe Lentine, Glen Greenberg, and the staff of New Haven's Owl Shop. Any errors or omissions are entirely my own.

1. JOHANN SEBASTIAN BACH, *Edifying Thoughts of a Tobacco Smoker*, *in* THE SECOND LITTLE CLAVIER BOOK FOR ANNA MAGDALENA BACH, *reprinted in* THE BACH READER 98 (Hans T. David & Arthur Mendel eds., 1945).

INTRODUCTION

The new millennium has witnessed a quiet revolution in smoking regulation. Legislation targeting secondhand smoke—formally known as Environmental Tobacco Smoke (ETS)—has erupted across the country in a majority of American states and countless municipalities. In the last five years, thirty-one states have passed comprehensive ETS regimes. In 2008 alone, Iowa, Nebraska, and Pennsylvania passed statewide smoking bans, Indiana debated and rejected one, the Illinois ETS statute took effect, and the Ohio Department of Health was dragged by advocacy groups through the full range of Ohio courts as it sought to implement the state's recent ban. Major ETS legislation is pending in South Dakota, substantial exemption revisions are pending in Ohio, and in the next few years, more restrictive provisions of several states' laws will kick in. These regimes are rapidly transforming the public domain from predominantly smoke-friendly to presumptively smoke-free.

It is high time to take stock of these developments, both to understand how the legal landscape is changing and to ensure that it develops responsibly. As this Note proposes, American states have been—and continue to be—engaged in the process of reversing the default rule on smoking in public from permissive to prohibitive. Whereas smoking was previously permitted in public, save for designated "No Smoking" areas, we increasingly live in a country where insular smoking spaces are carved out of a public domain in which smoking is generally forbidden.

This is hardly the first sea change in smoking regulation. Both the mid-seventeenth century[2] and the early twentieth century[3] saw global surges in

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2. *See* SANDER L. GILMAN & ZHOU XUN, SMOKE: A GLOBAL HISTORY OF SMOKING 15-16 (2004). In 1624, Pope Urban VIII banned the taking of snuff in churches, finding the effects of tobacco sacrilegiously similar to sexual ecstasy. *See* IAIN GATELY, LA DIVA NICOTINA: THE STORY OF HOW TOBACCO SEDUCED THE WORLD 80 (2001). In 1633, Sultan Murad IV closed the coffeehouses of Istanbul and prohibited the smoking of tobacco. *See* James Grehan, *Smoking and "Early Modern" Sociability: The Great Tobacco Debate in the Ottoman Middle East (Seventeenth to Eighteenth Centuries)*, 111 AM. HIST. REV. 1352, 1363 (2006). A Tobacco Court established by Mikhail Feodorovich, Russia's first Romanov tsar, doled out such barbarous punishments as lip-splitting and castration. *See* GATELY, *supra*, at 85. In China, following the prohibition of tobacco-smoking in 1637, an enforcement decree was issued providing that "[t]hose who hawk clandestinely Tobacco, and sell it to foreigners, shall, no matter the quantity sold, be decapitated, and their heads exposed on a pike." L. Carrington Goodrich, *Early Prohibitions of Tobacco in China and Manchuria*, 58 J. AM. ORIENTAL SOC'Y 648, 650 (1938).

3. The global temperance movement was the motivating force at this stage. In the United States, the effects were slightly delayed, but after securing the Prohibition Amendment, the National Women's Christian Temperance Union unsuccessfully attempted a similar constitutional

regulatory activity—often severe, always transient. Tobacco regulation in America can be traced to 1629, when the first General Letter of Instructions from the New England Company limited the production and use of tobacco in the Massachusetts Colony to medicinal purposes.[4] Soon thereafter, "Blue Laws" grew up in more theocratic colonies like New Haven, rigorously enforcing chaste Christendom by regulating ostentatious dress, the maternal kissing of children on the Sabbath, and the consumption of tobacco and liquor.[5] Smoking on the streets was prohibited in Plymouth County in 1638, and Massachusetts banned smoking within five miles of any town in 1646.[6] These regulations proved short-lived, however, as did the later revival of tobacco legislation during the Temperance Movement.

Recent legislation, however, marks a radical departure from earlier efforts. Where governments once cited religious or moral reasons for prohibiting smoking, we now regulate smoking for a public health purpose: to prevent unwilling exposure to secondhand smoke. The health consequences of ETS have been established and confirmed by a parade of Surgeons General. If we proceed responsibly with ETS legislation, we will leave an important and enduring legacy.

This departure, however, presents a new set of challenges. When smoking was prohibited on moral or religious grounds, regulatory schemes could be bluntly drawn—simply execute smokers on the spot, for instance.[7] With a public health rationale, however, the endeavor becomes more complicated and requires greater nuance. Legislators must tread the line between protecting the unwilling from exposure to secondhand smoke and allowing consenting smokers to gather where unwilling exposure is unlikely. This delicate balancing act is the central challenge of ETS regimes that aspire to be both effective and responsible.

Early ETS regimes were extremely tentative, leaving most of the public domain unregulated. With the recent introduction of what this Note terms "modern statewide bans," or bans which fully reverse the default rule by

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tobacco ban. *See* Maureen O'Doherty, *The Price of a Soul: At What Cost Can the Tobacco Issue Be Resolved?*, 2 J. HEALTH CARE L. & POL'Y at v, ix. Fourteen American states passed legislation restricting the sale or use of cigarettes, and New York prohibited women from smoking in public. *See* Peter D. Jacobson, Jeffrey Wasserman & John R. Anderson, *Historical Overview of Tobacco Legislation and Regulation*, 53 J. SOC. ISSUES 75, 77 (1997).

4. *See* GUSTAVUS MYERS, YE OLDEN BLUE LAWS 10-11 (The Century Co. 1921); Leon Goodman, *Blue Laws, Old and New*, 12 VA. L. REG. (n.s.) 663, 668 (1927).

5. Blue laws regulated the modesty of clothing, imposed penalties for entertaining Quakers, and prohibited the kissing of children on the Sabbath. *See* Goodman, *supra* note 4, at 667, 669-70; Henry G. Newton, *Blue Laws of New Haven*, 7 YALE L.J. 75 (1897).

6. *See* Goodman, *supra* note 4, at 668.

7. *See* Grehan, *supra* note 2, at 1363 ("Smokers unfortunate enough to be caught red-handed were executed on the spot.").

prohibiting smoking in most restaurants and bars, ETS regimes abandoned their reticence. Now, a new and different danger looms, as many recent ETS regimes fail to tailor regulatory provisions to their public health purpose. Disturbingly, the exemption provisions which, as this Note contends, determine the character of an ETS regime, receive very little attention. Debates over smoking regulation focus on the larger question—to ban or not to ban—and ignore the finer but equally essential questions of which areas to exempt. As a result, we have ceased to ask how far is far enough, or how far is too far.

Procedural realities of the ETS debates, which this Note will explore, have exacerbated this disturbing state of affairs. As the regulatory juggernaut advances, the passage of smoking legislation has become a brawl between health advocacy lobbyists on the one side, and the tobacco and hospitality industries on the other side. Advocacy groups demand regimes that exceed the regulatory warrant, eliminating smoking even in places which exclude non-smokers. On the other hand, tobacco and hospitality industries urge complete non-regulation, dismissing the well-documented threat posed by ETS to the public health. Exemption areas are ignored or shouted over. This stalemated conversation is badly in need of reorientation.

When ETS legislation was passed by state legislatures, the influence of these contending lobbies could be tempered by legislative deliberation. In the last three years, however, advocacy groups have successfully foreclosed legislative oversight, taking advantage of ballot initiative provisions in state constitutions and circumventing the legislative process. Increasingly, the shape of ETS legislation is determined entirely by the savvy with which advocacy groups outmaneuver their opponents in persuading a malleable and inexpert voting population. If we aspire to create responsible and enduring ETS regimes, we must revisit these laws and tailor new legislation more closely to its proper function: to prevent unwilling exposure to environmental tobacco smoke.

Despite the profound reach of these recent developments, the statutory landscape is deeply undertheorized. We lack a theoretical framework within which to place statewide smoking bans—or even a basic survey of laws. Presently, an inchoate landscape of confused legislation confronts the observer as she surveys states' ETS regimes. A baffling array of exemption provisions emerges from the catalogue of legislation, documenting states' efforts simultaneously to prevent involuntary exposure to secondhand smoke, limit unnecessary regulation, and avoid unintended consequences.

As the legal landscape evolves apace, the need for theoretical guidance becomes increasingly acute. This Note offers a modest beginning—surveying the current state of the law, identifying major areas of concern, and suggesting directions in which solutions might usefully be sought. Part I reviews the landscape of statewide ETS legislation and proposes a theoretical framework within which it coheres. Part II examines a recent and disturbing trend in the

passage of ETS legislation through a case study of a recent ballot initiative. Part III analyzes the factors that make direct legislation such a clumsy tool for creating responsible ETS regimes, and Part IV calls for remedial legislative attention to exemption provisions, proposing a balancing test that can be used to remedy deliberative failures in ETS statutes passed by direct or conventional legislation. Part V applies this test to an exemption area—tobacco lounges—on which strong ETS regimes divide. This Note aims to provide a starting point for renewed analysis as American states aspire to craft effective ETS regimes without sacrificing regulatory responsibility.

I. THE LANDSCAPE OF STATEWIDE ETS LEGISLATION

The health consequences of tobacco smoking were widely revealed by the Surgeon General in 1964,[8] but the regulatory imperative for ETS legislation did not emerge until 1972, when the Surgeon General reported that ambient tobacco smoke could damage the health of non-smokers as well.[9] Arizona passed the first statewide ETS legislation in 1973, banning smoking in all indoor theaters, art museums, libraries, elevators, and buses used by the public.[10] Since then, state and local governments across America have gradually gone on to expand the sphere of non-smoking public establishments.[11] In 1975, Minnesota passed the first statute to forbid smoking in most workplaces.[12] Other states followed suit with tentative ETS legislation, and by 1980, over half the country—some twenty-eight states—had statutes on the books restricting smoking in public areas.[13] Through the eighties and nineties, various county and city governments followed Minnesota's lead, prohibiting smoking in many workplaces.

State and federal government action in those years was limited. At the state level, little was banned aside from smoking in the narrow range of

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8. ADVISORY COMM. TO THE SURGEON GEN. OF THE PUB. HEALTH SERV., SMOKING AND HEALTH (1964).

9. *See* OFFICE OF THE SURGEON GEN., THE HEALTH CONSEQUENCES OF SMOKING 125-27 (1972) (noting harmful effects of carbon monoxide exposure caused by proximity to smoking).

10. ARIZ. REV. STAT. ANN. § 36-601.01 (1991).

11. Though many localities have implemented innovative ETS regimes atop state legislation, the landscape of ETS regulation can be most clearly discerned with reference to state legislation. Nearly every American state has an ETS regime that sets a baseline prohibition on smoking in public places. Increasingly these laws are quite comprehensive, leaving little room in most cases for significant regulation at a local level. Accordingly, this Note focuses primarily on state legislation, noting significant local variations when appropriate.

12. MINN. STAT. § 144.414 (2005).

13. *See* Robert A. Kagan & William P. Nelson, *The Politics of Tobacco Regulation in the United States*, *in* REGULATING TOBACCO 11, 20 (Robert L. Rabin & Stephen D. Sugarman eds., 2001).

uncontroversial public spaces, such as schools and elevators, covered in Arizona's 1973 statute. The federal government lent the anti-ETS movement only occasional and minor assistance—such as the Environmental Protection Agency's (EPA's) designation of ETS as a Class A carcinogen in 1993.[14]

Shortly after the EPA's designation, legislative action on the state level picked up. In 1994, states started passing new types of laws, which this Note terms "modern statewide bans." Modern statewide bans extend smoking prohibitions to three crucial categories of establishments: 1) restaurants, 2) bars, and 3) most other enclosed workplaces—effectively the entire indoor public domain. California was the first to institute a modern statewide ban by amending its labor code in 1994 to prohibit smoking in most enclosed places of employment, including restaurants.[15] Bars, initially exempt from the new law's coverage, were required to be smoke-free by 1998.[16] In the five years after California's ban took full effect, a handful of other vanguard states joined in—including Delaware, which passed a modern statewide ban in 2002, and New York, which instituted a much-discussed statewide ban in 2003.[17] In the past five years, statewide ETS legislation has snowballed. Since 2004, thirty-one state legislatures have passed statewide smoking bans.[18]

As thoroughgoing as the transformation wrought by modern ETS legislation has been, we lack both a general survey of laws and an analytical framework within which to understand them. Thus far, the only systematic evaluation of ETS legislation has been conducted inside the public health community.[19] The

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14. Press Release, Envtl. Prot. Agency, EPA Designates Passive Smoking a "Class A" or Known Human Carcinogen (Jan. 7, 1993), http://www.epa.gov/history/topics/smoke/01.htm. In 1994, the Occupational Safety and Health Administration proposed a comprehensive ban on smoking in over six million workplaces. *See* William N. Evans, Matthew C. Farrelly & Edward Montgomery, *Do Workplace Smoking Bans Reduce Smoking?*, *in* TOBACCO CONTROL POLICY 233, 234 (Kenneth E. Warner ed., 2006).

15. 1994 Cal. Adv. Legis. Serv. 310 (Deering).

16. CAL. LAB. CODE § 6404.5 (West 2003).

17. *See, e.g.*, DEL. CODE ANN. tit. 16, §§ 2901-2908 (2008); N.Y. PUB. HEALTH LAW §§ 1399-n to -x (McKinney 2008).

18. *See infra* Appendix A.

19. In 2002, an advisory committee convened by the National Cancer Institute published a study rating state clean indoor air laws by the extent of regulation, effectiveness of enforcement procedures, and severity of penalties. J.F. Chriqui et al., *Application of a Rating System to State Clean Indoor Air Laws (USA)*, 11 TOBACCO CONTROL 26, 31 (2002). In years since, the American Lung Association has published an annual "Report Card" that, drawing largely from the ranking methodologies established in the NCI's original study, ranks individual states on the effectiveness of their clean indoor air laws. *See* AM. LUNG ASS'N, STATE OF TOBACCO CONTROL 2007 REPORT, *available at* http://www.lungusa.org (follow "Tobacco Control" tab; then select "Tobacco Control Reports"). Concerned primarily with the medical consequences of statewide bans, these releases

legal academy has not provided a theoretical overview of statewide ETS legislation.[20] Some studies focus in detail on an individual state or countywide ban, but provide only cursory glimpses of broader nationwide trends in ETS legislation.[21] The rest are almost entirely normative pieces—some of which advocate stronger legislation, such as a federal clean air act,[22] while others bluntly repudiate ETS regulation wholesale.[23] This Part seeks to address this gap by providing an overview of statewide smoking bans and proposing a theoretical framework for the disorderly corpus of statewide ETS legislation.

Most modern statewide bans share a common intent: to protect non-consenting individuals from exposure to tobacco smoke in the public domain. From this common purpose, however, a chaotic landscape of wildly varying legal regimes has ensued. Though they may agree that non-smokers should be protected from secondhand smoke, lawmakers have struggled to determine how and where the line between smoking and non-smoking domains should be drawn.

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elide the legal mechanics and broader policy questions presented by statewide ETS regimes.

20. The closest we have to a general survey is *Synopsis of State Case and Statutory Law*, 3 YALE J. HEALTH POL'Y L. & ETHICS 157 (2002), which usefully assembles citations to cases and legislation concerning smoking in public. Sadly, this survey is now outdated. Jessica Niezgoda provides a good but limited review of California and New York regimes, but she does not develop the national landscape. Jessica Niezgoda, Note, *Kicking Ash(trays): Smoking Bans in Public Workplaces, Bars, and Restaurants: Current Laws, Constitutional Challenges, and Proposed Federal Regulation*, 33 J. LEGIS. 99 (2006). Marot Williamson collects information on constitutional challenges to statewide smoking bans, but provides limited analysis. Marot Williamson, Note, *When One Person's Habit Becomes Everyone's Problem: The Battle Over Smoking Bans in Bars and Restaurants*, 14 VILL. SPORTS & ENT. L.J. 161, 168 (2007).

21. Though narrow, some of these articles are quite helpful. *See, e.g.*, Jody Hodgdon, *Live Smoke Free or Die: The Battle for Smoke Free Restaurants in New Hampshire*, 3 PIERCE L. REV. 49 (2004); Jordan Raphael, *The Calabasas Smoking Ban: A Local Ordinance Points the Way for the Future of Environmental Tobacco Smoke Regulation*, 80 S. CAL. L. REV 393 (2007); Adrienne Detanico, Comment, *Banning Smoking in Chicago's Social Scene: Protecting Labor and Broadening Public Health Policy*, 40 J. MARSHALL L. REV. 1063 (2007); Justin C. Levin, Note, *Protect Us or Leave Us Alone: The New York State Smoking Ban*, 68 ALB. L. REV. 183 (2004); Keith Woodeshick, Note, *Smoking Ban Legislation in New Jersey: Should Casinos Be Immune from Smoke?*, 3 RUTGERS J.L. & URB. POL'Y 496 (2006). Jordan Raphael's piece in particular effectively reviews the early history of ETS legislation.

22. *See* Samuel J. Winokur, Note, *Seeing Through the Smoke: The Need for National Legislation Banning Smoking in Bars and Restaurants*, 75 GEO. WASH. L. REV. 662 (2007).

23. *See, e.g.*, Mark J. Horvick, *Examining the Underlying Purposes of Municipal and Statewide Smoking Bans*, 80 IND. L.J. 923 (2005); Thomas A. Lambert, *The Case Against Smoking Bans*, 13 MO. ENVTL. L. & POL'Y REV. 94 (2005); Joni Ogle, *Why Smoking Bans Are a Butt to Texas: The Impact of Smoking Bans on Private Property Rights and Individual Freedom*, 39 TEX. TECH L. REV. 345, 347 (2007) (arguing that "by using smoking bans to protect citizens from their own choices, the government violates the sacred right of private property").

Nonetheless, organizing principles emerge. All statewide smoking bans 1) establish a default rule on smoking in public, and 2) carve out exemptions from that default rule. Indeed, a coherent spectrum of statewide ETS legislation is evident from a survey of states' exemption schemes, for it is through exemption provisions that the line between smoking and non-smoking domains is drawn. After all, the central question in crafting effective and responsible ETS legislation is which, if any, areas should be exempted from the operation of the new default rule? Responsible ETS legislation must strike a delicate balance. With overly expansive exemptions, states fail to meaningfully reverse the default rule and protect the public health. On the other hand, overly narrow exemption schemes lead to regimes that exceed the public health justification for statewide ETS legislation, with serious and often unintended consequences.

Ultimately, this Note calls upon state legislatures to tailor exemption schemes more closely to the public health function of an effective ETS regime and articulates an approach which legislators may find useful. Before we can determine how the lines between smoking and non-smoking spaces should be drawn, however, we must understand how states draw them now.

A. The Function and Intent of Statewide ETS Legislation

All ETS statutes are drafted to prevent involuntary exposure to secondhand smoke, a threat identified by several Surgeons General as a serious public health hazard.[24] Significantly, statewide ETS legislation does not seek to prevent smokers from harming themselves, but rather to prevent them from harming non-consenting bystanders by producing ambient tobacco smoke.[25] Employees, therefore, are a chief concern as potentially unwilling but captive participants in

24. *See, e.g.*, OFFICE OF THE SURGEON GEN., THE HEALTH CONSEQUENCES OF INVOLUNTARY EXPOSURE TO TOBACCO SMOKE: A REPORT OF THE SURGEON GENERAL, at i (2006), *available at* http://www.surgeongeneral.gov/library/secondhandsmoke/report/fullreport.pdf.

25. *See, e.g.*, OR. REV. STAT. § 433.840 (2005) ("The people of Oregon find that because the smoking of tobacco creates a health hazard to those present in confined places, it is necessary to reduce exposure to tobacco smoke by requiring nonsmoking areas in certain places."). Until 2009, when more restrictive provisions kick in, Oregon further provides that the Department of Human Services can waive the prohibition in areas "where a waiver will not significantly affect the health and comfort of nonsmokers." OR. REV. STAT. § 433.865 (2005); *see also* MINN. STAT. § 144.412 (Supp. 2008) ("The purpose of [this statute] is to protect employees and the general public from the hazards of secondhand smoke by eliminating smoking in public places, places of employment, public transportation, and at public meetings."); 2006 Haw. Sess. Laws 295 ("The purpose of this act is to protect the public health and welfare by prohibiting smoking in places open to the public and places of employment to ensure a consistent level of basic protections statewide from exposure to secondhand smoke."); 2007 Tenn. Pub. Acts ch. 410 ("Non-Smoker Protection Act").

the activities of co-workers or customers.[26] In short, it is the externality problem posed by smoking—the costs smokers impose upon non-consenting non-smokers by subjecting them to carcinogens—which ETS legislation targets.

By seeking to prevent the exposure of unwilling individuals to ambient tobacco smoke, ETS legislation reflects public opinion fairly accurately. As Fred Pampel summarizes:

> Public opinion surveys indicate that people respect the rights of smokers to enjoy their tobacco, if they are aware of the harm it does themselves, but also the rights of nonsmokers to stay free from the unwanted smoke of others and from the risks of involuntary smoking. Likewise a majority of smokers accept the need to place restrictions on where they can light up.[27]

It is thus unsurprising that the modern statewide bans we see today—legislation intended to protect the latter "right" (a non-smoker's right to smokeless air) without trampling unnecessarily on the former "right" (a smoker's right to smoke)—have been so popular. They are motivated by a goal that, excepting a hardcore fringe of "smokers' rights" advocates, is almost universally accepted: protecting the unwilling from being exposed to the ill effects of secondhand smoke.

B. A Typology of Modern Statewide ETS Legislation

ETS regimes in American states vary widely in both nature and scope. Five distinct classes, however, can be discerned with reference to exempted areas and preemption provisions, ranging from the most smoke-friendly to the most smoke-free, which this Note labels as follows: (I) "Right To Smoke" States; (II) "Hands-Off" States; (III) "Mild Ban" States; (IV) "Strong Ban" States; and (V) "Draconian" States.

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26. *See, e.g.*, N.H. REV. STAT. ANN. § 155.64 (2008) ("The purpose of this subdivision is to protect the health of the public by regulating smoking in enclosed workplaces and enclosed places accessible to the public, regardless of whether publicly or privately owned, and in enclosed publicly owned buildings and offices."); WASH. REV. CODE § 70.160.011 (Supp. 2008) ("In order to protect the health and welfare of all citizens, including workers in their places of employment, it is necessary to prohibit smoking in public places and workplaces."); 2004 Mass. Acts 137 ("to protect the health of the employees of the commonwealth").

27. *See,* FRED C. PAMPEL, TOBACCO INDUSTRY AND SMOKING 62 (2004). 2007 Gallup poll data reveal that 54% of Americans would totally ban smoking in restaurants, 29% would totally ban smoking in bars, and 44% would totally ban smoking in workplaces. Gallup Politics & Gov't, Tobacco and Smoking, http://www.gallup.com/poll/1717/Tobacco-Smoking.aspx (last visited Nov. 17, 2008).

1. Class I: Right To Smoke States

We start at the most permissive end of the spectrum, a narrow category that has dwindled to only two states: North Carolina and South Dakota.[28] Though these states have passed ETS legislation that regulates smoking in public areas, the function of these state laws is far more preemptive than regulatory. Class I statutes share two characteristics. First, the smoking regulations are quite lax, permitting smoking in bars and restaurants. Second, each of these statutes preempts local jurisdictions from passing more aggressive smoking bans.

North Carolina's ETS regime is the weakest in the country.[29] Most statewide bans exclusively target the health interests of non-smokers, but North Carolina's statute expressly adopts the interests of smokers, seeking "to address the needs and concerns of both smokers and nonsmokers in public places by providing for designated smoking and nonsmoking areas."[30] Solicitude for the rights of smokers is manifest in the operation of the statute. Aside from a narrow class of uncontroversial public spaces including schools and school buses, hospitals and nursing homes, libraries, museums, elevators, and a few other public spaces—largely mirroring Arizona's 1973 ban—North Carolina's current statute permits smoking in virtually all enclosed areas frequented by the public, including all restaurants and bars.[31] State-owned arenas, coliseums, and auditoriums may be designated non-smoking—but only if they provide smoking areas in their lobbies.[32] The statute bears the second hallmark of Class I regimes: a preemption

28. *See infra* Appendix A. Except where other statutes have been cited, references to state statutes discussed in this Note are located *infra* Appendix A.

29. This has everything to do with the primacy of North Carolina's tobacco crop to the state's economy. North Carolina remains the biggest producer of tobacco in the United States. *See* N.C. Dep't of Agric. & Consumer Servs. (Mktg. Div.), Field Crops: Tobacco, http://www.ncagr.com/markets/commodit/horticul/tobacco (last visited Nov. 17, 2008) ("Tobacco has always been an important part of North Carolina's economy and a vital crop to our producers. Many people raised in this state can find a heritage relating to some area of the tobacco industry.").

30. N.C. GEN. STAT. § 143-595 (2007).

31. The statute provides that a narrow category of state government buildings, such as libraries and museums, "may be designated as nonsmoking." *Id.* § 143-597(a). They do not, however, have to be. Other state-government buildings may include designated non-smoking areas so long as at least twenty percent of interior space—of equal quality—is reserved for smoking. *Id.* In all such buildings, the authority to decide whether to make any given state building predominantly non-smoking is vested in "the appropriate department, institution, agency, or person in charge of the State-controlled building or area." *Id.* § 143-597(b). Even when such officials decide to include non-smoking areas on their premises, however, the statute ensures the inadequacy of such non-smoking areas by explicitly stating that it does *not* require installation of separate ventilation systems or other physical barriers.

32. *Id.* § 143-597(a)(4).

clause prohibiting local governments from implementing stricter measures.[33] Save for a narrow group of buildings subject to public ingress, the designation of an area as smoking or non-smoking is entirely at the discretion of its owner. Enterprising publicans could, of course, voluntarily implement and enforce house rules prohibiting smoking, but such measures are virtually unheard of.

This is a disappearing class of statewide smoking ban. Until 2008, Pennsylvania and Iowa filled out Class I, with older statutes—1988 and 1987, respectively—which exempted bars and most restaurants statewide[34] and preempted further regulation.[35] After contentious litigation affirmed the preemptive authority of the state statutes, state action became the only available avenue for ETS regulation.[36] Both states have passed omnibus ETS statutes within the last year, replacing their earlier Class I regimes.[37]

South Dakota is North Carolina's last remaining companion in Class I. Though South Dakota's current ETS statute formally prohibits smoking in restaurants, licensed premises are exempt from coverage, leaving restaurants that

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33. *Id.* § 143-601(b) ("Any local ordinance, law, or rule that regulates smoking adopted on or after October 15, 1993 [the date of the state statute's enactment], shall not contain restrictions regulating smoking which exceed those established in this Article."). Recent legislation suggests that this regulatory freeze is starting to thaw, however slowly. In 2007, North Carolina banned smoking in state government buildings and permitted local governments to regulate smoking in local government buildings. *Id.* §§ 130A-493, 130A-498.

34. *See, e.g.*, 35 PA. CONS. STAT. § 1230.1 (2003) (exempting all restaurants with seventy-five seats or fewer and requiring larger restaurants to designate a non-smoking seating area).

35. *See* IOWA CODE § 142B.6 (2008) (explaining preemption rationale as promoting "equitable and uniform implementation, application, and enforcement of state and local laws and regulations"); 35 PA. CONS. STAT. § 1235.1 (2003).

36. As states across the country were passing modern statewide bans, rebellious local jurisdictions in both Iowa and Pennsylvania tested the preemption clauses by passing more stringent local bans. Allegheny County, Pennsylvania sought to completely ban smoking in restaurants and bars, and the city of Ames, Iowa passed a citywide ordinance seeking to ban smoking in all of its restaurants between the hours of 6:00 a.m. and 8:30 p.m. *See* Anita Srikameswaran, *Allegheny City Council Passes Smoking Ban*, PITTSBURGH POST-GAZETTE, Sept. 27, 2006, *available at* http://www.post-gazette.com/pg/06270/725335-85.stm; Frank Santiago, *Cities, Towns Monitor Fate of Ames Smoking Ban*, DES MOINES REG., Aug. 19, 2002, at 1B. In both cases, restaurants financially backed by tobacco companies promptly sued, arguing that the counties had exceeded their authority under state law and that the local bans should thus be overturned. Ames responded by claiming it had an inherent authority to pass such an act under "home rule" powers granted by the state constitution. *See* James Enterprises, Inc. v. City of Ames, 661 N.W.2d 150 (Iowa 2003). Allegheny County defended its smoking ban by arguing that the state law's preemption clause had been implicitly overridden by subsequent state legislation. *See* Mitchell's Bar & Rest. v. Allegheny County, 924 A.2d 730 (Pa. Commw. Ct. 2007). Neither argument prevailed. *See, e.g.*, *id.* at 739.

37. *See* IOWA CODE §§ 142D.1 to .9 (Supp. 2008); 2007 Pa. Laws 27.

serve alcohol unregulated.[38] As the statute preempts municipal regulation, South Dakota is properly considered a Class I state, though perhaps not for long.[39]

2. Class II: Hands-Off States

The next class of statewide smoking ban adopts a more freewheeling approach. Like their Class I counterparts, Class II states have not adopted general prohibitions on smoking in restaurants, bars, and most workplaces. They differ, however, in one key regard—preemption. These states take a "hands-off" approach to ETS regulation of bars and restaurants, leaving the matter to local jurisdictions. This is the most common form of statewide ETS legislation, presently implemented in Alabama, Alaska, Idaho, Indiana, Kansas, Kentucky, Michigan, Mississippi, Missouri, Oklahoma, South Carolina,[40] Texas, Virginia, West Virginia, Wisconsin, and Wyoming.

Naturally, in granting broad discretion to local governments, Class II regimes vary widely in practice. Across the board, large cities located in Class II states—such as Detroit, Milwaukee, and major Texan cities—have their own smoking bans, many of which ban smoking in restaurants and bars. Living in a large city in a "Hands-Off" state can be much like living in one of the Class III, IV, or V states discussed below. Even among major metropolises, there is enormous variation. Some large cities, such as Dallas, still permit smoking in all bars—placing themselves closer to the regulatory regimes found in Class III.[41] Other large cities in Class II, such as Madison, Wisconsin, and Fort Wayne, Indiana, have made virtually all enclosed public spaces—including smoking lounges—smoke free, situating themselves closer to Class V.[42] Smaller towns occasionally implement their own bans, as do some rural areas. As a general

38. S.D. CODIFIED LAWS § 22-36-2 (2002).

39. The early months of 2008 saw serious debate about eliminating the preemption clause. *See* Terry Woster, *Local Control Bill Killed*, ARGUS LEADER, Feb. 1, 2008, at 4A (bill to eliminate preemption provision rejected nine to four in committee). The state legislature is considering a bill that would expand ETS regulations. *See* H.B. 1237, 2008 Leg. Assem., 83d Leg. Sess. (S.D. 2008).

40. In *Foothills Brewing Concern, Inc. v. City of Greenville*, 660 S.E. 2d 264 (S.C. 2008), the South Carolina Supreme Court reversed a trial court ruling that invalidated a local ETS ordinance. The court ruled that the ordinance violated neither state law nor the state's constitution. *Id.*

41. DALLAS CITY CODE § 41-2(d)(3).

42. Madison passed a city-wide ban in 2005 that prohibits smoking in restaurants, bars and workplaces, but grandfathers in specially designated, separately ventilated rooms presently in existence in restaurants if approved by the Public Health Department. *See* Madison, Wis., Ordinance 23.05 (July 1, 2005), *available at* http://publichealthmdc.com/documents/23.05-070105.pdf. The Fort Wayne City Council passed an extremely rigorous smoking ban in 2007. FORT WAYNE, IN., CODE OF ORDINANCES § 95.60-99 (June 1, 2007), *available at* http://www.fw-ac-deptofhealth.com/PDF/Smoking%20Resources/Fort%20Wayne%20Ordinance.pdf.

matter, however, aggressive regulation is far more common in larger cities. In Michigan, for instance, only twenty-four counties—counties that include all of the state's major cities—have adopted their own smoking bans.[43] Michigan's other sixty-three counties, which together account for the vast majority of the state's rural area, are currently ban-free.

Despite these variations in practice, the state-level legal regimes of Class II states fall on the more permissive end of the state law spectrum. Neither Class I nor Class II regimes attempt to reverse the default rule at the state level. Rather, these regimes declare narrow classes of the public domain smoke-free, and Class I regimes prohibit local jurisdictions from regulating further. All of the remaining states that have passed statewide ETS legislation, however, do attempt to reverse the default rule from generally permissive to generally prohibitive of smoking in public, addressing one or both of the areas identified in the 2006 Surgeon General's report—restaurants and bars.[44]

3. Class III: Mild Ban States

Continuing along the spectrum of statewide ETS legislation from permissive to prohibitive, the next class is composed of states that begin to reverse the default rule. Prohibiting smoking in restaurants but exempting bars, Class III states include Arkansas, Florida, Georgia, Idaho, Louisiana, Montana,[45] Nevada, North Dakota, Oregon,[46] Pennsylvania, and Tennessee.[47] This compromise reflects the opinion of many Americans that, while smokers should be prevented from lighting up in dining establishments, they should be allowed to do so in bars.[48]

Class III bans vary on two important points: the definition of a "bar" and the

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43. *See* MakeMIAirSmokeFree, Smokefree Progress, http://www.makemiairsmokefree.com/smokefree-progress.php (follow "In Michigan" hyperlink) (last visited Nov. 17, 2008).

44. OFFICE OF THE SURGEON GEN., *supra* note 24, at 145-54 (identifying restaurants, cafeterias, and bars as public places presenting the most serious ETS concerns).

45. In 2009, Montana will become a Class V state. *See infra* Appendix A.

46. In 2009, Oregon will become a Class IV state. *See infra* Appendix A.

47. Some qualification is necessary with respect to Georgia and Oregon. In these states, the dispositive factor is not the nature of the establishment—restaurant or bar—but the age of the patrons. An establishment which neither employs minors nor permits them to enter its premises may allow smoking. *See* GA. CODE ANN. § 31-12A-6 (2006); OR. REV. STAT. § 433.835 (2005). It is likely that this functions much like a restaurant/bar split, however, because most restaurants permit children.

48. *See* Lydia Saad, *More Smokers Feeling Harassed by Smoking Bans*, GALLUP NEWS SERVICE, July 25, 2007, at 2, *available at* http://www.gallup.com/poll/28216/More-Smokers-Feeling-Harassed-Smoking-Bans.aspx (quoting survey results from July 2007 showing that, while 54% of Americans support smoking bans in restaurants, only 29% favor banning it in bars).

question of preemption. For example, Florida limits the bar exemption to "stand-alone bars," with a list of specific qualifications.[49] Other states define bar fairly generally.[50] With regard to preemption, the majority of Class III statutes function as floors, not ceilings: local jurisdictions remain free to ban smoking in bars.[51] Some states explicitly preserve this authority.[52] As a result of these variations, Class III laws range from states like Arkansas—which defines bar broadly and frees local jurisdictions to impose their own more rigorous bans, to states such as Oregon, which defines bar more narrowly and preempts local jurisdictions from passing stricter bans. In prohibiting smoking in restaurants statewide, however, Class III states cohere as having made significant progress beyond Classes I and II towards the aspiration expressed in the 2006 Surgeon General's report: to protect the unwilling from exposure to ETS. By exempting bars from statewide coverage, however, and in some cases preempting further regulation, Class III states leave a significant section of the public domain unregulated.

4. Class IV: Strong Ban States

Fourth on the ETS spectrum are regimes that ban smoking in the vast majority of enclosed public spaces statewide, including not only all restaurants,

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49. FLA. STAT. § 386.203 (2007) (stipulating that "the licensed premises is not located within, and does not share any common entryway or common indoor area with, any other enclosed indoor workplace").

50. *See, e.g.*, GA. CODE ANN. § 31-12A-2 (2006) ("'Bar' means an establishment that is devoted to the serving of alcoholic beverages for consumption by guests on the premises and in which the serving of food is only incidental to the consumption of those beverages, including, but not limited to, taverns, nightclubs, cocktail lounges, and cabarets.").

51. Only Oregon, Tennessee, and now Pennsylvania employ preemption clauses. *See* OR. REV. STAT. § 433.863 (2007); TENN CODE ANN. § 39-17-1551 (2003); 2007 Pa. Laws 27, § 11(a)(2). Oregon's preemption clause expires, however, in 2009. 2007 Ore. Laws 602, at § 12. Pennsylvania's 2008 smoking ban presents a special case on preemption, which was a contentious issue in the ban's passage. Initially, the bill was deadlocked until a compromise committee agreed that the statute would preempt local regulations, but that Philadelphia would be exempted from the preemption statute and permitted to retain its stricter municipal ban. Amy Worden, *Pa. Smoking Ban Approved,* PHILA. INQUIRER, June 11, 2008, at A1. Representatives from municipalities that wanted to pass their own, stricter ordinances blocked the bill once again, until the deadlock was broken in early June when state representatives from Allegheny and Scranton were promised the opportunity to introduce legislation which would permit their municipalities to pass stricter smoking bans. Tom Barnes, *Smoking Ban Passes in Senate Reversal,* PITTSBURGH POST-GAZETTE, June 11, 2008, at A1.

52. *See, e.g.*, GA. CODE ANN. § 16-12-2(b) (2007) ("This Code section shall be cumulative to and shall not prohibit the enactment of any other general and local laws, rules and regulations of state or local agencies, and local ordinances prohibiting smoking which are more restrictive than this Code section.").

but conventional bars as well. These states carve out exemptions, however, for bars and cafés devoted primarily to the smoking of tobacco. California, Colorado, Connecticut, the District of Columbia, Maine, Massachusetts, New Jersey, New Mexico, New York, and Rhode Island are all Class IV states. Though the first statute went into force in 1998, the vast majority of Class IV regimes are far more recent, taking effect between 2003 and 2007. Both Class IV and V regimes warrant the designation "modern statewide ban," which this Note uses to distinguish these strong, recent regimes from other forms of statewide ETS legislation.

Class IV regimes differ most significantly in how they define exempted smoking establishments. These statutes generally distinguish tobacco lounges from conventional bars by specifying a minimum percentage of revenue that must issue from the on-site sale of tobacco products. Washington, D.C., for instance, defines a "tobacco bar" as "a restaurant, tavern, brew pub, club, or nightclub that generates 10% or more of its total annual revenue from the on-site sale of tobacco products, excluding sales from vending machines, or the rental of on-site humidors."[53] Some states, such as Rhode Island, require more than half of the store's revenue to come from sale of tobacco products—a standard that can be very difficult for establishments that serve alcohol to meet.[54] Other states, such as Massachusetts, impose no mandatory numerical minimum percentage of revenue that must come from tobacco products, but require that the sale of tobacco be the store's "primary" purpose and that the sale of food and drink be "incidental to" the sale of tobacco products.[55]

Not all states, however, exempt all forms of the tobacco lounge. Maine's statute, for instance, allows most types of tobacco products to be smoked in specialty tobacco stores, but was amended in 2007 expressly to disallow the smoking of hookah pipes.[56] Colorado exempts "cigar-tobacco bars."[57] These curious distinctions have caused quite a bit of confusion.[58]

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53. D.C. CODE § 7-741 (2001).

54. R.I. GEN. LAWS § 23-20.10-2 (Supp. 2007) (requiring that exempted smoking bars "annually demonstrate that revenue generated from the serving of tobacco products is greater than the total combined revenue generated by the serving of beverages and food").

55. MASS. GEN. LAWS ch. 270, § 22 (2008). California exempts "private smokers' lounges," which must be in or attached to retail shops. CAL. LAB. CODE § 6404.5 (Deering 2007).

56. ME. REV. STAT. ANN. tit. 22, § 1542 (2007) ("Smoking a waterpipe or hookah is prohibited in a tobacco specialty store that is newly licensed or that requires a new license after January 1, 2007.").

57. COLO. REV. STAT. § 25-14-203 (2008) (defining a cigar-tobacco bar as generating more than five percent of total gross revenue from the on-site sale of tobacco products).

58. Many of the shisha lounges in New York, for instance, were initially held not to qualify for the state's cigar bar exemption because they did not serve alcohol on their premises. *See* Corey Kilgannon, *A Cultural History Faces Stringent Smoking Laws*, N.Y. TIMES, Mar. 9, 2004, at B3

Class IV states vary in one other significant respect: whether they include per se exemptions for tobacco bars or grandfather clause provisions. The first category of statute, the less restrictive of the two, permits smoking in tobacco bars regardless of incumbency. Class IV states extending per se exemptions to tobacco bars include California, the District of Columbia, Massachusetts, and Rhode Island. These statutes typically define and exempt "tobacco" or "cigar" bars and require all such bars to satisfy some form of registry or permit requirement.

Grandfather clause exemptions, which only exempt tobacco bars in operation at the time of a ban's passage, have been implemented in Colorado, Connecticut, Maine,[59] New York, New Jersey, and New Mexico. These function much as do the comprehensive exemptions above—only the definition includes a cut-off date. No tobacco lounge opened after this cut-off date qualifies for exemption.

Where grandfather clause exemptions are in effect, no new cigar bar or shisha lounge seeking to allow its patrons to smoke is permitted to do so—unless it finds a different loophole, such as those for "owner-operated businesses" or "private clubs." Most grandfather clause provisions not only forbid new tobacco lounges from opening, but they also forbid existing lounges from expanding or even changing ownership—a condition which may facilitate their gradual extinction.[60] On the spectrum from smoke-friendly to smoke-free states, the strong ban states with grandfather clauses toe the line between their per se counterparts in Class IV and the final category of statewide smoking bans.

5. Class V: Draconian States

At the end of the ETS spectrum, Class V bans are the most aggressive. These states, which include Arizona, Delaware, Hawaii, Illinois, Iowa, Ohio, Maryland, Minnesota, Nebraska, New Hampshire, Utah, Vermont and Washington, are

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(quoting City Councilman Mark Vallone: "I've asked that the city give [the shisha lounges] exclusion from the smoking laws because they fit into a cigar bar exemption . . . . The only difference is that they don't serve alcohol. But should they be punished for that?"). New Jersey's exemption partially avoids confusion by expanding coverage to include the "cigar lounge" as well as the "cigar bar," thereby clarifying that an establishment need not serve alcohol in order to qualify for the exemption. N.J. STAT. ANN. § 26:3D-57 (West 2007).

59. Maine exempts all "tobacco specialty store[s]" that, by the end of 2006, possessed licenses to serve alcohol or food, effectively creating a grandfather clause exemption for tobacco lounges. ME. REV. STAT. ANN. tit. 22, § 1542(2)(L) (Supp. 2007).

60. *See, e.g.*, N.Y. PUB. HEALTH LAW § 1399-q(5) (McKinney 2008) (stating that an exemption, which must be annually reauthorized, is only granted if "the cigar bar has not expanded its size or changed its location from its size or location since December thirty-first, two thousand two").

similar in virtually all regards to Class IV bans, except that they do not exempt tobacco lounges. Due to their uncompromising rigor in stamping out smoking from the public domain, and their refusal to countenance establishments populated exclusively by consenting smokers, statutes in this category earn the moniker "Draconian." These statutes represent the most recent wave of statewide smoking bans, and they are increasingly drafted by health advocacy lobbies and passed as ballot initiatives rather than debated and passed by lawmakers.

Under Class V regimes, smoking indoors is prohibited nearly everywhere outside private residences. Other exemptions are either tightly constrained or insubstantial. Washington, for instance, nebulously exempts "certain private workplaces" and virtually nowhere else.[61] Other Class V statutes exempt several tightly defined areas. Minnesota's Clean Indoor Air Act, for example, allows smoking in several areas ranging from heavy commercial and farming vehicles to buildings where scientific studies of smoking are being conducted, or where traditional Native American ceremonies are held.[62] Whether they choose a very small number of broad exemptions, or a large number of narrow ones, the result is largely the same: smoking in virtually the entire indoor public domain—and some of the outdoor—is verboten. Some bans, such as Washington's, also prohibit smoking within a certain distance of a building opening through which smoke could conceivably enter—such as building entrances, windows, or ventilation intakes.[63]

Consistent with this aggressive stance on secondhand smoke, none of the Class V statutes are negatively preemptive. Though "Draconian" smoking bans would seem to leave little room for additional municipal strictures, some creative localities have expanded coverage to prohibit smoking in parks, sidewalks, and cars with open windows.[64] Some local jurisdictions are beginning to extend smoking bans into the home.[65]

C. ETS Legislation: Flipping the Default

American states have established a patchwork quilt of ETS regimes, intended to protect the unwilling from exposure to ambient tobacco smoke. At first glance, statewide ETS legislation seems to present a jumbled and unsightly

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61. The statute defines these as "a private enclosed workplace, within a public place, even though such workplace may be visited by nonsmokers." WASH. REV. CODE ANN. § 70.160.060 (West 2002).

62. MINN. STAT. ANN. § 144.4167 (West Supp. 2007).

63. WASH. REV. CODE ANN. § 70.160.075 (West Supp. 2008).

64. *See, e.g.*, Pam Belluck, *Maine City Bans Smoking in Cars Carrying Children*, N.Y. TIMES, Jan. 19, 2007, at A16.

65. *See, e.g.*, Sanjay Bhatt, *Smoking Foes Bring the Fight to Apartment Buildings*, SEATTLE TIMES, Jan. 16, 2007, at A1.

landscape of law. A regulatory spectrum can be discerned, however, with reference to exemption provisions, to which we look to determine whether the default rule of the resulting regime is meaningfully prohibitive or permissive of smoking in public.

On the permissive side lie bans which leave the pre-regulation default rule in place and prohibit smoking in narrow categories of public places. These regimes may prohibit further regulation at a local level (Class I) or permit municipalities to institute further prohibitions (Class II). In permitting smoking in restaurants and bars at a state level, however, both Classes leave the pre-regulation default rule substantially unmodified. Class III regimes challenge the default rule, but by leaving bars unregulated at a state level, and in some cases preempting local action, Class III statutes ultimately fail to reverse the default rule. On the prohibitive side are bans that successfully reverse the default rule and carve out exemption areas in which smoking is permitted. Some (Class IV) tailor legislation narrowly to exempt areas where non-smokers are unlikely to be present, such as tobacco bars. Others (Class V) create a near-complete prohibition of smoking in public with little concern for whether a threat to non-consenting non-smokers is plausible. It is clear that Classes IV and V, or "modern statewide bans," are a distinct species of statewide ETS legislation. These statutes reverse the default rule to establish a presumptive prohibition of smoking in public, against which exemptions can be carved by state legislatures. Codified in twenty-three states, modern statewide bans are incrementally reversing the nationwide default rule on smoking in public places.

The element that distinguishes modern statewide bans from earlier efforts, however, is precisely the element that makes them so difficult to implement responsibly. Though we still tend to ask simply whether or not a state has a smoking ban on the books, the key element is hardly the existence of a ban, but rather the nature of its exemption scheme. Modern statewide bans have—or should have—changed the focus of the debate: today, the central question is which public spaces should be exempted from the operation of the new default rule. And this calls for a far more sensitive approach to ETS regulation than has historically been the case, for modern statewide bans are truly exemption-centric, delicately poised between strong and draconian. Whether a statute reverses the default rule is determined by its exemption scheme, and the happenstance of a single exemption provision, or a fine point in a definition, may change the character of a ban from controlled to severe.

For this reason, variations among modern statewide bans may be less innocent than one might wish. Modern statewide bans share a common intent: to prevent unwilling exposure to environmental tobacco smoke. At their best, then, modern statewide bans attempt to balance the two "rights" in play—the smoker's against the non-smoker's—by isolating areas that do not undermine the function of an effective ETS regime: those in which non-smokers are unlikely to be

exposed to ambient tobacco smoke. However, modern statewide bans are startlingly incoherent in judging which areas do not undermine a strong ETS regime. This should give us reason for pause. Perhaps the variety represents the considered judgment of different states concerning how much protection is warranted—an optimistic "states as laboratories" view—but it may also be that some caprice is responsible for the variation, and deliberative failures drew states away from narrowly tailored, responsible, and effective ETS legislation. The delicately balanced, exemption-centric nature of ETS legislation invites these types of errors, because the character of an ETS regime can be dramatically altered by the inclusion of one exemption, the exclusion of another, or the manner in which an exemption is defined. The next Part examines a recent trend in the passage of statewide smoking bans that presents serious concerns on this point: the aggressive use of the ballot initiative by interest groups to pass ETS legislation.

D. ETS Legislation by Ballot Initiative

"Plebiscite, *n.* A popular vote to ascertain the will of the sovereign."[66]

Through the enactment of modern statewide bans, we have made significant progress in flipping the default rule on smoking in public. Though in the past this has been chiefly accomplished by conventional legislative means, the tempo of ETS ballot initiatives has accelerated dramatically in recent years. Following the successful 2005 passage of a statewide ETS ballot initiative in Washington, three states saw the passage of similar initiatives in 2006: Ohio, Arizona, and Nebraska.[67]

Insofar as ballot initiatives have contributed to the process of reversing the default rule on smoking in public, they should be commended. However, ballot initiatives present serious dangers to good law in the context of ETS legislation, because such initiatives are prone to focusing attention on a yes-or-no policy question at the expense of discrete elements within the proposal. As we have seen, in reversing the default rule on smoking in public, the essential question is which areas will be exempted. Many areas may be consistent with the public health function of ETS legislation, and recognizing this, states have carved out exemptions from the default rule that tailor the legislation more closely to its purpose. Though some are overbroad, and others are overly narrow, these exemptions represent the efforts of states to confront the problem—to debate and decide where the line is best drawn between protecting the public health and

66. AMBROSE BIERCE, THE DEVIL'S DICTIONARY 101 (Dover 1958) (1911).

67. *See* ARIZ. REV. STAT. ANN. § 36-601.01 (2003); NEB. REV. STAT. §§ 71-5716 to -5734 (LEXIS 2008); OHIO REV. CODE ANN. §§ 3794.01 to .09 (LexisNexis Supp. 2008).

needlessly intruding on unproblematic areas of the public domain. Ballot initiatives are ill-suited to draw this fine line.

This Part undertakes a case study of a recent ETS law passed by ballot initiative. As Ohio's unfortunate experience reveals, the mere fact of an ETS bill's passage by ballot initiative may say very little about public support for, let alone the substantive advisability of, its exemption scheme.

This Part then proceeds to analyze the procedural and structural deficiencies that make direct legislation such a poor vehicle for responsible ETS legislation. From the outset, the odds of meaningful public deliberation are discouraging. The interest landscape in ETS debates makes for poor proposals and poorer deliberation. The most powerful voices are situated on the extreme ends of the debate—lobbyists from well-funded advocacy groups and the tobacco industry—while the voices central to crafting reasonable exemptions, such as retailers, private clubs, and tobacco lounges, are marginalized. The balloting process invites procedural exploitation, as cleverly defined statutes, briefly summarized on a voter's ballot, can hide their true nature until after passage. Most fatally, ballot initiatives are shrink-wrapped packages, incapable of expressing voter conclusions on specific exemption areas. Nonetheless, once passed, courts will not inquire into the circumstances of passage and victorious lobbyists can claim the imprimatur of the people, rendering ballot initiatives substantially irremediable either by courts or executive agencies.

II. THE OHIO SMOKE FREE WORKPLACE ACT

The passage of the Ohio Smoke Free Workplace Act presents a sharp example of the dangers ballot initiatives pose to responsible ETS legislation. According to the summary on the ballots, the proposed statute would "restrict smoking in places of employment and most places open to the public," with a list of exemptions including outdoor patios, tobacco stores, private clubs, and most private residences.[68] The statute had been cleverly drafted, however, and within weeks it was clear that the exemptions promised by the bill's sponsors and on the ballot had been cleverly defined out of existence. In the words of an infuriated law professor, Ohioans had "voted for a lie."[69] Though the Department of Health attempted to give force to several exemptions that had been promised on the ballot and referred to in statutory language, its rulemaking was immediately

68. *See* Ohio Sec'y of State, State Issue 5 Certified Ballot Language (Nov. 7, 2006), http://www.sos.state.oh.us (follow "Elections & Ballot Issues" hyperlink; then follow "Election Results" hyperlink; then follow "2006 Official Results" hyperlink; then follow "State Issue 5" hyperlink; then follow "Certified Ballot Language" hyperlink) [hereinafter Ballot Language]. The full text of the ballot is reproduced *infra* Appendix B.

69. David F. Forte, Op-Ed., *More Smoke-Free Than You Thought*, CLEV. PLAIN DEALER, Nov. 17, 2006, at B9.

challenged by special interest groups. An Ohio trial court was forced to concede that a prominent exemption had never existed in fact.[70] By December 2007, an appellate court threw up its hands and handed the imbroglio over to the General Assembly to resolve.[71]

Incredibly, legislators have been pressured by lobbyists to reject any amendments out of deference to the Act's status as "the will of Ohio voters." A fuller understanding of the more tragic elements in this farce, however, exposes the unsightly underbelly of direct legislation and its liability to procedural abuse by well-funded special interests. In the context of ETS legislation, there is nothing more dangerous to good law.

A. Proposals

On March 10, 2005, the American Cancer Society (ACS), through its Ohio agent "SmokeFree Ohio" (SFO) delivered an ultimatum to the Ohio General Assembly. Having drafted an ETS bill, SFO demanded a rubber-stamp. If the General Assembly were to debate and possibly amend the proposal, SFO would launch a petitioning campaign to pass the draft statute by ballot initiative.[72]

Ohio, one of the states swept up by the tide of direct democracy during the Progressive era, amended its Constitution in 1912 to provide for legislation by ballot initiative. By filing a sufficient number of signatures with the Secretary of State, any citizen or organization can place legislation before the General Assembly. The legislature may then elect to pass, amend and pass, or reject the proposal. If amended or rejected, upon the filing of further signatures the petition is placed on the state ballot for adoption by Ohio voters, and trumps any amended version passed in the interim by the legislature.[73] Once passed, the initiative is codified.

That ETS legislation for Ohio was imminent was not in dispute. As a lobbyist for the Ohio Licensed Beverage Association (OLBA) observed, "there

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70. Ohio Licensed Beverage Ass'n v. Ohio Dep't of Health, No. 07CVH04-5103, slip op. at 7 (Franklin County Ct. C.P. May 17, 2007).

71. Ohio Licensed Beverage Ass'n v. Ohio Dep't of Health, 2007-Ohio-7147, ¶ 41, *available at* http://www.precydent.com/OriginalVersion/2007-ohio-7147.pdf?id=190595 ("[A]ny potential change to the exemption as enacted would be a matter for the legislature, not the administrative agency, to address.").

72. Press Release, SmokeFree Ohio, American Cancer Society Launches Campaign To Pass a Statewide Clean Air Law (Mar. 10, 2005), http://smokefreeohio.org/oh/news/050310Launch Campaign.aspx ("If the Ohio General Assembly does not take action, or tries to amend the law, the American Cancer Society and its partners will collect another 100,000 signatures to put the ordinance before all Ohio voters in November 2006.").

73. OHIO CONST. art. II, § 1b.

will be a statewide policy. The question is what will that be?"[74] On that point, however, public opinion was unclear. A 2005 poll conducted by the statewide trade organization revealed a 55% majority in support of a very limited statewide ban. A 2006 poll conducted by health activists, on the other hand, revealed a 52.3% majority in favor of a blanket ban, with a 3.4% margin of error.[75]

The restaurant and bar industry hoped that the legislature would tackle the issues raised in the bill and craft a more "reasonable" bill.[76] Unwilling to subject their bill to potential amendment by the legislature, however, the ACS's lobbyists instructed the legislature "to do nothing" and "leave this to the Ohio voters,"[77] insisting that the legislature neither debate nor amend their bill and "allow the issue to go to the statewide ballot next November."[78] Legislators obliged, but the anti-deliberative nature of this tactic was not lost on the news media. Noting the "aggressive" character of SFO's proposal, the *Cleveland Plain Dealer* observed that "[t]heir plan leaves no room for compromise."[79]

The hospitality industry responded to the ACS's ultimatum with a proposal of its own. On April 19, Ohio's Attorney General approved language for a constitutional amendment sponsored by OLBA, which had formed an organization called "SmokeLess Ohio" (SLO) for the purpose, generously backed by the tobacco industry. Where SFO's approach had been anti-deliberative, OLBA's was flatly misleading. Though the proposed constitutional amendment was pitched as an alternative "smoking ban," prohibiting smoking in some limited public spaces, it would also supersede municipal clean air ordinances and preempt legislation concerning secondhand smoke in restaurants and bars, effectively enshrining the right to smoke in restaurants and bars in the Ohio Constitution.[80]

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74. Jim Provance, *Anti-Tobacco Activists File Petitions to Ban Most Public Smoking in Ohio*, TOLEDO BLADE, Nov. 18, 2005, *available at* http://toledoblade.com/apps/pbcs.dll/article?AID=/20051118/NEWS24/511180417.

75. Peggy O'Farrell, *Smoking Ban Gets Support*, CINCINNATI ENQUIRER, Feb. 6, 2006, at 1B.

76. Provance, *supra* note 74.

77. *See* Podcast: Oct. 30, 2006 featuring Jacob Evans vs. Tracy Sabetta, Debate: Smoke Less Ohio vs. Smoke Free Ohio, held at the Cleveland City Club, at 8:50-9:19, *available at* http://www.cityclub.org/content/podcasts/index/Podcasts.aspx.

78. Press Release, SmokeFree Ohio, SmokeFree Ohio Turns in Petitions for Statewide Law (Nov. 17, 2005), http://smokefreeohio.org/oh/news/051117Petition.aspx.

79. Harlan Spector, *Cancer Society Tells Ohio to Ban Indoor Smoking*, CLEV. PLAIN DEALER, Mar. 11, 2005, at A1.

80. Reginald Fields, *Smoking Ban Amendment Exempts Bars, Eateries*, CLEV. PLAIN DEALER, Apr. 20, 2006, at B2.

B. Petitioning

Through the summer of 2006, the restaurant and bar lobby faced off against the ACS lobby in a race to gather enough petitions to appear on the November 2006 ballot. The ACS, through SFO, pushed its legislation on public health grounds, and the OLBA, through SLO, opposed the initiative on economic grounds, concerned that small businesses relied on smoking patrons. These arguments were blurred, however, by the deceit, confusion, and misinformation that marred the signature-gathering phase. Both organizations employed professional signature-gathering companies, either paying a set price per signature or contracting to purchase a set number of signatures.[81] Enterprising signature-gatherers worked for both organizations, simultaneously obtaining signatures for both bills.[82]

Petition-gatherers suffered no restrictive allegiance to the truth. SLO circulators pitched the constitutional amendment as a more reasonable alternative to the ACS bill, asking registered voters to sign and indicate support for "the statewide ban on public smoking" and falsely assuring signatories that the initiative would not supersede municipal clean air ordinances.[83] SFO circulators employed scare tactics bolstered by well-spun data. Indeed, SFO's cavalier use of scientific studies drew fire from a professor of public health, who denounced SFO propaganda as "wildly misleading and inaccurate."[84] Tactics grew increasingly desperate as the summer wore on. A health official reported that SLO petition circulators told him that the stricter SFO proposal would "prohibit smoking in your home, which it doesn't."[85] Petition circulators forged signatures, sometimes with the names of deceased voters.[86] Contracted petition circulators traded on the ACS's reputation, concealing their mercenary status and incentive structure by passing themselves off as concerned ACS employees.[87] This last

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81. *See In re* Protest of Evans, 2006-Ohio-4690, ¶ 20, *available at* http://www.sconet.state.oh.us/rod/docs/pdf/10/2006/2006-ohio-4690.pdf (describing the American Cancer Society's contract with Arno Political Consultants to collect 75,000 signatures).

82. Harlan Spector, *Anti-Smoking Group Alleges Deception by Opposing Effort*, CLEV. PLAIN DEALER, Aug. 1, 2006, at B2.

83. *See, e.g.*, Spector, *supra* note 82; Alice Duncanson, Letter to the Editor, *Smoking Lobby Disingenuous with Petition*, COLUMBUS DISPATCH, May 15, 2006, at 06A.

84. Harlan Spector, *Health Advocate Questions Anti-Smoking Drive's Data*, CLEV. PLAIN DEALER, June 28, 2006, at A3.

85. Spector, *supra* note 82.

86. Press Release, SmokeFree Ohio, Smoke Less Ohio Turns in Additional Signatures: Expect More of the Same Lies, Dead Voters, and Fraud (Sept. 22, 2006), http://smokefreeohio.org/oh/news/documents/092206nr.pdf.

87. T.C. Brown, *SmokeLess Amendment OK'd for Ballot*, CLEV. PLAIN DEALER, Sept. 28, 2006, at B2.

development resulted in a lawsuit and a string of appeals, all of which were resolved against SFO.[88] The full extent of confusion caused by these contracted signature-gatherers is impossible to ascertain, but even from the documented frauds, there can be no doubt that it was severe. The constitutional requirements for placing the initiatives on the ballot, however, had been satisfied. Both groups had marshaled enough signatures to present their proposals to Ohio voters for ratification. The two opposing initiatives would be placed on the November 2006 ballot.[89]

C. Balloting

More problems emerged during the balloting stage, as ballot language was adopted and campaigning began. For most voters, the ballot summaries would be the full extent of engagement with the initiatives themselves, but the Ballot Board devoted only cursory attention to the ballot language, deferring entirely to the language drafted by the initiative sponsors.

On August 22, the Ohio Ballot Board rubberstamped language from SLO that would summarize its proposed constitutional amendment as Issue 4 on the November ballot.[90] At the language hearing, which was attended by lobbyists from SFO and SLO, the Ballot Board "quickly handled" SLO's proposed language after ruling on language for two other ballot measures, allowing SLO to summarize the proposed constitutional amendment as a prohibition of, rather than protection for, public smoking.[91]

SFO's language was equally misleading, promising a lengthy list of exemptions including retail tobacco shops, private clubs, outdoor patios, and

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88. *In re* Protest of Evans, 167 Ohio App. 3d 674, 2006-Ohio-3453, 856 N.E. 2d 999, ¶ 3 (granting summary judgment to plaintiff Evans, the SmokeLess lobbyist, on grounds that "the circulators of the petitions were not Ohio residents, and, second, that the circulators had failed to disclose that they were employed by professional petition circulating companies, not the sponsors of the electoral initiative"), *aff'd*, 2006-Ohio-4690.

89. Provance, *supra* note 74. For a detailed description of the process, see *State* ex rel. *Evans v. Blackwell*, 2006-Ohio-2076, *available at* http://www.sconet.state.oh.us/rod/docs/pdf/10/2006/2006-ohio-2076.pdf.

90. The Ballot Board, a five-member panel composed of the Secretary of State and four other legislators, is charged with prescribing ballot language on initiative petitions and constitutional amendments. *See* OHIO CONST. art. II § 1g; *id.* art. XVI § 1. Its obligations are less than strenuous: the Ballot board need merely "properly identify the substance of the proposal to be voted upon. The ballot need not contain the full text nor a condensed text of the proposal." *Id.*

91. Aaron Marshall, *State Preps Ballot Text on Slots; Approved Language Underwhelms Both Sides*, CLEV. PLAIN DEALER, Aug. 23, 2006, at B1. See *infra* Appendix B for the text of the statement.

private residences.[92] Nonetheless, it was unanimously approved.[93] Though the fine print of the statute undid most of these exemptions, the Ballot Board hardly batted an eye at SFO's proposed language for what would become Issue 5 on the ballot. At the close of the hurried hearings, the ballot language for the competing proposals failed in both completeness and accuracy to describe the bills they purported to summarize.

As the ballot campaign commenced in earnest, SFO focused its efforts on defeating Issue 4, playing the moral villain card against the tobacco lobby.[94] Despite a significant financial disadvantage (only $1.5 million, to R.J. Reynolds' $5.3 million),[95] the ACS held and exploited the moral high ground. Editorial columnists took up the cause, and letters to the editor revealed public ire over the tobacco industry's role in the proceedings.[96] Indeed, R.J. Reynolds' grandson publicly condemned the profiteering motives of the tobacco lobby and urged Ohio voters to support Issue 5.[97] The villain factor of SLO's largest donor would be a—perhaps *the*—decisive factor in the ballot results.[98]

SLO, for its part, still relied on economic arguments, forecasting the loss of Ohio jobs and the closure of bars and restaurants.[99] Despite some sympathetic press coverage, these efforts were doomed. Ohioans' sympathies for the profits of the small-business owner were understandably wanting in light of the very real public health threat posed by ETS in restaurants and bars. Additionally, SFO did an excellent job of exposing faults in the details of the ill-conceived constitutional amendment. In the weeks leading up to the election, the tide swiftly turned against Issue 4. Attempting to persuade voters that the economic

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92. *See infra* Appendix B.

93. Aaron Marshall, *Smoke Free Group's Wording To Go on Ballot*, CLEV. PLAIN DEALER, Aug. 24, 2006, at B5.

94. Harlan Spector, *Public Smoking Issues Offer Two Choices: Less or None*, CLEV. PLAIN DEALER, Oct. 22, 2006, at T14.

95. *See* Jon Craig & Annie Hall, *Smoking and Gambling Campaigns Well Funded*, CINCINNATI ENQUIRER, Oct. 27, 2006, at 5B; Spector, *supra* note 94.

96. *See* Regina Brett, Editorial, *Let's Clear the Air on 2 Hot Issues*, CLEV. PLAIN DEALER, Oct. 29, 2006, at B1 (noting that "Big Tobacco is spending millions to confuse you"); Bob Taft, Op-Ed., *Reject Issue 4, But OK Issue 5*, CINCINNATI ENQUIRER, Oct. 30, 2006, at 7B (editorial by Ohio Governor noting that R.J. Reynolds "has marketed candy-flavored cigarettes, clearly targeted toward our youth").

97. Peggy O'Farrell, *Tobacco Heir Backs Smoke Ban*, CINCINNATI ENQUIRER, Oct. 27, 2006, at 1B.

98. Harlan Spector, *Sweeping Prohibition on Smoking Is Adopted*, CLEV. PLAIN DEALER, Nov. 8, 2006, at S7 (crediting SmokeFree Ohio's "relentless public relations blitz" and messaging of Issue 4 as a "big-tobacco campaign to deceive Ohio voters" with success at voting booths).

99. Harlan Spector, *Many Cleveland Bar Workers Afraid To Lose Their Customers*, CLEV. PLAIN DEALER, Oct. 30, 2006, at A9.

harms to small businesses outweighed the public health concerns of unregulated ETS in all restaurants and bars, SLO was tilting at windmills.

As voting day drew near, the ACS effectively commanded the public discussion, focusing on the importance of voting against the tobacco lobby's creature.[100] Through the ACS's successful messaging, voters became aware that they were choosing between a ban on smoking in restaurants and bars and an industry plot to give constitutional protection to its bottom line. Political endorsements were quick to follow, beginning in late September with the Governor's unsolicited endorsement[101] and climaxing with a blowout news conference in October, at which the influential support of the Mayor and the Cleveland Clinic was announced.[102]

On voting day, Ohio voters passed Issue 5. In sum, 58.52% of ballots cast supported Issue 5.[103] Issue 4 was more clearly repudiated, receiving only 35.89% of votes cast.[104] Voter turnout was approximately 56%.[105]

Throughout the balloting process, the SFO proposal had gone almost entirely unexamined. Public attention had been diverted from the mechanics of the ACS bill to the tobacco industry's sponsorship of the competing proposal, and this had been a decisive factor.[106] Forced to choose between a bill that would "make it

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100. *See* Brett, *supra* note 96 ("Big Tobacco is spending millions to confuse you . . . . Issue Four means smoke more. Issue Five keeps you alive."); Craig & Hall, *supra* note 95 ("R.J. Reynolds Tobacco company has spent more than five times as much money as the American Cancer Society in a statewide battle over how far Ohio should go in banning smoking at work, restaurants and other public places."); Editorial, *No to Issue 4; Yes to Issue 5*, CLEV. PLAIN DEALER, Oct. 8, 2006, at M2 ("Many lawmakers may be willing to surrender their consciences to the tobacco industry, but voters should be wiser."); O'Farrell, *supra* note 97 (quoting the grandson of R.J. Reynolds in opposition to the tobacco lobby's proposal: "They're doing it to protect future profits."); Harlan Spector, *A Clear Look at Two Smoking Initiatives*, CLEV. PLAIN DEALER, Oct. 30, 2006, at A1 (noting "deceptive tactics" of R.J. Reynolds); Taft, *supra* note 96.

101. Reginald Fields, *Taft Backs SmokeFree Ohio Ballot Measure*, CLEV. PLAIN DEALER, Sept. 21, 2006, at B3.

102. Harlan Spector, *Smoking Ban Gains Political Clout*, CLEV. PLAIN DEALER, Oct. 12, 2006, at B4.

103. 2,370,369 votes were counted in favor of Issue 5, and 1,679,956 against. 135,272, or approximately 3.2% of voters, did not express an opinion on Issue 5. *See* Ohio Sec'y of State, State Issue 5: November 7, 2006, http://www.sos.state.oh.us (follow "Elections & Ballot Issues" hyperlink; then follow "Election Results" hyperlink; then follow "2006 Official Results" hyperlink; then follow "State Issue 5" hyperlink).

104. Ohio Sec'y of State, State Issue 4: November 7, 2006, http://www.sos.state.oh.us/SOS/ElectionsVoter/results2006.aspx?Section=1858 (follow "Elections & Ballot Issues" hyperlink; then follow "Election Results" hyperlink; then follow "2006 Official Results" hyperlink; then follow "State Issue 4" hyperlink).

105. *Id.*

106. *See* Harlan Spector, *Partnership Key to SmokeFree's Success; Medical Community Helped*

unconstitutional to protect half a million Ohioans employed in the hospitality industry from secondhand smoke"[107] and an ETS law that would function as such, voters passed the latter.

Throughout the entire balloting process, voters had paid little attention to the bill itself—much less the details of its exemption scheme. Private clubs were never discussed. Cigar and hookah bars were never mentioned. The absurd mechanics of the bill's exemptions for outdoor areas and the nonsensical structural requirements for retail tobacco shops were not discussed. Voters believed that they were voting for a bill that would "restrict smoking in places of employment and in most public places,"[108] under which "servers and bartenders would be protected from the ill effects of secondhand smoke,"[109] preserving "reasonable exclusions"[110] that "legislators can tweak . . . if necessary."[111] Throughout, exemptions had been less than an afterthought.

D. Backlash

Ohioans were stunned to discover what they had voted into law.[112] Within two weeks of the Smoke Free Workplace Act's passage, a blistering opinion piece by a local professor of law appeared in the *Cleveland Plain Dealer,* revealing the functional non-existence of promised exemptions and highlighting the stark disjuncture between what voters had been led to expect and what the text of the bill provided. Noting the general belief that Issue 5 was "a ban on smoking in public places, with some reasonable exceptions," Professor Forte explained that "[w]hat you are getting is not what you voted for."[113]

As the disingenuous exemption scheme was finally revealed, the voting

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Issue 5 Pass, CLEV. PLAIN DEALER, Nov. 12, 2006, at A1 ("Some say reports that R.J. Reynolds bankrolled the campaign with $5.4 million was the kiss of death for Issue 4. It also may have swung some undecided voters to Issue 5."); *see also* Harlan Spector, *Voters Send a Message: No Ifs, Ands or Butts in Ohio*, CLEV. PLAIN DEALER, Nov. 9, 2006, at B1 (quoting Cleveland doctor's characterization of the results as "giving [R.J. Reynolds] the finger").

107. O'Farrell, *supra* note 97.

108. Ballot Language, *supra* note 68; *see also infra* Appendix B.

109. Editorial, *supra* note 100; *see also* O'Farrell *supra* note 97 (summarizing Issue 5 as banning smoking "in workplaces and public places such as restaurants and bars"); Spector, *supra* note 99 (characterizing ETS effects on bartenders as an "important theme" in the SmokeFree campaign).

110. Editorial, *supra* note 100.

111. *Id.*

112. Cliff Peale, John Eckberg & Polly Campbell, *Smoking Just Got Harder*, CINCINNATI ENQUIRER, Nov. 9, 2006, at 1A ("[P]eople were confused .... They didn't have a good understanding of what Issue 4 and Issue 5 meant.").

113. Forte, *supra* note 69.

public was blindsided. A Cleveland doctor who voted for the ban told a reporter that "it didn't occur to him" that the hookah bar he frequented was a target of the legislation.[114] The "reasonable exceptions" promised in the ballot summary of the bill were functionally nonexistent. Definitions of private clubs,[115] restaurant patios, [116] and retail tobacco shops[117] had been cleverly written so as to render the purported "exemptions" meaningless.

Professor Forte's piece effectively captures the sense of betrayal felt by supporters of the measure. "With so many important issues on the ballot, many of us did not read the lengthy statute itself. Instead, we relied on the good faith of those who summarized the law for us. That good faith was misplaced. . . . The fact is that we did not vote for a reasonable limitation on smoking on Nov. 7. Without knowing it, we voted for a lie."[118]

The exemption scheme was opaque even to the state agency responsible for putting the new law into effect. Responding to confusion and frustration, a spokesman demurred that "[we] didn't write it,"[119] and another noted that "we

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114. Chris Seper, *Hookah Bars Smoke Out Loopholes in Ban*, CLEV. PLAIN DEALER, Dec. 18, 2006, at A1. Another Cleveland doctor and regular at Kan Zaman noted that the hookah was "the centerpiece of an evening of conversation." *Id.*

115. Private clubs were required to have no employees, to be located in a free-standing structure, and to prohibit guests from the premises. OHIO REV. CODE tit. 37, § 3794.03 (Supp. 2008). Furthermore, the statute broadened the definition of employee to include anyone who "performs services" in the club, whether compensated or not. *See id.* § 3794.01(D) ("'Employee' means a person who is employed by an employer, or who contracts with an employer or third person to perform services for an employer, or who otherwise performs services for an employer for compensation or for no compensation.").

116. Doors and windows that connect a restaurant patio to the restaurant must be closed. *Id.* § 3794.03(F).

117. A retail tobacco shop was required to be the sole tenant of a free-standing building. *Id.* § 3794.03(E). A grandfather clause permitted existing tobacco shops temporarily to continue in operation, but when ownership changed, or if the building moved, the exemption would disappear. *Id.*

118. Forte, *supra* note 69; *see also* Peter Bronson, Editorial, *Stop Smoking or We Will Kill You*, CINCINNATI ENQUIRER, Dec. 12, 2006, at 7B (noting that "even some supporters are wondering, 'I voted for what?'"). Investigative reporters were confused as well: *The Plain Dealer* printed a correction on November 15 to an article mentioning the "private club" exemption, stating that only a narrowly defined entity qualified. The inaccurate former description was no mere oversight: the reporter had been misinformed. Harlan Spector, *Voters Send a Message: No Ifs, Ands or Butts in Ohio*, CLEV. PLAIN DEALER (Correction Appended Final Edition), Nov. 9, 2006, at B1 (incorporating November 15 correction: "Because of *inaccurate information provided to a reporter*, stories on Oct. 30 and Nov. 9 gave an incomplete account of the status of private clubs under the smoking ban" (emphasis added)).

119. Bronson, *supra* note 118.

had to play the hand we were dealt."[120] Two lawsuits challenging the new regime were filed immediately, one by a state liquor trade association alleging violation of the state constitution and another by an Ohioan alleging unlawful taking. Neither could be resolved, however, because the law was insufficiently specific to evaluate the specious constitutional violations alleged by the plaintiffs.[121] Accordingly, the Attorney General's office, through settlement negotiations with the plaintiffs, agreed that the ban would not be enforced until specific enforcement rules had been promulgated by the Ohio Department of Health, for which task the agency was given six months.[122]

In the meantime, confusion and frustration continued. Restaurateurs and bar owners were unable to determine how the ban would affect them or how it would be enforced.[123] Hookah bars received a provisional exemption until the Cleveland Health Department figured out what to make of the ethnic tradition.[124] Stadiums and outdoor concert pavilions wrote to state officials seeking compliance advice, to no avail.[125] After the state's non-enforcement agreement, hard feelings erupted between voluntarily compliant establishments and those renegade outposts that still permitted smoking.[126] A frustrated suburban mayor demanded immediate

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120. Mike Boyer, *Health Department Speeds Up Process*, CINCINNATI ENQUIRER, Jan. 5, 2007, at 15A.

121. The trade association, Buckeye Liquor Permit Holders Association, filed a complaint on December 6, 2006, alleging that the act was unconstitutional on its face and requesting injunctive relief. After negotiations with the defendant, Ohio Department of Health, the Court entered a consent decree providing that enforcement would be delayed until the Department of Health promulgated rules. *See* Buckeye Liquor Permit Holders Ass'n v. Ohio Dep't of Health, No. A0610614, at 3 (Hamilton County C.P. Ct. May 2, 2007), *available at* http://www.hamilton-co.org/cinlawlib/blog/Nelson_decision.pdf (order denying plaintiffs' motion for preliminary injunction).

122. *See* Bill Bush & Matt Tullis, *Smoking Ban Put on Hold; Deal Means Law Might Not Be Enforced Until June*, COLUMBUS DISPATCH, Dec. 8, 2006, at 1A; James McNair, *Smoking Ban Takes a Breather*, CINCINNATI ENQUIRER, Dec. 8, 2006, at 1A.

123. *See* Henry Gomez, *Snuff 'Em Out: It's the Law; Employers Hurry To Comply, Figure Out What Happens if They Don't Ban Smoking*, CLEV. PLAIN DEALER, Dec. 4, 2006, at E1; James McNair, *Smokers Fume as Ban Draws Near*, CINCINNATI ENQUIRER, Dec. 3, 2006, at 1A.

124. *See* Tony Brown & Debbie Snook, *They Had 'Em, Smoked 'Em, Put 'Em Out*, CLEV. PLAIN DEALER, Dec. 7, 2006, at 16; Seper, *supra* note 114 ("Cleveland's Health Department has told Kan Zaman it can keep letting customers smoke its hookahs until the state provides more guidance."); Quon Truong, *Smoking Ban Threatens To Put Local Hookah Restaurants Out of Business*, CINCINNATI ENQUIRER, Dec. 31, 2006, at 2B (proprietor "still without clear answers").

125. *See* Lori Kurtzman & Mike Boyer, *Dozens of Places Still Allow Smoking*, CINCINNATI ENQUIRER, Jan. 5, 2007, at 1A (Cincinnati Bengals stadium officials still "waiting for direction from the state"); James McNair, *Ban's Coming, But How Do You Enforce It?*, CINCINNATI ENQUIRER, Dec. 3, 2006, at 10A.

126. Harlan Spector, *Air's Still Not Clear at Bars, Restaurants*, CLEV. PLAIN DEALER, Dec. 16,

enforcement by the Ohio Health Director: "Make the rules. It's not rocket science."[127] In the end, all parties had to wait until the Ohio Department of Health promulgated the rules that would determine how the statute was to be enforced.

E. Enforcement Rules

The process by which enforcement rules would be promulgated appeared to encourage meaningful public comment on the bill. After private meetings with lobbyists and business associations, the Department of Health posted draft rules on the bill, accepted comments, and held a public hearing.[128] Appearances, unfortunately, foundered in the face of vigorous lobbying. Though this process began at last to air the defects in the proposed legislation, it compounded the narrow interest landscape at the petitioning and ballot stages with a new problem. ACS lobbyists took this opportunity to advance more aggressive agendas in the guise of "the voters' intent," ultimately rebuffing efforts by the Department of Health to remedy some of the more misleading definitions.

For the first time in official channels, however, the deceptive statutory language was confronted as the Health Department's efforts to promulgate enforcement guidelines revealed the Trojan nature of the bill. One attendee testified that voters had been betrayed by the ballot language: "It said private clubs were exempt . . . we were misled."[129] The Department of Health responded by proposing new rules that would enable the promised exemption for private clubs to operate in practice by amending the definition of "employee" to exclude members of the club. As the Health Department's spokesman observed, "Many people [at the hearing] pointed to that ballot language and said we voted for an exemption for private clubs"[130] and "we feel we are more in line with the will of the voters having made this change."[131]

Responding to testimony from voters who took the ballot language at its word, the Health Department had given substance to the promised exemption. Having secured the Act's passage, however, the ACS no longer needed to maintain a reasonable façade. Its lobbyists executed a startling *volte-face*, condemning the exemption promised by their own ballot language as "this

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2006, at A1.

127. Harlan Spector, *Patrons Complain Smoke Ban Ignored; Parma Mayor Wants Taft To Enforce Law Now*, CLEV. PLAIN DEALER, Dec. 21, 2006, at B1.

128. Boyer, *supra* note 120.

129. Liz Long, *State's Rule Makers Hear Debate on Smoking*, CINCINNATI ENQUIRER, Feb. 28, 2007, at 1B.

130. Harlan Spector, *Cancer Society Sues, Challenges Smoking in Private Clubs*, CLEV. PLAIN DEALER, Apr. 19, 2007, at B2.

131. Dan Horn, *Cancer Society Sues over Smoking Exemption*, CINCINNATI ENQUIRER, Apr. 19, 2007, at 1B.

loophole that skirts the law."[132] Noting that "the revised rules would allow private clubs to get an exemption by making their employees members," ACS and American Lung Association lobbyists declared the prospect of a meaningful private club exemption "contrary to the intent of what voters approved in November."[133] Arguing that "[t]he will of the voters and the letter of the law is to protect every single worker from secondhand smoke" and that "[t]he point of the law was to be strong—it provided no loopholes," the American Cancer Society filed suit in Franklin County immediately after the rules had been approved.[134]

Suddenly OLBA found itself allied with its former nemesis. Now that the promised exemption for private clubs appeared to have substance, restaurants and bars feared having to compete with private clubs for customers.[135] OLBA, too, construed the voters' intent against the language on the very ballot they adopted. Their lobbyist (and former SLO lobbyist) Jacob Evans argued that the new language "was not at all what was presented to voters. Private businesses—clubs and taverns—should be treated the same as private clubs in regard to the smoking law."[136] In the context of a ban that was presented to voters as including an exemption for private clubs while prohibiting smoking in restaurants and bars, this was a bold claim. Nonetheless, because the voters' intent was an inscrutable black box, it could be reconstructed with impunity, even against contrary ballot language. Both OLBA and the ACS would press this claim in Ohio trial courts.

F. The Courts

OLBA prevailed over the Ohio Department of Health in the summer of 2007, alleging that by amending the definitional elements of the private club exemption to accord with the ACS's ballot language, the Department of Health had exceeded its rulemaking authority.[137] Reconstructing voter intent from an

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132. *Id.* (quoting spokeswoman for the Ohio division of the American Cancer Society).

133. Mark Rollenhagen, *Ohio VFW Wins One in the Smoking Wars; Veterans Posts May Be Able To Allow Puffing*, CLEV. PLAIN DEALER, Mar. 22, 2007, at B1.

134. Complaint, State *ex rel.* Am. Cancer Soc'y v. Ohio Dep't of Health, No. 07-CV-005306 (Franklin County Ct. C.P. Apr. 23, 2008). The case was resolved against the Department of Health on April 23, 2008. State *ex rel* Am. Cancer Soc'y v. Ohio Dep't of Health, No. 07-CV-005306 (Franklin County Ct. C.P. Apr. 23, 2008). Both parties cross-appealed, largely on organizational standing issues, but voluntarily dismissed the appeals following the Ohio Supreme Court's refusal to take the OLBA case. Notice of Joint Voluntary Dismissal, Am. Cancer Soc'y v. Ohio Dep't of Health, No. 08AP436 (Ohio Ct. App. June 27, 2008).

135. Jon Newberry, *Smoking Ban Remains Hazy*, CINCINNATI ENQUIRER, Apr. 30, 2007, at 1A (reviewing proprietors' anxiety over lost profits to private clubs).

136. Kevin Mayhood & James Nash, *For Now, Smoking Lamp Dark at VFW*, COLUMBUS DISPATCH, May 1, 2007, at 1A.

137. This argument had been raised but not pursued as a void for vagueness challenge in

audacious angle, given ballot language that had specifically promised a private club exemption, the hospitality industry argued that "[p]rivate businesses—clubs and taverns—should be treated the same as private clubs in regard to the smoking law."[138]

Though the trial court ultimately sustained OLBA's challenge, palpable frustration is unmistakable in the opinion. The question, "Was the ballot language . . . misleading[?]" was only the beginning.[139] Judge Cain unleashed a barrage of questions barred from his analysis, including, "Did the sponsors, promoters and drafters of the SmokeFree Act sell it to the public under the presumption of the existence of an exemption that was not really there?" and "Was the Ohio voting public fooled by a ballot issue that purported to be something that it was not?"[140]

Though Judge Cain clearly suspected that the inclusion of the private club exemption was "just a sham to get more votes,"[141] the legal issue presented was quite narrow. Because the exemption in question was undone by the definition of private club—"The Court cannot think of a scenario under the SmokeFree Act in which the 'private club' exemption would actually apply"[142]—the court reluctantly concluded that the text of the bill taken as a whole did not actually exempt private clubs, and therefore the Department of Health had exceeded its rulemaking authority in giving substance to this illusory exemption.

> When viewing the above definitions . . . it becomes clear that the "private club" exemption found in the SmokeFree Act is an exemption in name alone. It lacks all substance. . . . Regardless of the statements made in R.C. 3794.03(G) that a "private club" exemption exists, no such exemption actually does exist.

Reviewing the Health Department's arguments, Judge Cain was sympathetic to the agency's efforts to redefine "employee" in order to give substance to the voters' intent, but ultimately had to presume that voters had intended every definitional intricacy.

> The Court applauds the efforts of Defendants in attempting to effectuate the will of the people. However, by doing so they have exceeded their rule making authority. The Court cannot determine the intent of individual voters when they

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Buckeye Liquor. Buckeye Liquor Permit Holders Ass'n v. Ohio Dep't of Health, No. A0610614, at 14 (Hamilton County C.P. Ct. May 2, 2007), *available at* http://www.hamilton-co.org/cinlawlib/blog/Nelson_decision.pdf (order denying plaintiffs' motion for preliminary injunction).

138. Mayhood & Nash, *supra* note 136.

139. Ohio Licensed Beverage Ass'n v. Ohio Dep't of Health, No. 07CVH04-5103, slip op. at 2 (Franklin County Ct. C.P. May 17, 2007).

140. *Id.*

141. *Id.*

142. *Id.* at 7.

> voted for the SmokeFree Act. This intent cannot be gleaned from the SmokeFree Act itself because it provides for both a "private club" exemption and definitions that swallow that exemption. The Court has to presume that the public at large knew what they were voting for. This is regardless of how the ballot language read.[143]

This conclusion, however legally clear, was unwelcome from an equitable standpoint, and Judge Cain made no attempt to conceal his irritation with the misleading statute and his limited ability to offer equitable relief. He concluded his opinion with "a final thought on this matter":

> [F]rom the very beginning there never was a "private club" exemption in the SmokeFree Act. There was an apparition that called itself a "private club" exemption, but that exemption did not really exist. It is not within the Court's power to correct this situation.[144]

The frustration evident in Judge Cain's opinion speaks to the powerlessness of courts to correct the deception and misinformation that can plague interest-group politics.[145]

On appeal, Judge Cain's conclusions were affirmed, bolstered by the court of appeals' reliance on an interpretative note buried in the text of the bill, stipulating that provisions "shall be liberally construed so as to further its purposes."[146] The court of appeals echoed Judge Cain's observations on the limited role the Ohio courts could play in resolving the deeper issues raised:

> Assuming that the SmokeFree Act falls short of providing the exemption contemplated by the agency or other groups, any potential change to the exemption as enacted would be a matter for the legislature, not the administrative agency, to address.[147]

Unable to look behind the statute regardless of the immensely problematic circumstances attending its passage, and suspicious that the inclusion of the

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143. *Id.* at 8.

144. *Id.* at 11.

145. Jane Schacter has argued persuasively for differential review of direct legislation. *See* Jane S. Schacter, *The Pursuit of Popular Intent: Interpretive Dilemmas in Direct Democracy*, 105 YALE L.J. 107 (1995). Though this case was a question of agency competence, not statutory construction, voter intent may not have been "frankly irrelevant" to the disposition of the case if the court had been willing to look beyond the four corners of the text of the statute, as Schacter recommends, to ballot language and the media, and find that voters intended a private club exemption. As Schacter notes, however, this would place a heavy burden on courts and might incentivize further manipulation of balloting procedures. *Id.* at 150.

146. Ohio Licensed Beverage Ass'n v. Ohio Dep't of Health, 2007-Ohio-7147, ¶ 40.

147. *Id.* ¶ 41.

private club exemption was a "sham to get more votes," the courts declared themselves powerless to resolve the issues at the root of the exemption controversy.[148] The only way Ohio could remedy its runaway statute was through the legislature.

G. The Legislature

Even as legislators turned to address the Act's nebulous exemption scheme, meaningful deliberation over the merits and demerits of specific exemptions was hamstrung by the vexing question of voters' intent. As Judge Cain made perfectly clear, the Ohio Department of Health was limited to rulemaking authority within the textual boundaries of the misleading Act. The legislature, however, knew no such bounds: Once passed, the initiative was simply another amendable statute. Thus, creative reconstruction of "voters' intent" reached a high-water mark as lobbyists flooded hearings with testimony, consistently pushing deference to "the will of Ohio voters" to discourage serious consideration of two proposed exemptions.

The first, for performing arts spaces, responded to fears that the Act jeopardized the ability of theaters to acquire the rights to stage dramas that specifically called for smoking onstage. Senate Bill 38 was to be an "antidotal" exemption to "allow smoking by a performer while performing a theatrical

148. This conclusion has since been affirmed by the Supreme Court of Ohio. The Solicitor General of Ohio declared the case "of public and great general interest," and sought review of the appellate opinion. Memorandum in Support of Jurisdiction of Defendants-Appellants at 8, Ohio Licensed Beverage Ass'n v. Ohio Dep't of Health, No. 2008-08-0356 (Ohio June 4, 2008). The Solicitor General contended that voter-enacted laws should be subject to the same canons of construction as conventional legislation to execute the will of the voters, *id.* at 11-13, and that the private-club exemption as implemented by the Department of Health was consistent with the overall statutory scheme, *id.* at 13-15. Unsurprisingly, the ACS filed an extensive *amicus* brief on the basis that "[f]rom its inception, the *amici* have led efforts to draft, pass, and bring this law to fruition through a vote of the People, and prevent the People's will from being undermined," and arguing that "the exemption ODH seeks to vindicate does not exist." Memorandum in Response to Memorandum in Support of Jurisdiction of Amici Curiae American Cancer Society et al. at 5-6, Ohio Licensed Beverage Ass'n v. Ohio Dep't of Health, No. 2008-0356 (Ohio June 4, 2008). Despite the Solicitor General's forceful arguments that that review was necessary "to vindicate the public's right to direct democracy," Memorandum in Support of Jurisdiction of Defendants-Appellants, *supra*, at 9, and redress wrongs done to public trust, the Supreme Court, divided four to three, declined jurisdiction. *See* Ohio Licensed Beverage Ass'n v. Ohio Dep't of Health, No. 2008-0356 (Ohio June 4, 2008) (dismissing appeal "as not involving any substantial constitutional question"); *see also* Jim Provance, *Smoke-Ban Appeal Loses Legal Battle; Justices Refuse To Hear Case Seeking Some Exemptions*, TOLEDO BLADE, June 5, 2008, *available at* http://www.toledoblade.com/apps/pbcs.dll/article?Date=20080605&Category=NEWS02&ArtNo=806050409&Ref=AR.

production if smoking is integral to, or is directed by the script or other story line of the performance being given."[149]

Worryingly, much of the testimony had nothing to do with the merits of the proposed exemption. Though some testimony was quite on point—the director of the Cleveland Playhouse testified in support that, as a result of licensing contracts, he would not be able to produce a number of well-known plays under the Act,[150] and an actor testified in opposition to the verisimilitude of special stage cigarettes[151]—ACS lobbyists demanded that the legislative committee adopt a hands-off policy.[152] According to opposition's testimony, "keeping the law strong and giving the voters of this state what they want and deserve" necessarily entailed a hands-off policy without debate or amendment.[153]

The next proposal was from the beginning a clumsy effort at a tobacco lounge exemption—largely because the establishment that inspired the exemption was not, strictly speaking, a cigar bar, but a steakhouse run by a constituent of the bill's sponsor. Defining "cigar bar" as an establishment containing a sufficiently large "walk-in humidor" with filtration systems,[154] Senate Bill 195 provided nearly no meaningful guidance as to what would constitute a cigar bar, nor did it distinguish cigar bars from restaurants and bars that happened to sell cigars. As opponents pointed out, this would open a Pandora's Box and functionally doom the Act if restaurants and bars statewide exploited the definitional vagueness.[155]

Testimony in support of the proposal was given by the proprietor of a large Cincinnati nightclub, the owner of the "cigar bar and grille" that inspired the bill, and letters from two national trade organizations representing cigar retailers and distributors. The chief arguments made by proponents were the same tired economic complaints concerning the diminishing profit margins of small business owners that had failed at the polls. Cigar bars per se were entirely

149. *Hearing on S.B. 38 Before the S. Health, Human Services, and Aging Comm.*, 127th Gen. Assem., Reg. Sess. (Ohio 2007) (statement of Sen. Schuler).

150. *Id.* (statement of Buzz Ward, Executive Dir., Cincinnati Playhouse in the Park).

151. *Id.* (statement of Susan Jagers, Am. Cancer Soc'y, referencing demonstration by actor Robert Dubec).

152. *Id.* (testimony of Tracy Sabbetta, Am. Cancer Soc'y) ("[O]ur organizations are adamantly opposed to opening up the Smoke Free Workplace Act to changes only a few short months after its passage.").

153. *See id.* (testimony of Marjorie Broadhead, Health Comm'r, Seneca County) ("[W]e are concerned that Senate Bill 38 would also offer the opportunity for other exemptions to be made to the law—exemptions which were clearly not the will of Ohio voters when they passed Issue 5.").

154. S.B. 195, 127th Gen. Assem., Reg. Sess. (Ohio 2007).

155. *Hearing on S.B. 195 Before the S. Health, Human Services & Aging Comm.*, 127th Gen. Assem., Reg. Sess. (Ohio 2007) (statement of Micah Berman, Executive Dir., Tobacco Pub. Policy Ctr. at Capital Univ. Law Sch.).

unrepresented—indeed, cigar bar owners appear to have been unaware that the hearing was taking place.[156]

As a result of the proposal's inadequacy, the merits of a cigar bar exemption were not debated. No arguments were made that might have distinguished cigar bars from conventional bars and restaurants for the public health purposes of the ban. Though the ACS renewed its demands to protect the "will of the voters" by refusing to consider any modifications to the Act, its vigorous exertions may have been unnecessary. Senate Bill 195 was a sufficiently ham-handed attempt at a cigar bar exemption that it will likely be condemned on unworkability alone.[157]

Following the Supreme Court's decision to decline review of the OLBA suit, two other exemption bills surfaced. One, Senate Bill 396, would remedy the outdoor patio and private club exemptions, but would also introduce an exemption for "family owned businesses."[158] The other, House Bill 592, would address the outdoor patio distinction, but would also exempt "stand-alone bars," changing Ohio's regime from Class V to Class IV.[159] These proposals will be hotly debated in the next legislative session, but have already drawn fire from both OBLA and ACS lobbyists.[160]

H. Conclusion

Reviewing the tortured enactment of the Smoke Free Workplace Act, the chief conclusion is that public deliberation, particularly concerning the exemption scheme, was stifled, enabling the ACS to slide an extremely aggressive ETS bill into law under the noses of Ohio voters. If the Ohio Smoke Free Workplace Act ever aspired to represent the considered deliberation of a state that supports effective ETS legislation, containing an exemption scheme reflecting the reasoned preferences of her citizens, it can only be adjudged a monumental failure.

Though responsibility for the deceptive bill and its illusory exemption scheme must ultimately rest with drafters of the legislation, structural realities of

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156. Posting of Tiffany Wuensch to Cigar Jack's News and Reviews, http://www.cigarjack.net/2007/07/19/ohio-cigar-bar-exemption-news/#comment-1960 (Oct. 19, 2007, 11:55 AM) ("I can't believe that all Cigar Bar Owners and Managers weren't properly informed.").

157. The bill remains undisturbed in the Senate Health, Human Services, and Aging Committee since the 2007 hearings. An enlightened friendly amendment may yet be introduced.

158. S.B. 346, 127th Gen. Assem., Reg. Sess. (Ohio 2008).

159. H.B. 592, 127th Gen. Assem., Reg. Sess. (Ohio 2008).

160. *See Anti-Smoking Coalition Cautions Legislature Against Revising SmokeFreeOhio Law; Poll Shows Support for Smoking Ban*, 77 GONGWER NEWS SERVICE, Ohio Rep. 180, Sept. 16, 2008; *State Tallies More Than 800 Smoking Ban Fines; Lawmakers Introduce Bills To Expand Exemptions*, 77 GONGWER NEWS SERVICE, Ohio Rep. 119, June 19, 2008, *available at* http://cpmra.muohio.edu/otaohio/Legislation/Weekly%20Updates/2008/062708.pdf.

direct legislation facilitated the usurpation of citizen authority and exacerbated the damage. Exemption candidates lacked the financial resources of the major players, the tobacco lobby and the ACS, and were unable to communicate with the voting public. Strategic drafting by the ACS successfully presented the mirage of a reasonable exemption scheme. Ohioans, evidently, were content to rely on assurances of a "reasonable" exemption scheme, reading the list of "exempted" areas on the ballot with a presumption of good faith, and the knowledge that the legislature could amend the bill to work out any unsatisfactory details. Institutional remedies were foreclosed by a stylized understanding of ballot initiatives as perfectly representative of voter intent. The Department of Health was prevented from giving force to what it concluded, based on the testimony of voters at public hearings, to be voter intent, because its authority was limited to enforcing the text of the bill. Courts, though savvy to the confusion and ignorance that plagued the electorate at the polls, were obliged to presume an unrealistic level of voter sophistication, enforcing the definitional language, which few voters read, against the ballot language, which most voters read. The legislature, the only institutional actor with the authority to pierce the veil of voter intent and consider the issues and exemptions on their merits, was assailed by commands of deference to "the will of Ohio voters" as retroactively (and inconsistently) explained by the ACS and the OLBA.

The Ohio Smoke Free Workplace Act is a case study in the liability of ballot initiatives to procedural abuse, and it demands remedial legislative attention. This was not a grassroots proposal, representing the considered deliberation of Ohio voters on all interests in play. This proposal was cleverly drafted by a well-funded special interest group, qualified for the ballot with signatures gathered by paid professionals, and sold to Ohio voters without meaningful consideration of the exemption scheme. It can only be hoped that enlightened legislators will have the courage to supply the deliberation absent from the enactment process—to moderate, as Madison aptly put it, "the blow mediated by the people against themselves."[161]

III. BALLOT INITIATIVES: A BLUNT TOOL FOR A DELICATE TASK

As the foregoing case study demonstrates, ballot initiatives can be a clumsy mechanism for instituting ETS regimes, ill-suited to address the central question—exemptions—posed by modern statewide bans. The passage of Ohio's Smoke Free Workplace Act highlights several aspects of ETS ballot initiatives that prevent meaningful consideration of proposed exemptions. First, the interests most active in ETS disputes marginalized the areas directly affected by the details of the ban. Despite plausible arguments for exemption, these voices were

161. THE FEDERALIST NO. 63, at 382-83 (James Madison) (Clinton Rossiter ed., 2003).

unrepresented in the public conversation. Second, deception and misinformation crippled meaningful public deliberation. The full extent of the damage is impossible to ascertain, but there can be no question that the use of paid signature-gatherers muddled the proposals and that strategic drafting shielded the details of the exemption scheme from public scrutiny.

The ballot initiative is an impermissibly clumsy vehicle for ETS legislation for a third reason. Though the focal point of modern ETS legislation is the exemption scheme, which determines where a state chooses to draw the line after flipping the default rule, voters on ballot initiatives not only tend to be uninformed concerning the exemption provisions, but are constrained to the shrink-wrapped package crafted by the drafters of the proposal, unable to indicate preferences on discrete points. Thus, although ballots can indicate support for an ETS regime, they cannot capture public opinion on exemption provisions. The danger is that our executive agencies and courts are required to pretend that they do.

A. Inadequate Interest Representation

Ballot initiatives are notoriously bad at eliciting meaningful public discussion, and in the context of ETS legislation this begins with poor interest representation. In Ohio, the interest landscape with respect to ETS policy was commanded entirely by voices on opposite extremes. On the one side, the ACS and its affiliates pushed a draconian bill that had been cleverly drafted to eliminate smoking even in promised exemption areas. On the other side, the tobacco and hospitality lobbies opposed meaningful ETS legislation entirely, peddling a constitutional amendment in the guise of a smoking ban that would have rendered meaningful ETS legislation unconstitutional. These were the only groups with the financial resources to mount ballot proposals, however, leaving voters generally in favor of ETS restrictions with an all-or-nothing choice. In the context of a regulatory arena in which the devil truly is in the details, this is a problematic state of affairs.

The interests most directly affected by the exemption scheme (and consequently most able to raise salient policy points), like private clubs, performing arts centers, hookah bars, cigar bars, and tobacco retailers, were marginalized. Despite persuasive claims for exemption, plausibly consistent with the larger purpose of ETS legislation, these spaces were unable to present their arguments because they lacked the resources of the major players. Even if the illusory nature of SFO's exemption scheme had been apparent during the balloting process, these establishments did not have powerful lobbies to represent their unique circumstances. They could not pressure SFO to craft a more meaningful exemption scheme. Nor could they afford to place a third ETS initiative on the ballot which might offer a strong ETS regime with more reasonably drafted exemptions, offering voters a chance to express a third, more

nuanced opinion. The hospitality industry did not advocate on behalf of these fringe establishments, as they presented different circumstances than the bars or restaurants targeted by ETS legislation. Indeed, the aggressive tactics of OLBA and the tobacco industry did exemption areas more harm than good, inviting inferences of guilt by association.

Unfortunately, this impoverished landscape of interests is fairly typical in the context of ETS ballot initiatives. ETS ballot initiatives have universally been sponsored by health advocacy groups, which generally propose extremely severe legislation.[162] Major players in the tobacco industry have sponsored opposition efforts quite similar to SLO's constitutional amendment in a number of other initiative contests, which are characteristically absolutist.[163] Theatres, shisha cafés, private clubs, veterans' organizations, and cigar bars, which are relatively scarce to begin with, cannot muster enough money to purchase the signatures required to enter the contests at the proposal stage, nor can they purchase enough political speech effectively to present their arguments for exemption. Thus, the clashing titans have no incentive to incorporate the concerns of these fringe areas into their proposals. As a result, voters are not called upon to consider the distinctive claims these establishments might have for exemption.

Furthermore, deferral by the legislature at the proposal stage is fairly common, even in states like Ohio that provide the legislature with an opportunity to amend and pass a proposed statute.[164] Though perhaps politically understandable—no doubt a legislator proposing an exemption would be condemned by opposition lobbyists as "pro-smoking," even if generally supportive of the ban—by deferring, a legislature squanders an opportunity to

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162. Opponents of tobacco regulation observe that political advocacy for smoke-free campaigns has been generously funded by the Robert Wood Johnson Foundation, the largest shareholder in a pharmaceutical manufacturer of cessation products. *See* Wanda Hamilton, *Pharmaceutical Players: Drug Companies Involved with "Cessation" Products*, July 13, 2001, http://www.forces.org/evidence/pharma/pdf/players.pdf ("The Robert Wood Johnson Foundation is the biggest single shareholder in J&J and began its massive funding of tobacco control in the U.S. in 1991, the same year the FDA approved the nicotine patch as a prescription drug."); *see also* 8 KAREN GERLACH & MICHELLE LARKIN, TO IMPROVE HEALTH AND HEALTH CARE: THE ROBERT WOOD JOHNSON PROGRAM 29-46 (2005), *available at* http://www.rwjf.org/pr/product.jsp?ia=143&id=14912 (describing how the Foundation "encouraged" political activism and lobbying in grantees, and its reliance on grantees like the American Cancer Society to conduct lobbying initiatives that the nonprofit Foundation "could not support directly").

163. Such competing proposals were made in Arizona, Nevada, and Ohio. *See* Amanda J. Crawford, *Tobacco Firm Joins Smoking Ban Fight; It Aims To Defeat Stricter Measure*, ARIZONA REPUBLIC, July 31, 2006, at A1; Steve Friess, *Even In Nevada, Smokers' Options Are Shrinking*, N.Y. TIMES, Oct. 31, 2006, at A19 (noting that the hospitality industry, proposing a more moderate ban, spurned the support of the tobacco lobby for fear of being "tainted" by association).

164. *See* OHIO CONST. art. II, § 1b.

consider the arguments of interested parties that cannot afford to be heard.

B. Misinformation and Deception

Misinformation and deception exacerbated the considerable problems of interest representation during the passage of the Smoke Free Workplace Act. The use by both sides of mercenary signature-gathering companies with no particular allegiance to the truth clouded the issues at stake throughout the signature-gathering and balloting stages. As voting day approached, voters were too busy trying to figure out the difference between the two proposals to consider the operation of the Smoke Free Workplace Act in any detail. Repudiating the tobacco lobby's effort to purchase a page of the Ohio Constitution consumed public attention.

Strategic drafting by the ACS had produced a remarkably clever bill, the definitions of which undid the promised exemptions. Having warned the legislature off of the proposal, the ACS ensured that the deceptive drafting would not become apparent until after the bill's passage. Certainly OLBA's proposed constitutional amendment was as fully a Trojan horse as was the Smoke Free Workplace Act, but with less artfully concealed contents. When it backfired in spectacular fashion, the credibility of the other, subtler artifice was enhanced. Thus, the finer points of the Smoke Free Workplace Act, particularly the illusory exemption scheme, remained concealed from Ohio voters, who took ballot language at face value and accepted assurances of reasonable exemptions on faith.

1. Paid Signature-Gatherers and Simplistic Campaigning

These twin dangers, misinformation during the signature-gathering and advocacy processes, and affirmative deception by strategically drafted legislation, are ineluctable features of what has been termed the modern "initiative industry."[165] Political scientists have noted with concern the omnipresence of "highly professional operations dominated by media consultants who run deceptive or simplistic operations."[166] In 1992, the California

165. DAVID MAGLEBY, DIRECT LEGISLATION: VOTING ON BALLOT PROPOSITIONS IN THE UNITED STATES 59 (1984).

166. BETTY ZISK, MONEY, MEDIA, AND THE GRASS ROOTS: STATE BALLOT ISSUES AND THE ELECTORAL PROCESS 258 (1987); *see also* MAGLEBY, *supra* note 165, at 61-65 (reviewing abusive practices by initiative industry signature-gatherers); Todd Donovan & Shaun Bowler, *An Overview of Democracy in the American States*, *in* CITIZENS AS LEGISLATORS: DIRECT DEMOCRACY IN THE UNITED STATES 12 (Shaun Bowler, Todd Donovan & Caroline J. Tolbert eds., 1998) [hereinafter CITIZENS AS LEGISLATORS] ("An 'initiative industry' has evolved, seemingly supplanting the original idea of a populist system that provides access to the legislative process. Composed of law

Commission on Campaign Financing published a report on ballot initiatives, observing the following:

> Professional signature-gathering firms now boast that they can qualify *any* measure for the ballot (one "guarantees" qualification) if paid enough money for cadres of individual signature gatherers, and their statement is probably true. Any individual, corporation, or organization with approximately $1 million to spend can now place any issue on the ballot .... Qualifying an initiative for the statewide ballot is thus no longer so much a measure of general citizen interest as it is a test of fundraising ability.[167]

The rising use of paid petition-circulators has created incentives for ruthless and deceptive practices.[168] Perhaps the most damning evidence is the statement of an immensely successful California petition drive manager, Ed Koupal: "Hell no, people don't ask to read the petition and we certainly don't offer .... Why try to educate the world when you're trying to get signatures?"[169]

Some states have attempted to limit the damage. Oregon, for example, amended its provisions for direct legislation in 1935 "to prohibit paid signature collection because of fear that wealthy interests were beginning to subvert the initiative process."[170] In 1974, finding that "voters had been misled, in some campaigns, about the purpose of the petitions they had signed," California legislators capped early spending on signature-gathering at $10,000 and prohibited certain well-known tactics, like the use of "dodger cards," which obscure the text of the proposal from the prospective signatory.[171] Illinois

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firms that draft legislation, petition management firms that guarantee ballot access, direct-mail firms, and campaign consultants who specialize in initiative contests across several states, the industry is visible in nearly all states where initiatives are used frequently."); David McCuan et al., *California's Political Warriors: Campaign Professionals and the Initiative Process*, *in* CITIZENS AS LEGISLATORS, *supra*, at 55 (tracing the central role professional consultants have come to play in California ballot propositions).

167. CAL. COMM'N ON CAMPAIGN FIN., DEMOCRACY BY INITIATIVE: SHAPING CALIFORNIA'S FOURTH BRANCH OF GOVERNMENT 265 (1992), *available at* http://www.cgs.org/images/publications/DemocracybyInitiative.pdf.

168. *See* MAGLEBY, *supra* note 165, at 62 (reviewing data suggesting that voters rarely read the petitions they sign); JOSEPH ZIMMERMAN, PARTICIPATORY DEMOCRACY: POPULISM REVIVED 49 (1986) ("A major problem with the employment of the petition referendum (and the initiative and the recall) is fraudulent petition signatures. The cost of collecting signatures leads unscrupulous petition circulators to forge signatures on petitions."); *id.* at 59 ("The public can be misinformed by both proponents and opponents of a proposition.").

169. Caroline Tolbert, Daniel H. Lowenstein & Todd Donovan, Election Law and Rules for Initiatives, in CITIZENS AS LEGISLATORS, *supra* note 166, at 34.

170. ZISK, *supra* note 166, at 260.

171. *Id.* at 260-61.

required an extraordinary demonstration of popular support, requiring that 25% of registered voters sign a petition to place a question on the ballot.[172]

These and other efforts to revive the integrity of the ballot initiative, however, have been ruled unconstitutional on First Amendment grounds.[173] The use of paid signature-gatherers remains a constitutionally protected and omnipresent aspect of modern ballot initiatives. In the context of ETS regulation, where so much hangs on the details of the exemption scheme, this is especially worrying. Misinformation seeded by ambitious signature-gatherers obscures potentially significant aspects of the exemption scheme, and it gives initiative drafters little incentive to create responsible exemption schemes.

2. Deceptive Drafting

The threat of deceptive drafting is similarly inextricable from modern ballot initiatives. As Jane Schacter observes, "the direct lawmaking process gives powerful leverage to initiative drafters, who are situated to construct a phantom popular intent through strategic drafting."[174] Because voters are likely to rely on the ballot summary to form an opinion, strategic drafting of the generally unread full-text of direct legislation "enables small groups to appropriate the political authority of the electorate."[175] Exemption schemes in ETS proposals are particularly vulnerable to this phenomenon, both because they tend to be absent from the public conversation and because the fine points of an exemption's operation require a sophisticated analysis of the relevant provisions and definitions. As Schacter observes, "The risk of abuse is especially severe . . . where the ballot measure is so lengthy or complex that legally significant details can easily be buried."[176] As Ohio voters discovered to their dismay, the presence of an exemption entitled "Private Clubs" on the ballot and in the text of the initiative provides no guarantee that it will be operational.

Ballot language is a serious problem in the context of ETS legislation. Though the proposed default rule may be fairly easy to understand, the severity

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172. Georges v. Carney, 546 F. Supp. 469, 477-78 (N.D. Ill. 1982).

173. In *Meyer v. Grant*, the Supreme Court unanimously struck down a Colorado statute criminalizing the use of paid petition circulators, rejecting "the State's arguments that the prohibition is justified by its interest in making sure that an initiative has sufficient grass roots support to be placed on the ballot, or by its interest in protecting the integrity of the initiative process." 486 U.S. 414, 425 (1988). In *Georges v. Carney*, the Northern District of Illinois invalidated the 25% signature requirement, stating that "we cannot suppose the Legislature intended that professional canvassers be employed in order to allow citizens to exercise their statutory right to place on the ballot advisory public questions." 546 F. Supp. at 477.

174. Schacter, *supra* note 145, at 111.

175. *Id.* at 129.

176. *Id.*

of the measure depends on the exemption scheme, and as a result an ETS regime is a complicated series of proposals. Voters' attention spans are limited, however, and ballot boards have a powerful incentive to sacrifice completeness for brevity. Most problematically, the process of adopting ballot language relies in large part on the good faith of the proponents. Even public hearings, as was unfortunately demonstrated in Ohio, provide no guarantee that ballot language will be accurate.

C. Constrained Public Choice and the Problem of Voter Intent

For the reasons reviewed above, meaningful public choice is unlikely in the context of ballot initiatives. Poor interest representation limits ballot options to extreme proposals, and the relative weakness of specific exemption constituencies makes it unlikely that the ballot proposals will accommodate their interests. Moreover, ballot initiatives tend to produce a nightmarish deliberative environment, replete with misinformation and outright deception. Powerful incentives exist for initiative sponsors to draft deceptive bills, for they can re-imagine voter intent after the fact with impunity and justify even the most offensive provisions.

Even in a deliberative Elysium, however, ballot initiatives would remain impermissibly clumsy vehicles for responsible ETS legislation for a straightforward structural reason: voters are not empowered to indicate preferences on the factors that determine how severe the regime will be. Rather, voters are restricted to the package of provisions crafted by the drafters of the proposal. As David Magleby has observed, this presents a number of problems:

> One problem is that voters are not permitted to vote on alternative bills; another is that voters cannot attempt to amend the proposed legislation to make it more acceptable. An additional problem is that voters are limited to an affirmative vote, a negative vote, or an abstention. . . . [V]oters often must choose the least inaccurate expression of their opinion.[177]

This is not to suggest that ballot results are meaningless. ETS ballot initiatives can certainly reveal general support for some form of ETS regime that reverses the default rule. In Ohio, the broad policy question was certainly evident: on the one hand, voters were presented with a "smoking ban" that failed to reverse the default rule by exempting bars and restaurants; on the other, voters considered a smoking ban that promised to reverse the default rule and take a strong stance on ETS in public places, with reasonable exceptions. On this point, the voters spoke relatively clearly.[178] In voting down Issue 4 and adopting Issue 5, Ohioans voted to reverse the default rule on smoking in public places.

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177. MAGLEBY, *supra* note 165, at 183.

178. Relatively, because some confused voters cast ballots for the two incompatible proposals.

Beyond the default rule, however, seeking intent with respect to particular elements of an ETS statute passed by ballot initiative is a Sisyphean endeavor. This became painfully apparent in Ohio. Not only were voters unaware of the operation of the exemption scheme, but also when it was implemented even voters who supported the initiative repudiated significant points. As Jane Schacter observes, analyzing what she aptly terms "the intractable search for popular intent," ascribing a single intent to the passage of a ballot initiative is even more problematic than in the context of conventional statutes.[179] The problem of intentionality in multi-member deliberative bodies is magnified in the context of ballot initiatives, which aggregate "what may be millions of voter intentions."[180] Additionally, voters are typically uninformed,[181] and strategic drafting may hide significant aspects of the proposal. Thus, "[a] vote in favor of a ballot question will often signify, at best, an electoral judgment on the salient and general policies in question."[182]

These problems are particularly acute in the context of ETS ballot initiatives, which present one easily-understood, general proposition (whether or not to flip the default rule) and a number of discrete, detail-oriented proposals (the exemption provisions) that determine the character of the new regime. Furthermore, voters may cast strategic ballots, abandoning specific exemption areas for the larger purpose of seeing the bill through. ETS ballot initiatives can certainly serve as referenda on whether a state chooses to switch the default rule, but they are structurally incapable of expressing voter intent on exemption provisions. When the dust settled, potential exemption areas like private clubs and tobacco lounges were incidental casualties of the Smoke Free Workplace Act. They were trapped in limbo between the draconian bill written by the ACS and the anti-regulatory constitutional amendment proposed by the tobacco industry. They were abandoned by legislators who might have spoken for them. They were ignored by voters who took assurances of a "reasonable" exemption scheme on faith, or who would rather pass an imperfect ETS bill than lose the opportunity because of a few insignificant victims. Because these fringe establishments lack the clout to elicit more nuanced propositions from the powerful, diametrically opposed interests, voters are neither presented with a full array of potential options nor able to express preferences on specific points.

179. Schacter, *supra* note 145, at 123-30; *see also* MAGLEBY, *supra* note 165, at 144 ("For many voters, direct legislation can be a most inaccurate barometer of their opinions.").

180. Schacter, *supra* note 145, at 125.

181. *See* MAGLEBY, *supra* note 165, at 62, 129-30, 144; *id.* at 198 (describing voting on ballot questions as "electoral roulette").

182. Schacter, *supra* note 145, at 127.

D. Limited Executive and Judicial Remedies

Courts, however, ignore these limitations and adhere to a stylized portrait of direct democracy, foreclosing remedial action by executive agencies. In Ohio, frustration with this legal pretense suffused Judge Cain's opinion; other courts have registered similar concerns.[183] As Professor Schacter's survey of relevant case law from 1984 through 1994 demonstrates, most courts continue to employ an intentionalist methodology in interpreting direct legislation, which renders them powerless to correct the grave procedural dangers presented by ballot initiatives. Not only do courts ignore the severe deliberative deficiencies that characterize ballot initiatives and "hold the legislature and the citizenry to the same standard when interpreting the laws they enact,"[184] they also "invert the informational hierarchy" in searching for popular intent, relying almost exclusively on formal sources, such as the text of legislation, instead of sources that more fully express public opinion, such as advertisements and the news media.[185]

Legal scholars have proposed interpretive methodologies that might empower courts to align direct legislation more closely with the will of the electorate through active interpretation of key provisions. Julian Eule proposes that courts take a "harder look" at ballot initiatives when constitutional rights are implicated.[186] Schacter proposes a compelling "metademocratic" interpretive framework, whereby courts acknowledge the problems inherent in ballot initiatives and apply more rigorous judicial oversight accordingly, perhaps looking beyond the text of the statute to other sources of public opinion or interpreting ballot initiatives as "a general policy directive rather than a vehicle for enacting specific rules in complex areas."[187]

Even if adopted, however, these approaches cannot fully remedy the deficiencies of ETS legislation by ballot initiative. Eule's model, relying on more rigorous constitutional analysis, does not apply to ETS regulation, which is well within the bounds of a state's police power. Schacter's proposals rely on the existence of provisions ripe for interpretation. Her interpretive model might have provided Ohio courts with a justification for giving force to the private club

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183. *See, e.g.*, Taxpayers to Limit Campaign Spending v. Fair Political Practices Comm'n, 799 P.2d 1220, 1235 (Cal. 1990) ("[T]his court must on occasion indulge in a presumption that the voters thoroughly study and understand the content of complex initiative measures."); Lemon v. United States, 564 A.2d 1368, 1381 (D.C. 1989) ("The difficulties inherent in discerning the collective intent of a legislative body . . . are even more pronounced where the decision was made directly by the electorate.").

184. Backman v. United States, 516 A.2d 923, 926 (D.C. 1986).

185. Schacter, *supra* note 145, at 130.

186. Julian Eule, *Judicial Review of Direct Democracy*, 99 YALE L.J. 1503, 1558 (1990).

187. Schacter, *supra* note 145, at 164.

exemption, but exemption areas that were not drafted into the proposal could not have been interpreted into existence *ex nihilo*. Moreover, the resources required to pursue an interpretative challenge would most likely present exemption areas with an insuperable obstacle. The litigation that presented these questions to the Supreme Court of Ohio was pursued by the state Attorney General's office. If the Department of Health had not attempted remedial action that implicated statutory interpretation, private clubs may not have been able to contest the provision. Certainly, as testimony from the hearing on the theater exemption made clear, performing arts spaces cannot afford litigation, and much smaller operations—particularly cigar and hookah bars—would be similarly unable to contest exemption provisions.

ETS ballot initiatives are thus largely judicially irremediable. Interestingly, the ultimate remedy has not been formally foreclosed: the Supreme Court has not determined whether or not direct legislation is compatible with the Guaranty Clause, holding in 1912 that the question was properly for Congress.[188] It is clear, however, that state constitutions that include such provisions do so at their own peril.[189] Courts have prevented states from implementing procedural requirements that would ameliorate the more egregious abuses of the balloting process—the First Amendment precludes limitations on the use of paid petition-gatherers or requirements that high percentages of public support be demonstrated before a proposal can be certified for the ballot.[190] In short, courts have limited ability to remedy clumsy ETS legislation passed by ballot initiative. To the contrary, they must hold executive agencies accountable for every detail of the statute.[191]

IV. A PROPOSAL

Ballot initiatives are prone to produce bad ETS legislation. In responsibly

188. Pac. States Tel. & Tel. Co. v. Oregon, 223 U.S. 118 (1912).

189. *See* Georges v. Carney, 546 F. Supp. 469, 476-77 (N.D. Ill. 1982) ("[A]lthough the right to place a question on the ballot is not fundamental in Illinois, the legislature has seen fit to confer such right. Once Illinois decided to extend this forum, it became obligated to do so in a manner consistent with the Constitution.").

190. *See* Meyer v. Grant, 486 U.S. 414 (1988); *Carney*, 546 F. Supp 469.

191. Though courts are obliged to demand stricter enforcement when the question is litigated, courts give executive agencies a great deal of leeway in the manner of enforcement. *See* Young v. Ohio Dep't of Health, No. 07CV-11-15317 (Franklin County Ct. C.P. Apr. 25, 2008) (upholding Board of Health's imposition of a fine on a private club for an ashtray found in a closed storage cabinet because "it could easily be taken out and used for smoking," despite conflicting testimony). Interesting Fourth Amendment issues may arise in the context of government investigators inspecting private clubs for violations. Young's Fourth Amendment challenge foundered because the investigator was invited in, waiving its expectation of privacy. *Id.*

reversing the default rule on smoking in public, the key question is which areas should be exempted—a question that ballot initiatives are ill-suited to answer.

Recent years, however, have seen a rising tide of ETS ballot initiatives, bearing many of the same worrying features of Ohio's Smoke Free Workplace Act. Florida's Clean Air Indoor Act was the first statewide ban passed by ballot initiative, in 2002.[192] In 2005, the ACS and its affiliates drafted and secured the passage of Initiative 901 in the state of Washington. In 2006, the ACS and its affiliates shepherded three similar bills into law by statewide ballot—in Ohio, Nevada, and Arizona. These regimes are among the most draconian nationwide—Washington's is the most severe, followed closely by Ohio and Arizona. The ballot campaigns in these states were bipolar affairs, pitting legislation drafted by the ACS against competing initiatives supported by hospitality organizations and the tobacco industry (or, in the case of Nevada, gambling trade associations), and exemption areas were marginalized.

As ETS ballot initiatives proliferate, the need for remedial action becomes increasingly acute. As we have seen, courts are unable to—indeed should not—undertake to make bad law good, and exemption schemes present policy questions that implicate neither state nor federal constitutions. Executive agencies are bound to enforce the text of these bills, and advocacy groups enthusiastically police their efforts. Remedial action, therefore, is incumbent upon state legislatures, who can supply the deliberation and interest representation in proportion to the deficiencies apparent in ballot campaigns.

Given the inability of direct legislation to reflect the reasoned opinions of voters on discrete points, it is likely that ETS exemption schemes are more the product of happenstance and procedural manipulation than "the will of the voters," to say nothing of sound policy judgment. This Part contends that state legislatures must devote specific remedial attention to ETS bills passed by ballot initiative. To assist legislators in this task, I propose a balancing test for use in evaluating exemption proposals.

A. The Question of Deference

In amending exemption schemes, legislators are confronted by a vexing question of deference. Though ballot initiatives can only meaningfully express a public consensus on reversing the default rule, vested interests pressure legislators against amending ETS bills, irresponsibly claiming a popular mandate on specific provisions in the text of the legislation and condemning efforts to undermine the "intent of voters."

Deference of this sort is misplaced and pernicious, grounded in an anachronistic understanding of direct legislation and producing inaction where

192. FLA. STAT. ANN. § 386.201 (LexisNexis 2008).

there should be action. Direct legislation in American states is the product of a particular historical moment in which rampant corruption in state legislatures created a siege mentality between the electorate and its representatives. The ballot initiative was born in the Midwest and West with the rise of the Populist Party in the last decade of the nineteenth century, and spread rapidly to over twenty states during the Progressive era.[193] Pushed at a grassroots level by cause organizations, notably "grange organizations, single-taxers, socialists, labor groups, prohibitionists, and evangelists," this new mechanism was introduced to combat the operation of machine politics in legislatures dominated by the influence of powerful special interests, notably railroads and large industrial corporations.[194]

As the twentieth century wore on, however, the professionalization of direct legislation and the rise of the initiative industry subverted the Populist ideal of direct democracy as the grassroots expression of an enlightened electorate. In this unanticipated environment, "interpreting direct legislation results as mandates or expressions of the 'popular will,'" as the most comprehensive study of voter behavior in ballot initiatives concludes, is "problematic."[195] The excellent work of political scientists and legal academics has swept the veil from our deformed descendent of an antique ideal. We know quite well that ballot initiatives cannot reveal intent on statutory niceties. Under these well-known conditions, legislative deference to exemption provisions on the theory that they represent the specific intent of voters is flatly impermissible.

Legislators may nonetheless be cowed into silence by political pressure, loath to draw fire from special interest groups keen to reconstruct the "intent" of the legislation and incurring charges of abrogating the will of the people. Given the inability of ballot initiatives to express popular will on discrete, specific points, however, and the particular liability of ETS ballot initiatives to procedural concerns, legislators should not be shamed by a stylized portrait of direct legislation into deference to specific exemption provisions. Rather, legislators must take up the gauntlet and examine the exemption schemes of ballot initiatives directly. As Madison put it in *The Federalist No. 10*, representative governments should serve "to refine and enlarge the public views, by passing them through the medium of a chosen body of citizens, whose wisdom may best discern the true interest of their country."[196] To do otherwise is to become complicit in what Schacter has accurately described as the appropriation of political authority by well-funded but unrepresentative interest groups.

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193. THOMAS E. CRONIN, DIRECT DEMOCRACY: THE POLITICS OF INITIATIVE, REFERENDUM, AND RECALL 50-59 (1989).

194. Donovan & Bowler, *supra* note 166, at 2.

195. MAGLEBY, *supra* note 165, at 183.

196. THE FEDERALIST NO. 10, at 76 (James Madison) (Clinton Rossiter ed., 2003).

B. A Balancing Test for Exemptions

Legislators, however, are presently ill-equipped to analyze potential exemption areas. The pluralist ideal of comprehensive interest representation has failed in the context of ETS legislation, and debates—both in policy circles and in secondary literature—have been crippled by extremism. The interests well-funded enough to exert significant pressure on legislators or influence the adoption process—hospitality trade organizations, tobacco companies, and advocacy groups—recreate the problem of interest representation at legislative hearings on proposed exemptions and revive a pernicious obsession with "voter intent." As a result, perspectives that should be considered in the context of exemption schemes may once again be shouted over.

It is imperative that legislators revisit modern statewide bans, with analytically rigorous attention to exemptions before they attain regulatory inertia.[197] It is time that legislators returned to the exemption schemes with the purpose of ETS regulation as the sole guiding light: to prevent unwilling exposure to tobacco smoke.

This Section focuses the analysis which should guide legislators evaluating exemption proposals into a straightforward balancing test. It consists of two prongs tailored to address deficiencies inherent in ETS ballot initiatives and the contorted interest landscape of ETS policy, while remaining compatible with the function of an effective regime. Focusing attention specifically on the merits of particular exemptions in the context of a rational, coherent, and narrowly tailored ETS regime, such a balancing test would reorient the regulatory conversation and provide clarity amidst the fanciful ex post reconstructions of special interest lobbyists.

Accordingly, I propose the following test for use in considering proposed exemptions to ETS regimes. On the one side of the scale lies the extent to which the proposed exemption area offends the essential purpose of ETS legislation—to eliminate involuntary exposure to secondhand smoke in public. On the other side of the scale lie any virtue defenses the proposed area may have to offer. If the virtues outweigh the vice, exemption is proper.

By asking legislators to examine the extent to which a proposed exemption area offends the purpose of ETS legislation, the first prong of the balancing test

197. While this Note has focused on ballot initiatives, which are easily the most concerning mechanism for ETS legislation, renewed analysis is highly appropriate for conventional legislation as well. Indeed, powerful lobbies have exerted decisive influence on statewide bans passed through state assemblies—one need only review the frequent appearance of casino exemptions even in strong ETS regimes, which defy any consistent public health rationale, or observe the exertions of ACS and hospitality industry lobbyists in seeing Class V bans into law, to have serious concerns about the extent to which pure policy analysis drove the exemption schemes.

highlights the fact that exemption candidates may offend the function of ETS legislation to different degrees and in different ways, and may warrant correspondingly greater or lesser degrees of state intrusion. The actor smoking a cigarette onstage presents a different circumstance than the veteran who smokes in his room at a nursing home, and an Egyptian's desire to smoke hookah at a neighborhood shisha café may be distinguished from a diner's desire to have a cigarette after a meal in a crowded restaurant. These differences must be probed on their merits, not on the degree to which they accord with the interests and relative clout of advocacy groups and organized lobbies.

The choice of exemptions represents a judgment on the severity of an ETS regime, a judgment ballot initiatives cannot express and one particularly prone to distortion by vocal interest groups. In focusing legislative attention on the precise degree to which an exemption candidate may offend the statutory purpose, this prong requires states that choose to institute extremely severe regimes to confront the variable degrees to which exemption areas offend the function of ETS legislation. Exemptions should, after all, be narrowly tailored within the context of an ETS regime and neither undermine its essential function nor outstrip it.

The second prong of the balancing test requires an evaluation of any virtues the proposed area may offer society—the reasons it warrants exemption. This "virtue defense" prong provides for the aggregation of significant "soft" factors: legislating the public health, after all, has consequences in a number of areas of concern to the state which may lack a scholarly niche or mobilized pressure groups. The vitality of cultural traditions, local institutions, artistic liberty, community life, and other concerns may all play different roles in how a state might appraise a particular exemption candidate, and this prong provides legislators with a way precisely to account for these inchoate factors against the extent to which they offend the core purpose of an effective ETS regime.

Significantly, this second prong avoids the deliberative stalemate characteristic of ETS debates. Autonomy arguments are often intractable, and in the context of ETS legislation, must be subordinated to the public health function of the regime. Some exemption areas, however, pose little or no threat to the function of an effective ETS regime. By asking legislators to measure the precise degree to which a given area offends the statutory purpose directly against the virtues of exemption, the second prong reframes the debate from the usual balancing of autonomy concerns against public health benefits, to an analysis that accepts the necessity of reversing the default rule but focuses on narrowly tailoring the exemption scheme to the specific circumstances of different exemption areas. Perhaps under this framing, the never-far-enough atmosphere that presently suffuses ETS advocacy will be tempered, unnecessary casualties will be avoided, and ETS legislation, having swung from extremely cautious to extremely aggressive, will at last settle at a responsible regulatory balance.

V. TOBACCO LOUNGES

"[I]t is our task not to complain or condone but only to understand."[198]

To illustrate the operation of the balancing test, this Part applies it to an exemption area that appears in many statewide ETS regimes, the tobacco lounge. The tobacco lounge merits particular attention, not only because it presents an intuitively strong case for exemption, but also because exemptions currently in operation are varied and uneven, producing substantial regulatory confusion. As we have seen, some states provide tobacco lounges with a permanent per se exemption, generally defining the establishments as those that derive a large percentage of revenue from the on-site sale of tobacco products. Others include a limited grandfather clause exemption for cigar bars, unwilling to countenance immediate destruction of local or cultural landmarks, or perhaps unwilling to provide proprietors of existing tobacco lounges with the incentive to raise strenuous and perhaps compelling objections. Finally, Class V regimes simply prohibit the operation of tobacco lounges altogether. Conceptual boundaries, however, are not always neatly drawn, leading to confused implementations of exemptions relating to tobacco lounges. Some states preserve a retail exemption, but not a cigar bar exemption, so retailers have begun to construct smoking lounges to provide a home for vagrant regulars of disestablished cigar bars.[199] Some states exempt hookah bars, but not cigar bars, and others have done the opposite. Particularly uncompromising ETS regimes have produced "smoke-easies," or underground smoking bars, in many cities.[200]

Much of this confusion can be attributed to the fact that tobacco lounges, a rare species of public establishment, are poorly understood. Legislators may lack familiarity with the subject. Additionally, many shisha cafés and hookah bars are cultural outposts in ethnic enclaves that interface infrequently or ineffectively

198. GEORG SIMMEL, THE METROPOLIS AND MENTAL LIFE (1903), *reprinted in* GEORG SIMMEL ON INDIVIDUALITY AND SOCIAL FORMS 339 (Donald N. Levine ed., Univ. of Chicago Press 1971).

199. David Savona, *A Smoker's Last Refuge*, CIGAR AFICIONADO, Sept./Oct. 2007, *available at* http://www.cigaraficionado.com/Cigar/CA_Archives/CA_Show_Article/0,2322,2065,00.html (noting trend among retail shops to create smoking lounges).

200. *See, e.g.*, Stu Bykofsky, *"Smoke-easys" Ignore the Tobacco Ban*, PHILA. DAILY NEWS, Mar. 26, 2007, at 6; Charlie Vascallero, *Smoke-Easies Offer Cover from Puff Police; Aficionados Just Want a Place To Light Up, Relax*, WASH. TIMES, Nov. 20, 2003, at M14. Some attempts are more creative, including "theater night" at Minneapolis bars, designating costumed patrons "actors" and their cigarettes "props." This attempt failed. Of particular interest from a law and economics perspective is the approach taken by an Iowa citizen, who openly rents ashtrays for $1 to patrons under the theory that the revenues will pay for the fines she incurs for violations. Scott Niles, *Owner Wants State To Butt Out: Birmingham Bar Allows Smoking*, OTTUMWA COURIER (Iowa), Sept. 12, 2008, *available at* http://www.ottumwa.com/local/local_story_256232617.html.

with the machinery of state and local government. As a result, tobacco lounges may remain analytically undifferentiated from conventional bars and cafés, the primary target of ETS legislation.

Furthermore, tobacco lounges rarely have informed advocates who can effectively assess their proper place within ETS regimes. Comprising a tiny slice of hospitality markets, and unrepresented by specific lobbies or activist groups, these establishments must rely on membership in licensed beverage associations that take a much more absolutist and oppositional approach than is appropriate in the context of tobacco lounges. General hospitality lobbies have no interest in demonstrating the unique circumstances of such a narrow interest, however compelling, for to do so would be to undercut their more sweeping, industry-wide opposition to the proposals. Indeed, it can be far easier for legislators to ignore the conceptual difficulties posed by tobacco bars than it is to tailor legislation closely to their circumstances within an ETS regime. Under these circumstances, the application of our balancing test to the tobacco lounge exemption is especially warranted.

This test will aid legislators in isolating the merits and demerits of the tobacco lounge exemption. Additionally, the test will help evaluate different types of tobacco bar exemptions, a function particularly useful given the panoply of available exemption mechanisms.

In this Part, I apply the balancing test in detail to tobacco bar exemptions. I begin by establishing portraits of the two most common types of tobacco lounges. Then I consider the extent to which tobacco lounges infringe on the statutory purpose of ETS legislation, and evaluate virtue defenses tobacco lounges may offer. After weighing these two prongs, I evaluate different tobacco bar exemption mechanisms in the context of the virtues and vices illuminated by the balancing test. Finally, I propose a new mechanism for the exemption of tobacco lounges within the context of effective ETS legislation.

A. Shisha Cafés and Cigar Bars

There are two types of tobacco lounge: the cigar bar, and the shisha café or hookah bar. The hookah bar, a modern descendant of the traditional Middle Eastern coffeehouse, is a small café in which patrons gather to drink coffees or teas and smoke shisha, a fruit-flavored tobacco, through an elaborate, stationary water-pipe called a hookah or nargile.[201] Typically owned by Yemeni,

201. *See* Grehan, *supra* note 2, at 1356 ("First popularized in India and Iran during the early seventeenth century, [the hookah] had quickly migrated westward to the Ottoman Middle East."); Kilgannon, *supra* note 58 (reviewing shisha cafés "owned mostly by Egyptian immigrants" who "contend that hookah smoking is a vital part of their culture"); Sebnem Timur, *The Eastern Way of Timekeeping: The Object and Ritual of* Nargile, DESIGN ISSUES, Spring 2006, at 19, 20.

Moroccans, Egyptians, and other Arab nationals, shisha cafés function as cultural centers in traditionally Middle Eastern enclaves in major cities.[202] Smoking a hookah can take an hour.[203] Increasingly, college students are becoming occasional patrons of hookah bars.[204] Patrons gather at hookah bars for shisha, culture, and camaraderie, finding hookah bars uniquely conducive to public socializing.[205]

The cigar bar is a similarly small operation in which patrons gather to smoke cigars. An intimate establishment with few employees—typically a bartender or barista, and a cigar expert—cigar bars function as local gathering places in urban areas. Unlike shisha cafés, cigar bars are often licensed premises, serving cocktails and liquors in the evenings, though during the afternoons many serve espresso drinks. Beverages, however, are a peripheral complement to the primary item sold at cigar bars, the cigar. Cigar bars sell only so-called "premium" cigars, or hand-rolled cigars consisting of long-leaf tobacco made by family-owned companies in Honduras, Nicaragua, or the Dominican Republic.[206] Sold for

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202. *See* Kilgannon, *supra* note 58; Bill Werde, *A Sad Ballad for the Water-Pipe Cafes of Astoria*, N.Y. TIMES, Feb. 23, 2003, § 14, at 7 (quoting patron as lamenting that "[s]hisha to an Arab is like cappuccino to an Italian. If this cafe closes, my social life will be shut down").

203. *See* Timur, *supra* note 201.

204. Tamar Lewin, *Collegians Smoking Hookahs . . . Filled with Tobacco*, N.Y. TIMES, Apr. 19, 2006, at B9 (quoting collegiate patron as saying that "[i]t's just a nice way to relax and be sociable").

205. Peter Kandela, *Nargile Smoking Keeps Arabs in Wonderland*, 356 LANCET 1175, 1175 (2000) ("In traditional Arab society. . . the nargile signifies a social occasion in which everyone can participate . . ."); Kilgannon, *supra* note 58 (quoting patron as saying that "[s]moking [shisha] brings our people together"); Werde, *supra* note 202 (quoting patron as saying that "people come to these cafes to sit with friends and smoke shisha").

206. The designation "premium" does not reflect pricing, which can range from three dollars to over twenty dollars. It merely distinguishes the cigars from the flavored, machine-made "blunts" with cardboard fillers and chemical additives manufactured by major cigarette companies and sold at drugstores and gas stations. *See* NAT'L CANCER INST., SMOKING AND TOBACCO CONTROL MONOGRAPH NO. 9: CIGARS: HEALTH EFFECTS AND TRENDS 52 (1998), *available at* http://cancercontrol.cancer.gov/tcrb/monographs/9/index.html (noting that large inexpensive cigars and cigarettes account for over 60% of "cigar" sales, while large premium cigars account for 6.5%). Cigar bars do not offer blunts, which have only been designated "cigars" to evade the stricter ingredient disclosure requirements triggered by a "cigarette" label. *See* Cristine D. Delnevo, *"A Whole 'Nother Smoke'" or a Cigarette in Disguise: How R.J. Reynolds Reframed the Image of Little Cigars*, AM. J. PUB. HEALTH, Aug. 2007, at 1373; David Satcher, *Cigars and Public Health*, 340 NEW ENG. J. MED. 1829, 1830-31. This point deserves particular emphasis, because the important distinction has been blurred by health advocates who have cited a rise in "cigar" smoking among urban youth as part of a call for more severe regulation. This extension of guilt by association makes for poor regulation, for by failing to distinguish between these very different products, different consumption habits are conflated.

consumption on the premises, premium cigars are stored in large wall-mounted humidors, and some cigar bars rent out "lockers," or small humidors in the wall, in which regular patrons can store their favorite cigars. Cigar bars generally install the most sophisticated ventilation systems available. Even in states that exempt cigar bars, there are never more than a few per city—major metropolitan areas may have as many as five,[207] where smaller cities have fewer, if any.[208]

Patrons come to cigar bars for premium cigars and conversation.[209] Smoking a premium cigar takes between thirty and sixty minutes, and cigar smokers are somewhat like oenophiles in preferring tobaccos from different soils, regions, and different curing processes.[210] Cigar smokers tend overwhelmingly to be

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207. For example, New York City has five cigar bars: the Carnegie Club, Club Macanudo, Bar and Books (Hudson), Bar and Books (Lexington), and Merchant's NY.

208. For example, New Haven, Connecticut has one cigar bar: the Owl Shop.

209. Indeed, to enter a cigar bar without the intention of having a cigar is extremely unusual. This is an important point, and it explains why this Note seems to ignore cigarette smokers. This Note focuses on cigar and hookah lounges because these establishments only attract smokers, and similar establishments have not yet materialized for cigarette smokers. Indeed, the tightly defined cigar bar exemption which will take effect in Oregon in 2009 expressly prohibits the smoking of any tobacco products other than cigars, presumably for this very reason. *See* 2007 Or. Laws 602, § 1(c) (requiring cigar bars to prohibit "the smoking of all other tobacco products in any form including, but not limited to, loose tobacco, pipe tobacco, cigarettes as defined in ORS 323.010 and cigarillos as defined by the Department of Human Services by rule"). That this reflects a rationale presuming the self-selective nature of cigar smokers is suggested by the waiver provisions that apply in the interim, before the cigar bar exemption is triggered. OR. REV. STAT. § 433.865(2) (2007) (permitting waivers where a "waiver will not significantly affect the health and comfort of nonsmokers"). Cigarette lounges, however, are not unthinkable under a per se exemption, and many of the same arguments would apply if some mechanism were established which would put potentially non-consenting individuals fully on notice, and the number of these establishments were restricted sufficiently to avoid the captive employee problem. In fact, R.J. Reynolds opened a showroom "cigarette lounge," Marshall McGearty's, in Chicago in 2005. The establishment surrendered its liquor license early on to operate under a retail exemption, and as the statewide ban loomed, it attempted creative solutions such as providing coffee free of charge and contemplated a bring-your-own-beverage policy. It ultimately closed soon after the statewide ban passed. *See* Newcity Chicago, *411: Seven Days in Chicago*, Jan. 15, 2008, http://www.newcitychicago.com/chicago/7346.html.

210. Cigar reviews read very much like wine reviews. *See, e.g.*, Dale Roush, *Camacho Diploma Cigar Review*, CigarJack.net, http://www.cigarjack.net/2008/03/14/camacho-diploma-cigar-review/#comment-5765 (last visited Nov. 17, 2008) ("The flavors start out nutty with toasted wheat. . . . Leather, exotic spice and damp earthiness join the chorus. The room aroma is heady and intoxicating. In the final third, the cigar just becomes full on power, yet no harshness. Pepper creeps in, the savory grain flavors subside . . . . The finish is long and retains that blend of leathery spice.").

"occasional" smokers, enjoying cigars infrequently.[211] An afternoon or evening at a cigar bar is a relaxed social occasion, and proprietors pride themselves on the conversational and civil character of their destinations. Decor is structured accordingly: couches and clusters of armchairs are the essence of traditional cigar bar design. Chess tables are common fixtures. Despite the well known stereotype of cigar smoking as an activity practiced by rich white males on Wall Street,[212] cigar smoking is increasingly gender-balanced[213] and socioeconomically diverse.[214] Indeed, proprietors pride themselves on inclusiveness.[215]

B. Contravention of Statutory Intent?

The first prong of the test provides an opportunity to consider the specific circumstances of tobacco bars, divorced from imperfect analogies to conventional bars and cafés. Tobacco lounges interface differently with the intent of modern ETS legislation, but these differences are often elided. The purpose of ETS legislation is to prevent involuntary exposure to tobacco smoke. As tobacco lounges are patronized exclusively by consensual smokers, the concerns that attach to restaurants and bars simply fail to apply. It would be superfluous to belabor this point, but its simplicity should not undo its force: The primary justification for ETS legislation *does not apply to tobacco lounges.*

By reversing the default rule, modern statewide bans moot the "captive employee" problem to which hospitality workers were once subject. The

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211. Cigar smokers are overwhelmingly "occasional." *See* NAT'L CANCER INST., *supra* note 206, at iii ("Most cigarette smokers smoke every day. In contrast, as many as three quarters of cigar smokers smoke only occasionally, and some may only smoke a few cigars per year."); Elizabeth A. Gilpin & John P. Pierce, *Cigar Smoking in California: 1990-1996*, 16 AM. J. PREVENTATIVE MED. 195, 195-97 (1999); A.L. Nyman, T.M. Taylor & M. Biener, *Trends in Cigar Smoking and Perceptions of Health Risks Among Massachusetts Adults*, 11 TOBACCO CONTROL (Supp.) ii25, ii26 (2002).

212. *See, e.g.*, WALL STREET (Amercent Films 1987) (main character curries favor with Wall Street tycoon Gordon Gekko by delivering a box of Cuban cigars).

213. *See* NAT'L CANCER INST., *supra* note 206, at 11 ("Increasing numbers of women, who historically have had very low rates of cigar use, are currently smoking cigars."); Gilpin & Pierce, *supra* note 211, at 199; Michael S. LaTour, Tony Henthorne & Kathryn Braun-LaTour, *Is a Cigar Just a Cigar? A Glimpse at the New-Age Cigar Consumer*, ACAD. OF MKTG. SCI. REV., 2003, at 9, http://www.amsreview.org/articles/latour12-2003.pdf (noting signs that "mixed gender and 'all-female' cigar 'outings' were becoming part of the cigar culture"); Nyman et al., *supra* note 211, at ii26. Cigar-smoking has been described as characteristic of third-wave feminists, who are "likely to be found at the 'local cigar bar.'" Jennifer Purvis, *Grrrls and Women Together in the Third Wave: Embracing the Challenges of Intergenerational Feminism(s)*, NAT'L WOMEN'S STUDS. ASS'N J., Fall 2004, at 93, 96.

214. Gilpin & Pierce, *supra* note 211, at 198-99.

215. *See* Savona, *supra* note 199.

assignation of this problem to tobacco lounges has always been somewhat unpersuasive. First, they are numerically scarce, making it far easier to get a job at a conventional restaurant or bar than at a rare specialist shop with few employees. Second, employees are largely self-selecting: bartenders often choose to work at tobacco bars because of an interest in the product. Personnel managers, in fact, screen non-smokers for an eminently practical reason: employees uncomfortable in smoky environments will likely be ineffective bartenders in tobacco lounges. In the context of the new default rule created by ETS legislation, however, the "captive employee" argument evaporates. Jobs in tobacco lounges, already scarce and selective for bartenders and baristas who have an interest in shisha or cigars, are coveted by bartenders who smoke.

So do tobacco lounges offend the statutory intent of statewide ETS legislation? Simply put, they do not. Patrons actively consent, entering tobacco lounges for the purpose of smoking. As ETS legislation flips the default in the hospitality industry from smoking to non-smoking, jobs at the few tobacco lounges in major metropolitan market become increasingly competitive, and already dubious concerns about employee coercion disappear. In fact, recent studies suggest that preserving a few public places where smokers can enjoy a cigar or hookah with friends away from the home might actually further the purposes of ETS legislation: economists have found that smokers are smoking more frequently at home after restrictive ETS legislation is passed.[216] The operation of a tobacco lounge fails to expose non-consenting individuals to secondhand smoke in public and does not offend the statutory intent of modern ETS legislation.

C. Virtue Defense

Poorly understood and unrepresented by specific lobbies, the civic virtues peculiar to cigar bars and shisha cafés have gone largely unacknowledged. Though the economic arguments unsuccessfully raised by restaurants and bars in opposition to ETS legislation obtain with unique force in the context of tobacco lounges, no affirmative reason for exemption has been heard. In applying the second prong of our balancing test to tobacco lounges, the distinctive social role served by these establishments can be accounted for, and an unintended casualty of ETS legislation can perhaps be preserved. Furthermore, understanding the virtues of cigar bars and shisha cafés will assist legislators and health department officials in tailoring exemptions to promote important civic functions.

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216. *See, e.g.*, Jérôme Adda & Francesca Cornaglia, *The Effect of Taxes and Bans on Passive Smoking* 19-25 (Inst. for the Study of Labor, Discussion Paper No. 2191, July 2006) (observing increased exposure of non-smokers to secondhand smoke produced by the "displacement effect" when smoking is banned in recreational destinations).

The proposition that public spaces that promote social exchange between members of society play a vital role in a healthy democracy is well rehearsed. Sociologists and political scientists have spilled a great deal of ink on this idea, pursuing influential conceptualizations such as Habermas's "public sphere"[217] and Arendt's "public realm."[218] Crudely generalizing, these theses demonstrate the ways in which publicness, particularly in the form of public interactions between individuals that promote the forming of social ties and the exchange of ideas and perspectives, bolsters healthy political community in a democracy by providing an arena where public opinion can be formed, promoting interaction with and understanding of different perspectives, and encouraging civic engagement and mobilization.

An equivalent wealth of attention has been devoted to diagnosing what emerges as a chief feature of the twentieth century—the erosion of publicness and the disintegration of civic community. Habermas and Arendt highlight these problems, respectively, in *The Structural Transformation of the Public Sphere* and *The Human Condition*; similar analyses have followed in their footsteps.[219] Recently, Robert Putnam has renewed the immediacy of these concerns, painting a stark portrait of "the decimation of American community life" in his sweeping study of American community and civic engagement, *Bowling Alone*.[220] By all available markers, every form of community involvement has receded,[221] political participation has plummeted,[222] and informal social connectedness has collapsed.[223] Americans are increasingly unlikely to meet new people or make new friends; they are prone to stay at home in the evenings and are loath to participate meaningfully in civic organizations or politics.[224] This disappearance of "social capital," Putnam argues, has severely undermined the health of our democracy.[225]

The effects of this phenomenon are particularly stark in cities. Social

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217. Habermas defines his influential conception of the public sphere as "a realm of our social life where something approaching public opinion can be formed." Jürgen Habermas, *The Public Sphere: An Encyclopedia Article,* NEW GERMAN CRITIQUE, Autumn 1974, at 49, 49; *see also* JÜRGEN HABERMAS, THE STRUCTURAL TRANSFORMATION OF THE PUBLIC SPHERE (Thomas Burger trans., MIT Press 1989) (1962).

218. HANNAH ARENDT, THE HUMAN CONDITION (1958).

219. *See, e.g.*, RICHARD SENNETT, THE FALL OF PUBLIC MAN (1978).

220. ROBERT PUTNAM, BOWLING ALONE: THE COLLAPSE AND REVIVAL OF AMERICAN COMMUNITY 42 (2000).

221. *Id.* at 41.

222. *Id.* at 38-39.

223. *Id.* at 108 ("[I]nformal social connectedness has declined in all parts of American society.").

224. *Id.* at 154-66.

225. *Id.* at 339-49.

theorists have long observed the unique predisposition of urban life to erode community ties.[226] Recently, the call has been raised for renewed attention to the effects of the character of urban life on the health of American democracy.[227]

These trends throw the virtues of tobacco lounges into sharp relief. Given the importance of the public sphere, and its striking recession in modern American cities, places that promote social publicness assume heightened importance. The coffeehouse has long served as the paradigm-setting anchor for a vibrant public sphere: indeed, Habermas located the inception of the public sphere in the English coffeehouses of the eighteenth century. In those cheery places, conceptually situated between the privacy of the home and the formal publicness of state affairs, patrons gathered to drink a "dish" of coffee, smoke a tobacco-pipe, and discuss affairs of common concern. The aristocracy was brought face-to-face with "intellectuals of the middling sort," and conversation was grounded by the literary and political pamphlets strewn about the coffeehouses.[228] Today, however, we are hard-pressed to think of establishments—usefully termed "third places," or places where informal conversation arises between non-intimates in public—that play this role.[229]

Tobacco lounges in modern cities, however, have taken up the role attributed to the early coffeehouses and abandoned by their modern, branded counterparts. Indeed, Habermas's typology of the elements that made coffeehouses such

226. *See* JANE JACOBS, THE DEATH AND LIFE OF GREAT AMERICAN CITIES (1961) (highlighting the dissociative pressures of city life); SENNETT, *supra* note 219, at 121-22 (surveying the "end of public life" in cities against a backdrop of the eighteenth-century metropolis); SIMMEL, *supra* note 198, at 329 (noting the blasé attitude of city dwellers and the isolation of urban life).

227. Susan Bickford, *Constructing Inequality: City Spaces and the Architecture of Citizenship*, POL. THEORY, June 2000, at 355, 355 (seeking "to reconnect political theory to the study of cities by probing the link between built environment, public life, and democratic politics").

228. The finer points of Habermas' description of eighteenth-century English coffeehouses have been picked at by historians for descriptive accuracy, but, as has been observed, his articulation of the virtues inherent in these places is better understood as comprising a normative claim for their value. *See* Markman Ellis, *Introduction* to 1 EIGHTEENTH-CENTURY COFFEE-HOUSE CULTURE, at xvii (Markman Ellis ed., Pickering & Chatto 2006).

229. Ramon Oldenburg & Dennis Brisset, *The Third Place*, 5 J. QUALITATIVE SOC. 265, 267 (1982). In *The Great Good Place*, Oldenburg makes a case for a similar role played by modern-day coffee shops. RAY OLDENBURG, THE GREAT GOOD PLACE (1989). As the leading scholar of coffeehouses has observed, however, "in their ubiquity, and uniformity, the branded coffee-shops also seem to reinforce the feelings of emptiness and alienation caused by modern life." Ellis, *supra* note 228, at xiii. Local, independent coffeehouses, sponsoring book discussions, reading groups, and distributing local pamphlets and bulletins, may yet carry the torch, but the dominance of branded chains and an oppressive to-go mentality have increasingly eroded the ability of modern-day coffee shops effectively to discharge the civic function of their antecedents.

exemplary foci for the public sphere applies neatly to tobacco lounges.[230] Tobacco lounges contain the essential elements of the coffeehouses Habermas found so crucial to the public sphere: they are conducive to an unfettered range of debate and conversation, they are relatively non-hierarchical, and they are accessible and inclusive.

First, and most importantly, tobacco lounges are centers of public conversation. This is partially inherent in the nature of the product—patrons associate the cigar or hookah with conversation, and their expectations shape social interactions at tobacco lounges.[231] Indeed, in both cases, the product is extremely conducive to conversation—a premium cigar or a shisha pipe takes a relatively long time to smoke, creating a situational stability which encourages longer and more in-depth discussions. Additionally, conversations frequently spring up between complete strangers who share this common interest.[232] Evidence can be found all over the Internet: As ETS legislation eliminates local tobacco lounges, a rich online community of cigar enthusiasts has grown up in chat rooms and discussion boards, seeking to recreate online the conversations which once sprung up spontaneously in public.[233] The traditionally conversational character of tobacco lounges is reinforced by operational features. Unlike conventional bars, tobacco lounges remain open during the daytime hours, and the atmosphere during daytime hours is even more conversational. Indeed, patrons of tobacco lounges become irritated when their local institutions become more like conventional bars, with increased volume levels and patron density.[234] The physical arrangement of tobacco lounges promotes relaxed conviviality—ottomans, lounge chairs, and small tables are the norm, instead of standing-room cocktail tables or a monolithic bar.[235] Additionally, tobacco

230. Ellis characterizes these elements as 1) non-hierarchical, 2) encouraging an unfettered range of debate and conversation, and 3) accessible and inclusive. Ellis, *supra* note 228, at xv.

231. *See* LaTour, Henthorne & Braun-LaTour, *supra* note 213. Of twenty-two patrons at the Owl Shop in New Haven, CT between 3:30 p.m. and 4:30 p.m. on a Saturday afternoon, seventy-six percent found the Owl Shop extremely conducive to conversation, and five respondents independently attributed this to a shared affinity for cigars, citing "a common bond," "something in common," and observing that "cigars open up people to talk." Survey results on file with author.

232. Forty-five percent of survey respondents at the Owl Shop reported conversing "often" with new people; forty-one percent reported doing so "sometimes."

233. A thriving online community of cigar-smokers, discussing everything from cigars to music, sports, and politics, has emerged. *See, e.g.*, Brothers of the Leaf, Community Forums, http://www.botl.org/community/forums (last visited Nov. 17, 2008); SocialCigar.com, Social Cigar Forum, http://www.socialcigar.com/forum (last visited Nov. 17, 2008).

234. Dave Thier, *Owl Shop: Old Yale in New Haven*, YALE DAILY NEWS, Nov. 9, 2007, at B4 (citing longtime patrons' disgust with bar-like atmosphere at night).

235. *See* Vascallero, *supra* note 200 (quoting a patron: "There's a certain atmosphere about a cigar bar where you feel more relaxed").

lounges often subscribe to multiple periodicals, which, as they did in eighteenth-century England, ground conversations.

Second, tobacco lounges are non-hierarchical. Patrons are surprisingly socioeconomically diverse[236] and represent a wide range of occupations.[237] Certainly the products are not priced prohibitively: a cigar or shisha costs about as much as a drink at a conventional bar, and it lasts much longer.[238] Cigar bars are no longer the province of Wall Street fat cats; hookah is no longer an ethnic curiosity. And by remaining open during the daytime hours, the tobacco lounge can serve as a gathering place for individuals in different professions, particularly the hospitality industry and retirees, who might otherwise not join the happy hour crowd.

Third, tobacco lounges are accessible and inclusive, serving in many cases as a center of local or cultural community. Operational characteristics help to explain this phenomenon as well—by remaining open during the day, tobacco lounges assume a perpetual presence in the social life of a city that conventional bars are unable to replicate. The uniquely conversational nature of tobacco lounges serves to make these places particularly inviting for local residents in search of relaxed, informal time with fellow residents. For shisha cafés, the accretion of local character is related to cultural traditions—the hookah bar functions as a neighborhood gathering place for Middle Eastern residents. The inviting character of cigar bars develops along more strictly local lines—cigar bars function as gathering places for those who enjoy cigars, and they assume a local character and identity along with a crowd of regulars.

In asserting the uniquely conversational aspect of tobacco lounges, it is not necessary to claim that the social capital of a modern metropolis relies exclusively on tobacco lounges. It is sufficient simply to note that tobacco lounges can be a fertile source for social capital and community vitality. Undoubtedly, not all tobacco lounges meet the aspirations of the ideal "third place," nor is a shisha café or cigar bar always a perfect microcosm of political society. Nor is it necessary to argue that the cigar bar or shisha lounge is so inviting and accessible as to exercise an inexorable draw on all passers-by. It is sufficient that for those who choose to smoke shisha or cigars, tobacco lounges are welcoming establishments. Indeed, an enjoyment of cigars or shisha cuts across factors that are often linked to exclusion and hierarchy, such as race, class, and gender.

Though rare, and though hardly indispensable to the expression of a rich

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236. *See* NAT'L CANCER INST., *supra* note 206, at 36; Gilpin & Pierce, *supra* note 211, at 198.

237. The Owl Shop survey returned an extremely varied list of occupations ranging from blue to white collar, skilled labor to service industry, hospitality to delivery, student to professional.

238. *See* Lewin, *supra* note 204 (quoting a student patron explaining the relative inexpensiveness of a night at a hookah bar).

urban community, tobacco lounges play a role in modern cities that is both increasingly rare and valuable, functioning as a rich locus for the expression of the public sphere. As Habermas observed, "A portion of the public sphere comes into being in every conversation in which private individuals assemble to form a public body."[239] Places that promote this phenomenon warrant special attention. Not all individuals enjoy cigars or smoke hookah, but the tobacco lounge nonetheless creates a vibrant public sphere where individuals from varying walks of life assemble to enjoy a common pastime and conversation. And according to scholars who evaluate the health of democracy in modern America, this is precisely what we need more of.

D. Evaluation

Applying the balancing test, there is a clear case in favor of exemption. On the one hand, though the tobacco lounge plays a unique role in the social fabric of a city and addresses a pressing item of concern to American democracy, it is hardly the keystone by which the entire edifice will stand or fall. On the other hand, the tobacco lounge fails entirely to offend the purpose of statewide ETS regimes. With an informed and consenting patron base, the open and notorious shisha café or cigar lounge presents a fundamentally different case than restaurants and bars, the main targets of ETS legislation. Employees are fully on notice of the centrality of their product to the establishment, and the rarity of tobacco lounges in the hospitality industry means not only that the choice to work at such an establishment is meaningful, but also that jobs are hotly contested.

In the absence of specific guidance from ballot initiative states on this point, or clearer statements of legislative intent beyond a broad construction clause and general solicitude for the health of employees, failure to exempt tobacco lounges, which present a unique circumstance under a conventional ETS regime, simply exceeds the regulatory warrant.

E. Exemption Schemes

But how to exempt? Given the panoply of available models, legislators may find it difficult to evaluate the merits of exemption schemes. Here, the balancing test can provide useful guidance. On the one hand, care must be taken to ensure that the first side of the scale does not become overbalanced, and that conventional bars and cafés do not secure frivolous exemptions and subvert the default rule. On the other hand, the virtues of the tobacco lounge must be enabled by the exemption. Care must be taken to ensure that the exemption is meaningful and that clever definitions or practical consequences do not render the exemption

239. *See* Habermas, *The Public Sphere: An Encyclopedia Article*, *supra* note 217, at 49.

illusory.

Ohio's proposed amendment fails the first avenue of analysis. Merely by constructing some form of on-site, walk-in humidor, and purchasing an inexpensive air filter, a bar can become a "cigar bar" and permit its patrons to smoke. This undermines the self-selective nature of traditional cigar bar patrons, and may expose the unwilling to secondhand smoke. On the second, as we have seen, cigar bars and shisha cafés are virtuous precisely because their products—premium cigars and hookah—are particularly conducive to conversation and local traditions. Permitting any bar with the wherewithal to engage in minor remodeling to become a dumping ground for revelers who hope to avoid interrupting the continuity of a night's drinking for periodic sidewalk cigarette breaks largely unseats the virtue defense. Accordingly, a per se exemption, if defined as in Ohio's Senate Bill 195, is unwise.

Grandfather clauses are similarly problematic. Laxity of principle is just the beginning: A first-iron rule for proprietors of existing tobacco lounges begs the question, from a public health perspective, why some if not all? More worrying, however, are the long-term effects of the grandfather clause. By withdrawing exemption upon change in ownership, grandfather clauses function as a maturing death warrant. Additionally, in preventing tobacco lounges from opening in the future, a grandfather clause grants a functional monopoly to incumbents, creating an incentive to leverage the monopoly on smoking in public by catering to a captive market of cigarette smokers who have been expelled from conventional bars and increasing the volume of alcohol sales. Rather than exempting cigar bars, these poisonous exemptions maim their character and destroy their virtues.[240]

The best tobacco lounge exemptions currently in place are the per se exemptions that define tobacco bars as those receiving a certain percentage of gross profits from the on-site sale of tobacco products for consumption. This scheme effectively balances the competing concerns by preventing conventional bars from subverting the default rule while protecting the shisha or cigar focus of the establishment, thus preserving the virtue defense. Given the realities of pricing, however, and the fact that drinks tend to be more profitable than cigars or hookah, these lines can be difficult to draw. Some establishments have taken to adding a cigar surcharge to meet requirements; some hookah bars simply cease to sell the more expensive alcohols. Most cigar lounges simply raise the prices of cigars, eroding the diversity characteristic of traditional lounges. Furthermore, with sufficient ingenuity, proprietors of conventional bars might be able to manipulate ledgers to satisfy exemption requirements. A superior per se definition might track Oregon's efforts to stipulate the structural characteristics

240. 2007 Or. Laws 1557, § 1(c), 1(g) (limiting seating capacity of grandfathered cigar bars to 40 patrons and prohibiting smoking anything but cigars).

of traditional cigar bars, but regulations at this level of detail are likely to be imperfect and exploitable.

One mechanism that has not been proposed, but which may furnish an optimal way to balance the twin concerns of responsible ETS legislation, may lie with local governments.[241] Empowering local boards of health in conjunction with chambers of commerce to license the on-site sale of tobacco in much the same way that liquor licenses are currently issued would permit establishments to be judged on a case-by-case basis, and more precisely evaluated for offense against the integrity of the ETS regime on one hand and preservation of civic virtues on the other.[242] Establishments that fail to live up to the ideal would be denied licenses, and the threat of revocation would ensure continued compliance. This solution effectively manages the first concern, as boards of health can promulgate guidelines for distinguishing authentic tobacco lounges from profit-seeking chameleons that pose a public health threat. The possibility of institutional overreaching by aggressive health commissioners might be effectively countered by the inclusion of members of the chamber of commerce on the review committee, and guidance could be provided in the form of a specific committee charge contained in the exemption language, which would stipulate that the exemption is to be discharged in a manner as consistent as possible with promoting the vitality of local and cultural community at tobacco lounges.

CONCLUSION

Many states have made inspiring progress in combating the involuntary exposure of their citizens to secondhand smoke, reversing the default rule on smoking in public. Twenty-five states currently have modern statewide bans on

241. Massachusetts' excellent definition comes quite close to implementing this model. MASS. GEN. LAWS ch. 270, § 22 (Supp. 2008) ("an establishment that occupies exclusively an enclosed indoor space and that primarily is engaged in the retail sale of tobacco products for consumption by customers on the premises; derives revenue from the sale of food, alcohol or other beverages that is incidental to the sale of the tobacco products; prohibits entry to a person under the age of 18 years of age during the time when the establishment is open for business; prohibits any food or beverage not sold directly by the business to be consumed on the premises; maintains a valid permit for the retail sale of tobacco products as required to be issued by the appropriate authority in the city or town where the establishment is located; and, maintains a valid permit to operate a smoking bar issued by the department of revenue"). This is perhaps the finest definition currently in place.

242. This has been employed as a temporary measure in Oregon until the more restrictive provisions of the statute kick in. The current statute provides that the prohibition can be waived by the Department of Human Services "for any public place if it determines that: (1) There are valid reasons to do so; and (2) A waiver will not significantly affect the health and comfort of nonsmokers." OR. REV. STAT. § 433.865 (2007).

the books—and relying on municipalities in Class II and III states to make up the balance, we can declare with some confidence that we have reversed, however narrowly, the national default rule on smoking in public. Increasingly, Americans live in a country in which the non-consenting need not fear exposure to secondhand smoke. The challenge, going forward, will be to ensure that the default rule is reversed in a responsible manner.

In some states, this will still mean passing more rigorous legislation. These states are rapidly disappearing, however. As we have seen, Class I is nearly extinct. South Dakota attempted to pass a statewide smoking ban, and even North Carolina is beginning to show willingness to regulate smoking in some public places. In Indiana, the state's recent failure to arrive at a workable compromise on an ETS bill may produce a ballot initiative in the near future.[243] Legislatures must take a proactive role if they hope to avert the type of deliberative catastrophe that struck Ohio. And it ought to be remembered that even in strong ban states, a number of exemptions might warrant examination under the balancing analysis articulated in this Note, particularly casinos and performance spaces.

In most other states, the challenge will be ensuring that the new default rule is implemented in a responsible manner, tailoring strong ETS regimes to remedy unduly draconian provisions. In Ohio, with the disposition of the Solicitor General's suit, it will be the task of the General Assembly to undo the damage done to public trust by the unfortunate passage of the Smoke Free Workplace Act. Several proposed exemption bills sit in committee, and the legislature will face a difficult task in evaluating and amending the proposals. The cigar bar exemption is deeply unsatisfactory and in need of redrafting, and the other two bills will introduce significant and very different changes to the state's ETS regime. All twelve Class V states, but particularly the ballot initiative states Ohio, Washington, and Arizona, would be well served to take a direct look at tobacco lounge exemptions. This Note has attempted to provide some guidance in this enterprise, shedding light on the landscape of laws and highlighting some areas of concern presented by modern ETS regimes. Ballot initiatives, in particular, raise disturbing questions, and tobacco lounges may warrant more attention and better advocates than they have received. The balancing test proposed in this Note may prove to be a useful tool for legislators in crafting exemption schemes that both prevent unwilling exposure to environmental tobacco smoke and preserve virtuous and unoffending spaces.

This Note achieved its goal, however, if it imposed some order on the corpus of statewide smoking bans and drawn attention to a regulatory juggernaut that

243. Woster, *supra* note 39 ("After the decision [to reject a bill that would have given local governments the power to regulate ETS], Gov. Mike Rounds said he wouldn't be surprised by a statewide initiative on local control of tobacco, or on a total ban on smoking.").

threatens exemptions on principle, whether repugnant to the public health purpose of ETS legislation or not. Exemption provisions warrant a more searching examination than they have hitherto been afforded, for they are indeed the beating heart of responsible ETS legislation.

APPENDIX A: STATEWIDE ETS LEGISLATION

(Complete and accurate to September 17, 2008)

State	Statewide ETS Law in effect	Modern Statewide Ban?[244]	Effective Date	Class	Smoking permitted in retail tobacco stores?	Smoking permitted in tobacco lounges?
AL	ALA. CODE §§ 22-15A-1 to -10	No	2003	II	Yes	Yes
AK	ALASKA STAT. §§ 18.35.300 to .365	No	1990	II	Yes	Yes
AZ	ARIZ. REV. STAT. ANN. § 36-601.01	Yes	2007	V	Yes	No
AR	ARK. CODE ANN. §§ 20-27-1801 to -1809	Yes	2006	III	Yes	Yes[245]
CA	CAL. LAB. CODE § 6404.5	Yes	1997	IV	Yes	Yes
CO	COLO. REV. STAT. ANN. §§ 25-14-201 to -209	Yes	2006	IV	Yes	Yes*
CT	CONN. GEN. STAT. § 19a-342	Yes	2004	IV	No	Yes*
DE	DEL. CODE ANN. tit. 16, §§ 2901 to 2908	Yes	2002	V	No	No
DC	D.C. CODE §§ 7-741 to -747	Yes	2007	IV	Yes	Yes
FL	FLA. STAT. §§ 386.201 to .2125	Yes	2003	III	Yes	Yes
GA	GA. CODE ANN. §§ 31-12A-1 to -13	Yes	2005	III	Yes	Yes
HI	HAW. REV. STAT. §§ 328J-1 to -15	Yes	2006	V	No	No
ID	IDAHO CODE ANN. §§ 39-5501 to -5511	No	2004	III	Yes	Yes

244. Reverses default rule by prohibiting smoking in restaurants and bars.

245. The statute's exemption applies to *all* bars, not merely tobacco bars.

* Designates a tobacco lounge exemption via grandfather clause.

State	Statewide ETS Law in effect	Modern Statewide Ban?[244]	Effective Date	Class	Smoking permitted in retail tobacco stores?	Smoking permitted in tobacco lounges?
IL	410 ILL. COMP. STAT. 82/1 to /75	Yes	2008	V	Yes	No
IN	IND. CODE §§ 16-41-37-1 to -9	No[246]	1998	II	Yes	Yes
IA	IOWA CODE §§ 142D.1 to .9	Yes	2008	V	Yes	No
KS	KAN. STAT. ANN. §§ 21-4009 to -4014	No	1987	II	Yes	Yes
KY	KY. REV. STAT. ANN. §§ 61.165 to .167	No	2006	II	Yes	Yes
LA	LA. REV. STAT. ANN. §§ 40:1300.251 to .263	No	2007	III	Yes	Yes
ME	ME. REV. STAT. ANN. tit. 22, §§ 1541 to 1548	Yes	2007	IV	Yes[247]	Yes*[248]
MD	MD. CODE ANN. HEALTH-GEN. §§ 24-205, 24-501 to -511	Yes	2008	V	Yes	No
MA	MASS. GEN. LAWS ch. 270, § 22	Yes	2004	IV	Yes	Yes
MI	MICH. COMP. LAWS §§ 333.12601 to .12617	No	1989	II	Yes	Yes

246. A 2008 bill that would have implemented a modern statewide ban, H.B. 1057, 115th Gen. Assemb., 2d Reg. Sess. (Ind. 2008), failed. Rick Yencer, *Statewide Smoking Ban Dies In Committee; Pull Tabs OK'd*, STAR PRESS (Muncie, Ind.), Jan. 24, 2008, at A1. The bill's sponsor has promised to continue to reintroduce the bill until the ban passes. *Id.*

247. The Maine Legislature amended the Clean Indoor Law in May 2007, specifically prohibiting smoking hookah in tobacco specialty stores licensed after January 1, 2007.

248. Maine exempts "tobacco specialty stores" that, by the end of 2006, possessed licenses to serve alcohol or food. This statute functions in precisely the same way as a grandfather clause exemption for tobacco bars. *See* 22 ME. REV. STAT. ANN. tit. 22, § 1542(L) ("Smoking is not prohibited in a tobacco specialty store. The on-premises service, preparation or consumption of food or drink, if the tobacco specialty store is not licensed for such service or consumption prior to January 1, 2007, is prohibited in such a store.").

State	Statewide ETS Law in effect	Modern Statewide Ban?[244]	Effective Date	Class	Smoking permitted in retail tobacco stores?	Smoking permitted in tobacco lounges?
MN	MINN. STAT. §§ 144.411 to .417	Yes	2007	V	Yes	No
MS	MISS. CODE ANN. §§ 29-5-161 to -163	No	2000	II	Yes	Yes
MO	MO. REV. STAT. §§ 191.765 to .777	No	1992	II	Yes	Yes
MT	MONT. CODE ANN. §§ 50-40-101 to -120	Yes	2009	V[249]	No	No
NE	NEB. REV. STAT. §§ 71-5716 to -5734	Yes	2009	V	Yes	No
NV	NEV. REV. STAT. § 202.2483	Yes	2006	III	Yes	Yes
NH	N.H. REV. STAT. ANN. §§ 155:64 to :77	Yes	2007	V	No[250]	No
NJ	N.J. STAT. ANN. §§ 26:3D-55 to -64	Yes	2006	IV	Yes	Yes
NM	N.M. STAT. §§ 24-16-1 to -20	Yes	2007	IV	Yes	Yes*
NY	N.Y. PUB. HEALTH LAW §§ 1399-n to -x	Yes	2003	IV	Yes	Yes*
NC	N.C. GEN. STAT. §§ 143-595 to -601	No	1993	I	Yes	Yes
ND	N.D. CENT. CODE §§ 23-12-9 to -11	No	2007	III	Yes	Yes

249. Montana will become a Class V state once its bars go smoke-free on October 1, 2009. Until that date it is a Class III state.

250. There is no explicit exemption for retail tobacco shops. "Smoking may," however, according to the statute, "be permitted in [certain] enclosed places of public access and publicly-owned buildings and offices, including workplaces . . . in effectively segregated smoking-permitted areas designated by the person in charge." N.H. REV. STAT. § 155:67II (Supp. 2007).

State	Statewide ETS Law in effect	Modern Statewide Ban?[244]	Effective Date	Class	Smoking permitted in retail tobacco stores?	Smoking permitted in tobacco lounges?
OH	OHIO REV. CODE ANN. §§ 3794.01 to .09	Yes	2006	V	Yes[251]	No
OK	OKLA. STAT. tit. 63 §§ 1-1521 to -1527	No	2003	II	Yes	Yes
OR	OR. REV. STAT. §§ 433.835 to .875	Yes	2009	IV[252]	Yes	Yes[253]
PA	2007 Pa. Laws 27 §§ 1 to 30	Yes	2008	III	Yes	Yes
RI	R.I. GEN. LAWS §§ 23-20.10-1 to -16	Yes	2004	IV	Yes	Yes
SC	S.C. CODE ANN. §§ 44-95-10 to -60	No	1990	II	Yes	Yes
SD	S.D. CODIFIED LAWS § 22-36-2	Pending	2002	I	Yes	Yes
TN	TENN. CODE ANN. §§ 39-17-1801 to -1812	No	2007	III	Yes	Yes[254]
TX	TEX. PENAL CODE ANN. § 48.01	No	1975	II	Yes	Yes
UT	UTAH CODE ANN. §§ 26-38-1 to -9	Yes	2009	V[255]	No	No

251. The exemption is narrowly worded, however, stipulating that retail shops must stand alone. Currently operating retail shops are exempt from the operation of this narrow definition by grandfather clause.

252. On January 1, 2009, Oregon's Indoor Clean Air Act will become a Class IV statute, pursuant to legislation passed in 2007. 2007 Ore. Laws 602, §§ 1-13. Until then, Oregon remains a Class III state.

253. On January 1, 2009, cigar bars, defined tightly to preserve their traditional character, will be exempt under a grandfather clause. 2007 Ore. Laws 602 at § 1. Until then, cigar bars may receive protection by seeking waivers from the Department of Human Services. OR. REV. STAT. § 433.865 (2007) (permitting waivers "where there are good reasons to do so" and where "a waiver will not significantly impact the health and comfort of nonsmokers"). This waiver provision will be eliminated in 2009 when the grandfather clause becomes operative. 2007 Ore. Laws 602, § 12. Thus, waivers could potentially be sought in the case of new cigar bars.

254. Exempts all age-restricted (twenty-one years and over) venues.

255. Utah remains Class II until 2009, when a number of exemptions, including some for private clubs and taverns, disappear.

State	Statewide ETS Law in effect	Modern Statewide Ban?[244]	Effective Date	Class	Smoking permitted in retail tobacco stores?	Smoking permitted in tobacco lounges?
VT	VT. STAT. ANN. tit. 18, §§ 37-1741 to -1746	Yes	2005	V	No	No
VA	VA. CODE ANN. §§ 15.2-2800 to -2810	No[256]	1990	II	Yes	Yes
WA	WASH. REV. CODE §§ 70.160.010 to .900.	Yes	2005	V	Yes	Yes
WV	W. VA. CODE §§ 16-9A-1 to -9; 31-20-5b	No	1987	II	Yes	Yes
WI	WIS. STAT. § 101.123	No	1983	II	Yes	Yes
WY	N/A[257]	N/A	N/A	II	Yes	Yes

256. In February 2008, a series of ETS proposals were rejected decisively by a House subcommittee. Mason Adams, *8 Bills that Ban Public Smoking Die in House*, ROANOKE TIMES, Feb. 8, 2008, at B1.

257. Wyoming is the only state in the country without a single ETS statute on the books.

APPENDIX B: CERTIFIED BALLOT LANGUAGE, THE OHIO SMOKE FREE WORKPLACE ACT

State Issue 5: Certified Ballot Language[258]

Prohibit Smoking in Places of Employment and Most Public Places – Smoke Free

PROPOSED LAW
(Proposed by Initiative Petition)

To enact Chapter 3794 of the Ohio Revised Code to restrict smoking in places of employment and most places open to the public.

The proposed law would:

- Prohibit smoking in public places and places of employment;
- Exempt from the smoking restrictions certain locations, including private residences (except during the hours that the residence operates as a place of business involving non-residents of the private residence), designated smoking rooms in hotels, motels, and other lodging facilities; designated smoking areas for nursing home residents; retail tobacco stores, outdoor patios, private clubs, and family-owned and operated places of business;
- Authorize a uniform statewide minimum standard to protect workers and the public from secondhand tobacco smoke;
- Allow for the declaration of an establishment, facility, or outdoor area as nonsmoking;
- Require the posting of "No Smoking" signs, and the removal of all ashtrays and similar receptacles from any area where smoking is prohibited;
- Specify the duties of the department of health to enforce the smoking restrictions[;]

258. Ballot Language, *supra* note 68.

- Create in the state treasury the "smoke free indoor air fund;"

- Provide for the enforcement of the smoking restrictions and for the imposition of civil fines upon anyone who violates the smoking restrictions.

A majority yes vote is necessary for passage.

	YES	**SHALL THE PROPOSED LAW BE ADOPTED?**
	NO	

FEATURE

A National Survey of Medical Error Reporting Laws

The *Journal*'s Editorial Staff

INTRODUCTION

A. The Institute of Medicine Report

In 1999, the Institute of Medicine (IOM) released a landmark report on medical errors, *To Err is Human*.[1] On the basis of studies in New York, Colorado, and Utah, the IOM estimated that between 44,000 and 98,000 Americans died in hospital settings in 1997 as a result of preventable medical errors.[2] These errors occurred at every phase of the medical system, including preventive care, diagnosis, treatment, and follow-up; errors with serious consequences were most frequent in settings where patients were most vulnerable.[3] If the rate of serious medical errors has remained constant since the IOM study, these events could have been responsible for between 49,000 and 109,000 deaths in 2006.[4] Researchers continue to publish alarming estimates of specific types of medical errors, which range from transfusion of incompatible blood products, to medication errors, to foreign objects left in bodies, to equipment failures, to mistaken identities of patients or body parts. For example, a recent study found that over the course of their careers, orthopedic hand surgeons had a one in five chance of performing a surgery on the wrong side of a

1. *See* INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 1999) [hereinafter TO ERR IS HUMAN]; *see also* Robert Pear, *Group Asking U.S. for New Vigilance in Patient Safety*, N.Y. TIMES, Nov. 30, 1999, at A1.

2. TO ERR IS HUMAN, *supra* note 1, at 26. The IOM defined an error as "the failure of a planned action to be completed as intended (i.e., an error of execution) or the use of a wrong plan to achieve an aim (i.e., an error of planning)." *Id.* at 28. Although this estimate already exceeds the number of Americans who died in 1997 from traffic fatalities, breast cancer, or AIDS, it may still be conservative. *Id.* The studies upon which the IOM relied only considered errors documented in patient records and for which two reviewers agreed that the adverse event was "preventable or negligent." *Id.* at 31. Moreover, deaths from health care-associated infections were not included in the overall estimate.

3. The IOM report concluded that "high error rates with serious consequences are most likely to occur in intensive care units, operating rooms, and emergency departments." *Id.* at 36.

4. *Journal* staff calculations are based on hospital admissions data reported in Am. Hosp. Ass'n, Fast Facts on US Hospitals 1-2, Oct. 22, 2007, http://www.aha.org/aha/content/2007/pdf/fastfacts2007.pdf. Calculations reflect eleven percent growth in hospital admissions between 1997 and 2006 and assume that the rate of medical errors has remained constant during this time period.

patient's body.[5] Health care-associated (nosocomial) infections are the most common complications among hospitalized patients, and they may now result in 90,000 to 100,000 patient deaths each year in the United States.[6]

Rather than ascribing these thousands of adverse events to errant individuals, the IOM argued that the scope of medical errors demanded change from health care systems. The report stressed that "although some of these cases [of preventable adverse events] may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place."[7] Health care delivery for any one patient involves a variety of complex interlinked systems. Different individual providers and teams of providers are often involved in the care of a single patient; those providers are governed by interwoven regulations emanating from provider groups, facilities, states and the federal government. Factors at every level of these systems affect the incidence of medical errors and the responses that they provoke. From this perspective, it is clear that preventing errors does not entail simply "getting rid of bad apples." Rather, "improving safety for patients require[s] a systems approach in order to modify the conditions that contribute to errors."[8] After reviewing the successful systems-based safety improvements in the airline industry and in workplace safety, the IOM noted, "[A]ccidents can be prevented through good organizational design and management."[9]

Policymakers and health care administrators need accurate data on the types, frequencies, and root causes of medical errors before they will be able to implement systemic reforms. In order to gather the information necessary to implement a systems approach, the IOM recommended that each state create a dual reporting system. First, the IOM encouraged Congress to establish a national system operated by the National Forum for Health Care Quality Measurement and Reporting to collect reports from individual states concerning the most

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5. Sameul C. Seiden & Paul Barach, *Wrong-Side/Wrong-Site, Wrong-Procedure, and Wrong-Patient Adverse Events: Are They Preventable?*, 141 ARCHIVES OF SURGERY 931, 932 (2006) (citing Eric G. Meinberg & Peter J. Stern, *Incidence of Wrong-Site Surgery Among Hand Surgeons*, 85-A J. BONE & JOINT SURGERY 193, 193-97 (2003)).

6. *See* John P. Burke, *Infection Control – A Problem for Patient Safety*, 348 N. ENG. J. MED. 651, 651 (2003) (estimating that nosocomial infections result in 90,000 deaths per year); R. Monina Klevens et al., *Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002*, 122 PUB. HEALTH REPORTS 160, 160 (2007) (estimating that health care-associated infections resulted in 98,987 deaths in 2002). In conducting this survey, *Journal* staff focused exclusively on hospital-acquired infections. Certain states may operate error reporting programs that cover health care-associated infections outside of the hospital setting.

7. TO ERR IS HUMAN, *supra* note 1, at 30.

8. *Id.* at 49.

9. *Id.* at 57. *See id.* at 71-74.

serious errors taking place in hospitals and other health care settings.[10] An underlying premise of the proposed mandatory reporting system was that serious adverse events are "easy to identify,"[11] enabling state departments of health to detect such errors, to hold facilities accountable, and to assist facilities in developing protocols to reduce future errors. The IOM also recommended that analyses of the root causes of these adverse events be available to the public,[12] thereby reinforcing facilities' incentives to minimize errors and invest in patient safety. Second, the IOM recommended that the Center for Patient Safety should develop a voluntary reporting mechanism for less serious medical errors. In contrast to the mandatory system, the IOM envisioned that reports under the voluntary system would receive legal protection from data discovery.[13] This confidentiality would enable monitors to collect sufficient data to "analyz[e] and understand[] the causes of errors in order to make improvements."[14]

B. Progress Since the IOM Report

The IOM report propelled a number of state governments to institute medical error reporting systems. At the time of the report's release in 1999, the IOM reviewed programs in thirteen states that collected medical error data.[15] By early 2008, programs in twenty-seven states were operational.[16] In addition to gathering data on medical errors, state departments of health have worked with hospitals and other care facilities on root cause investigations, protocols to address known errors, and the implementation of best practices to prevent future errors. Many of these state efforts have utilized a list of serious reportable events created by the National Quality Forum (NQF),[17] a nonprofit organization that

10. *Id.* at 86.

11. *Id.* at 88.

12. *Id.* at 86-87.

13. *Id.* at 87-89.

14. *Id.* at 87.

15. *Id.* at 91. As of 2000, fifteen states had authorized adverse event reporting systems. JILL ROSENTHAL & MARY TAKACH, NAT'L ACAD. FOR STATE HEALTH POLICY, 2007 GUIDE TO STATE ADVERSE EVENT REPORTING SYSTEMS 4 (2007), *available at* http://www.nashp.org/Files/shpsurveyreport_adverse2007.pdf.

16. Using the methodology described *infra*, *Journal* staff identified twenty-four states operating medical error reporting programs. This list of twenty-four states was supplemented with three additional states (Colorado, Kansas, and South Carolina) identified in ROSENTHAL & TAKACH, *supra* note 15. A fourth state, Georgia, was also identified by the same authors, but *Journal* staff omitted it from this analysis since the statutes cited pertained to committees conducting peer review, rather than government or non-profit entities conducting external oversight. For the purpose of this survey, we refer to the District of Columbia as a state.

17. These events have been labeled "never events" because they should never occur; they include errors such as unintended retention of a foreign object or patient death associated with a fall

promotes system-wide quality improvement in health care.[18] The NQF first issued a list of twenty-seven serious events in 2002, then added artificial insemination with the wrong donor sperm or egg in 2006 to reach its current total of twenty-eight "never" events.[19] State Medicaid programs in at least four states have attempted to create incentives for improving patient safety by publicly announcing that they will no longer reimburse providers for some or all of the events on the NQF list.[20]

The federal government has also encouraged efforts to promote patient safety. As of October 2008, Medicare will no longer pay for ten "reasonably preventable" conditions caused by medical errors, such as bed sores, injuries from falls, and some hospital-associated infections.[21] The Centers for Medicare and Medicaid Services also require hospitals to report forty-two measures of quality, including some measures of medical errors, in order to receive a full payment update to rates in the following fiscal year.[22] The Agency for Healthcare Research and Quality (AHRQ), part of the Department of Health and Human Services, is the focal point for patient safety at the federal level; in 2001, this agency established the Center for Quality Improvement and Patient Safety[23] to gather and disseminate information on health care quality measurement and to

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during care. *See* NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE – 2006 UPDATE: A CONSENSUS REPORT [hereinafter NQF LIST]. For the updated list of twenty-eight events issued in 2006, see Press Release, Nat'l Quality Forum, National Quality Forum Updates Endorsement of Serious Reportable Events in Healthcare (Nov. 15, 2006), http://www.qualityforum.org/pdf/news/prSeriousReportableEvents10-15-06.pdf.

18. *See* Nat'l Quality Forum, About Us, http://www.qualityforum.org/about (last visited Nov. 15, 2008).

19. Press Release, Nat'l Quality Forum, *supra* note 17. See *infra* Appendix for the list of NQF "serious reportable events."

20. Kevin Sack, *Medicare Won't Pay for Medical Errors*, N.Y. TIMES, Sept. 30, 2008, at A1, *available at* http://www.nytimes.com/2008/10/01/us/01mistakes.html.

21. *Id.*; *see also* Press Release, Ctrs. for Medicare & Medicaid Servs., Office of Pub. Affairs, Medicare and Medicaid Move Aggressively To Encourage Greater Patient Safety in Hospitals and Reduce Never Events (July 31, 2008) (on file with journal).

22. CTRS. FOR MEDICARE & MEDICAID SERVS., FISCAL YEAR 2009 QUALITY MEASURE REPORTING FOR 2010 PAYMENT UPDATE (2008), http://www.cms.hhs.gov/HospitalQualityInits/Downloads/HospitalRHQDAPU200808.pdf; *see also* Sack, *supra* note 20.

23. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, AHRQ'S PATIENT SAFETY INITIATIVE: BUILDING FOUNDATIONS, REDUCING RISK ch. 3 (2003), *available at* http://www.ahrq.gov/qual/pscongrpt/psini3.htm. The Center for Quality Improvement and Patient Safety was the successor organization to the Center for Quality Measurement and Improvement. This transformation was an "initial step in a series of efforts to re-focus and concentrate in one organizational unit activities designed to improve the safety of the health care Americans receive." *Id.*

implement evidence-based preventive practices.[24] In December 2000, Congress allocated $50 million to AHRQ for research on ways to reduce medical errors.[25] By 2004, nearly all of this funding was earmarked for information technology development rather than error prevention research, but the first three years of funding established medical error research as a legitimate, critical, and underdeveloped academic field.[26] In July 2005, Congress reinforced its support for error monitoring with the Patient Safety and Quality Improvement Act, which encouraged voluntary and confidential reporting of adverse events and created a certification process for patient safety organizations to collect and analyze patient safety information.[27]

Executive federal efforts to monitor the incidence of health care-associated infections remain focused in the Centers for Disease Control and Prevention (CDC). The CDC have operated a National Nosocomial Infections Surveillance System since the early 1970s, which as of 2005 included at least 300 hospitals.[28] In 2005, the National Nosocomial Infections Surveillance System was replaced by the National Healthcare Safety Network (NHSN), which also incorporates surveillance data from the Dialysis Surveillance Network and the National Surveillance of Healthcare Workers.[29] The NHSN issued its first report on health care-associated infections in 2007.[30] To date, however, no "comprehensive nationwide monitoring system" exists for medical error reporting, and recent attempts to estimate error rates show little movement in actual error incidence

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24. *See* Agency for Healthcare Research & Quality, Center for Quality Improvement and Patient Safety: Mission Statement, http://www.ahrq.gov/about/cquips/cquipsmiss.htm (last visited Nov. 15, 2008).

25. H.R. REP. NO. 106-1033, at 40 (2000) (Conf. Rep.); *see also* INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 5 (1999), http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf (official summary of full report); Press Release, Agency for Healthcare Research & Quality, HHS Announces $50 Million Investment to Improve Patient Safety (Oct. 11, 2001), http://www.ahrq.gov/news/press/pr2001/patsafpr.htm.

26. *See* Lucian L. Leape & Donald M. Berwick, *Five Years After* To Err Is Human: *What Have We Learned?*, 293 JAMA 2384, 2385 (2005).

27. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (codified at 42 U.S.C. § 299b-24 (Supp. 2005)); *see also* Agency for Healthcare Research & Quality, Patient Safety Organization Overview, http://www.pso.ahrq.gov/psos/overview.htm (last visited Nov. 15, 2008); Agency for Healthcare Research & Quality, Welcome to AHRQ's Patient Safety Organization Web Site, http://www.pso.ahrq.gov (last visited Nov. 15, 2008).

28. Ctrs. for Disease Control & Prevention, National Nosocomial Infections Surveillance System, http://www.cdc.gov/ncidod/dhqp/nnis.html (last visited Nov. 15, 2008).

29. Jonathan R. Edwards et al., *National Healthcare Safety Network (NHSN) Report, Data Summary for 2006*, 35 AM. J. INFECTION CONTROL 290, 290 (2007), *available at* http://www.cdc.gov/ncidod/dhqp/pdf/nhsn/2006_NHSN_Report.pdf.

30. *Id.*

nationwide.[31]

In the years since the IOM report, non-governmental actors have also been at the forefront of efforts to document and prevent medical errors. Professional associations such as the Joint Commission on Accreditation of Healthcare Organizations, the American Hospital Association, and the American College of Physicians have reinforced state and federal efforts to improve patient safety standards, and the NQF has played a critical role in classifying medical errors and promoting best practices to avoid them.[32] Under the Patient Safety and Quality Improvement Act, non-governmental organizations are eligible to become Patient Safety Organizations, which are authorized to gather medical error reports protected from legal disclosure.[33] At least three states (Florida, Nebraska, and Pennsylvania) rely on non-governmental organizations to analyze reports of medical errors at facilities statewide.[34] Private insurers in seven states, including WellPoint, Aetna, Cigna, and Blue Cross Blue Shield, have ceased to provide coverage for procedures to correct medical errors.[35] Further, many state hospital associations have entered voluntary agreements to refrain from billing for medical errors. Government-run programs such as Medicare and Medicaid have followed in the footsteps of these private arrangements, aiming to create financial incentives for safeguards on patient safety.[36]

I. OBJECTIVE

Given the progress to date in promoting best practices and research on patient safety, as well as the growing involvement of federal actors and health care payers in addressing medical errors, it is a propitious time to reexamine state efforts to gather the data on which system reforms are based. As the IOM acknowledged in its original report, state monitoring systems are uniquely poised to collect the data necessary to sustain system-level reform efforts.

The objective of this survey is to catalogue and describe the medical error reporting regimes established in the twenty-seven jurisdictions with reporting systems. State reporting procedures vary dramatically with regard to the types of incidents that must be reported, the speed with which those incidents must be reported, the penalties imposed for failures to report, and the level of protection

31. *See* Leape & Berwick, *supra* note 26, at 2384 (citing AGENCY FOR HEALTHCARE RESEARCH & QUALITY, 2004 NATIONAL HEALTHCARE QUALITY REPORT, http://www.ahrq.gov/qual/nhqr04/nhqr2004.pdf).

32. *See id.* at 2386.

33. Agency for Healthcare Research & Quality, Patient Safety Organization Overview, *supra* note 27.

34. *See infra* Table.

35. Sack, *supra* note 20.

36. *Id.*

offered from legal discovery. By describing these various systems, the staff of the *Yale Journal of Health Policy, Law, and Ethics* hopes to provide valuable information to those states considering the institution of reporting programs, to aid policymakers from states refining their current systems, and to assist practitioners and non-governmental entities working towards patient safety improvements.

After the completion of research for this survey, our staff became aware of a similar study by the National Academy for State Health Policy (NASHP) published in December 2007, which collected data current through October 2007.[37] Given the brisk pace of reporting system reforms,[38] our study provides a timely update, with current information on state reporting systems as of September 2008. We also used the opportunity to cross-reference our findings with the earlier survey as an added check on accuracy.

Overall, we aimed for our survey to be uniquely responsive to the concerns of clinicians, policymakers, advocates, and legal practitioners by updating statutory and regulatory citations, clarifying separate requirements where states have more than one reporting program, and adding Internet citations to program descriptions where available. We also report specific information on state-by-state deadlines for reporting, penalties for failures to report, regimes for reporting health care-associated infection incidence, and enactment of pay-for-performance programs. Finally, we have included an explicit description of our methodology for transparency and to ensure that any other research teams seeking to update this report can replicate our study.

II. METHODOLOGY

Research for this project proceeded in four stages: 1) a systematic literature review of state statutes; 2) a systematic literature review of state regulations, with supplementary literature searches using Google and individual state department of health websites; 3) data extraction using standardized extraction forms; and 4) verification of results with state program administrators. The *Journal* received no external support or funding for the survey.

A. Systematic Review of State Statutes

In the first stage of our analysis, *Journal* staff designed a single, highly sensitive search strategy to locate state statutes related to medical error reporting. The staff then replicated this search strategy within each of the individual state

37. ROSENTHAL & TAKACH, *supra* note 15.

38. *Id.* at 1 (noting that between 2005 and 2007, fifteen states and the District of Columbia enacted or revised their reporting systems).

statutory databases maintained electronically by Westlaw.[39] We did not filter search results by date or any other restriction. If these searches yielded more than one hundred search results, we used Boolean operators to narrow the search to occurrences of the terms within the same paragraph.[40] *Journal* staff then reviewed the content of every search result for relevance. If any reviewer believed that a specific statute was relevant, that reviewer downloaded and examined the statute in its entirety. As an external check on these results, we then compared our list of retrieved statutes to the statutes listed in the Thomson/West publication, *50 State Statutory Surveys: Patient Safety and Medical Errors Reforms* (2007).[41] If a potentially relevant statute listed in the West publication had not been retrieved in the course of our initial search, we downloaded it for review in its entirety and scanned it for additional relevant citations.

We completed the first stage of this study in February 2008; therefore, this national survey represents the state of the law as it was published on February 1, 2008. The statutes retrieved by this literature search are current through at least the close of the 2007 legislative session in each state.[42]

B. Systematic Review of State Regulations with Supplementary Internet Research

The second stage of research was a systematic literature search and review of state regulations pertaining to medical error reporting. The *Journal* staff jointly designed a single replicable search strategy to retrieve administrative regulations[43] and then executed this search strategy within each of the individual state administrative code databases maintained electronically by Westlaw or

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39. Specifically, we conducted "Terms and Connectors" searches of the following form, aiming to maximize sensitivity: 1) healthcare & quality & report*; 2) error & report* & health*; and 3) adverse & health* & report*.

40. That is, we used "/p" instead of "&" in the search strategies described *supra*.

41. While the Thomson/West survey is relatively recent, it is not comprehensive, includes a number of statutes that do not govern medical error reporting, and does not provide summary information regarding those statutes.

42. In early September 2008, in order to apprise ourselves of major legislative changes, *Journal* staff also established an automated alert on LexisNexis to monitor any additional publications in NCSL LegisBriefs, NCSL State Legislatures Magazine, and NCSL State Legislative Reports. This alert used the following search string: (healthcare & quality & report*) or (error & report* & health*) or (adverse & health* & report*). We also set an alert from the "Combined State & Federal Code Archives" database to report new results from the following search string: ("adverse event" or "sentinel event") & report* & health. Finally, we set an alert from the "State Administrative Codes" database to report new results from the following search string: ("adverse event" or "sentinel event" or error) & report* & health.

43. Specifically, we conducted "Terms and Connectors" searches of the following form: 1) health & adverse & report!; and 2) health & report! & quality.

LexisNexis.[44] Again, to maximize sensitivity, we placed no restrictions on our search results by date or any other criterion. We reviewed the content of the first one hundred search results for each state. If any reviewer considered a regulation to be relevant, the reviewer downloaded the full text of the regulation and reviewed it in its entirety. If we had previously retrieved a statute that contained distinctive terms for a given state (e.g., "sentinel event" or "Patient Safety Center"), we conducted additional searches of the administrative code database utilizing those terms. The second stage of this study was also complete as of February 2008, and we verified data with state departments of health as of September 2008.

To supplement the results of our Westlaw and LexisNexis searches, we conducted a web-based search using the Internet search engine Google.[45] We reviewed the content of the first twenty results and extracted relevant data. Finally, we searched the website of each state department of health for any information regarding medical error reporting.

During the first two stages of this study, we recovered a number of statutes and regulations that appeared relevant but that upon closer inspection did not apply to medical error reporting. Based on the scope and objective of our survey, we excluded statutes, rules, and regulations that required practitioners to report adverse medical malpractice settlements or claims to an external body. We also excluded any statute, rule, or regulation that required the reporting of data related to "quality," but did not 1) indicate specific categories of incidents, events, or errors that must be reported or 2) provide an operational definition of incidents, events, or errors that must be reported.

C. Data Extraction

After we reviewed the results of our searches, we created a common data extraction form to organize the data from relevant statutes and regulations. The staff members jointly agreed to organize and gather data according to the following sixteen prompts:

1) Provide a general description of the error reporting program;

2) Specify whether error reports are mandatory or voluntary;

3) List the specified recipient of error reports;

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44. At the time of our research, Westlaw did not maintain separate administrative code databases for all states, so we used LexisNexis databases for the remaining states.

45. Specifically, for each state, we conducted the following two searches: 1) health <state name> quality report; and 2) health <state name> adverse report.

4) Specify whether error reports are submitted electronically (i.e., through secure transmission over the Internet);

5) Specify which facilities must provide reports of medical errors;

6) Explain which medical errors, adverse events, and/or incidents must be reported;

7) Specify whether hospital-acquired infections are reportable as a separate category;

8) Specify the allowable duration of time for a health care provider to submit an initial report and any additional reports, including a root cause analysis and a corrective action plan;

9) Describe what penalties, if any, health care providers may face for noncompliance with the reporting regime:

(a) Specify whether the report recipient has the authority to revoke, suspend, or alter the license of a health care provider for noncompliance;

(b) Record whether the report recipient conducts audits (random or announced) of medical records to ensure compliance with reporting requirements;

10) State whether any of the data collected under the reporting regime are made available to the public;

11) Indicate whether reports of medical errors, adverse events, or other incidents are protected from legal discovery;

12) Specify whether the applicable statutes and regulations provide civil immunity for health care employees that report medical errors;

13) Indicate whether the state has implemented any positive financial incentives for health care providers that reduce their rate of medical errors or adverse events;

14) List all statutes and regulations directly relating to medical error reporting programs;

15) Specify any secondary resources encountered in the course of our

research; and

16) List the date the medical error reporting program started.

When we were unable to discern the answer from the retrieved information, we marked the answer as "Unclear from statutes and regulations."

We selected these sixteen categories based on two considerations. First, our initial review of all the retrieved statutes helped us determine the types of data that we could feasibly extract. We paid particular attention to categories that would be of interest to medical and legal practitioners, such as reporting deadlines, penalties, and resources for further information. Second, we supplemented our list of data fields with categories from similar surveys conducted by NASHP in 2000 and 2001.[46]

Our initial review of available data shaped our data extraction process most visibly in the area of defining which events must be reported. Initially, we had planned to inquire whether a reporting program required each of the twenty-eight "serious reportable events" listed by the NQF.[47] However, a brief review of the statutes revealed that many states featured broad definitions of "adverse events" that did not map onto the NQF categories.[48] Moreover, we encountered several states with additional, discrete categories of events not encompassed by the lengthy NQF list.[49] As a result, we decided to summarize the types of medical errors, adverse events, and incidents that must be reported under each state program. We have specifically noted those states that have adopted a reporting regime encompassing all or most of the NQF list.

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46. JILL ROSENTHAL, MAUREEN BOOTH & ANNE BARRY, NAT'L ACAD. FOR STATE HEALTH POLICY, COST IMPLICATIONS OF STATE MEDICAL ERROR REPORTING PROGRAMS: A BRIEFING PAPER (2001), *available at* http://www.nashp.org/Files/GNL_38_Cost_Implications.pdf; JILL ROSENTHAL, TRISH RILEY & MAUREEN BOOTH, NAT'L ACAD. FOR STATE HEALTH POLICY, STATE REPORTING OF MEDICAL ERRORS AND ADVERSE EVENTS: RESULTS OF A 50-STATE SURVEY (2000), *available at* http://www.nashp.org/Files/GNL_31_Reprint.pdf.

47. For the NQF list of "serious reportable events," see *infra* Appendix.

48. *See, e.g.*, NEV. REV. STAT. § 439.830 (2007) (requiring reporting of any sentinel event, which is broadly defined as "an unexpected occurrence involving facility-acquired infection, death or serious physical or psychological injury or the risk thereof, including, without limitation, any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. The term includes loss of limb or function.").

49. *See, e.g.*, UTAH ADMIN. CODE. r. 380-200-3(1)(d) (2008) (Utah regulations include four additional events not found in the National Quality Forum list: "(iv) unanticipated death of a full-term newborn; . . . (ix) Prolonged fluoroscopy with cumulative dose greater than 1500 rads to a single field; (x) Radiotherapy to the wrong body region; (xi) Radiotherapy greater than 25% above the prescribed radiotherapy dose; and (xii) Death or major permanent loss of function related to a health care acquired infection.").

D. Personal Communication and Verification

After data extraction, *Journal* staff personally contacted the relevant government agency or department of health in each state to verify our results. In September 2008, we contacted each of these administrative bodies using the mailing address posted on its website. Our mailing enclosed either our summary of the state program for medical error reporting or a letter indicating that we were unable to locate any evidence of a statewide reporting program. We requested that administrators in each state verify the accuracy of information we provided, and if we had made errors, provide corrections or clarification. As this issue went to press, agencies in nineteen states had responded to our requests.[50] The majority of responses came from states actually operating medical error reporting programs.

III. RESULTS AND SELECTED TRENDS

Twenty-seven states have instituted medical error reporting systems as of September 2008, and each of these regimes is described in detail in the Table below. Although there is extensive variability across state systems, we discerned several trends that may interest policymakers and practitioners: the persistence of underreporting despite reporting deadlines, licensing penalties, and restrictions protecting reported information from legal discovery; a shift toward requiring the reporting of health care-associated infections; and the influence of pay-for-performance programs in several pioneering states.

A. Underreporting

The IOM recognized that practitioners might be reluctant to voluntarily report medical mistakes. At the time of the IOM report, underreporting was known to be a serious problem for error reporting programs. The IOM noted that "[u]nderreporting is believed to plague all programs, especially in their early years of operation. Colorado's program received seventeen reports in its first two years of operation, but ten years later, received more than 1000 reports. On the other hand, New York's program receives approximately 20,000 reports annually."[51] However, the IOM hoped that safeguards on the confidentiality of data would resolve the underreporting problem, writing that "[p]atient safety is also hindered through the liability system and the threat of malpractice, which discourages the disclosure of errors. The discoverability of data under legal

50. The states that responded to our inquiries were Arizona, Connecticut, the District of Columbia, Illinois, Kentucky, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oregon, Pennsylvania, Tennessee, Utah, and Washington.

51. TO ERR IS HUMAN, *supra* note 1, at 92.

proceedings encourages silence about errors committed or observed. Most errors and safety issues go undetected and unreported, both externally and within health care organizations."[52] The IOM also believed that serious errors would be difficult for practitioners to conceal.[53]

Twenty-one of the twenty-seven state reporting programs presently in operation contain explicit protections against legal discoverability of error reports in civil actions.[54] Whether confidentiality protections are extended to error reports could not be determined for five additional states.[55] Only the state of Washington explicitly refuses to protect error reports from legal discovery.[56] Despite the ubiquity of confidentiality protections, underreporting appears to affect numerous state systems. In Figure 1, we compare the number of "serious reportable events" submitted by hospitals in a given state to the number of residents in that state.[57] For this illustration, we rely exclusively on states that

52. *Id.* at 43.

53. *Id.* at 88.

54. Colorado's reporting program only provides protection from legal discovery to reports of hospital-acquired infections. COLO. REV. STAT. § 25-3-605 (2008). Reports of other types of occurrences are not protected from use in regulatory proceedings. *Id.* § 25-1-124(4).

55. These states are California, New York, Oregon, Rhode Island, and South Carolina.

56. WASH. REV. CODE § 70.56.050 (2007). In Tennessee, "[t]he affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility." TENN. COMP. R. & REGS. 1200-8-1.11(8)(j) (2007). In Florida, victims of adverse events have the right to their records and adverse event reports. Patient's Right-to-Know About Adverse Medical Incidents Act, FLA. STAT. § 381.028 (2007). It remains unclear how the patient and family notification provisions for Tennessee and Florida can reasonably coexist with protections against data discoverability.

57. *See* CONN. DEP'T OF PUB. HEALTH, LEGISLATIVE REPORT TO THE GENERAL ASSEMBLY: ADVERSE EVENT REPORTING 7-10 (2007), *available at* http://www.ct.gov/dph/lib/dph/hisr/hcqsar/healthcare/pdf/adverseeventreportoct2007.pdf (reporting 176 adverse events from July 1, 2006 to June 30, 2007, 91 percent of which we assume occurred in a hospital setting); IND. STATE DEP'T OF HEALTH, INDIANA MEDICAL ERROR REPORTING SYSTEM: REPORT FOR 2007 (2008), at 2, *available at* http://www.in.gov/isdh/files/2007_MERS_Report.pdf (reporting 101 adverse events in hospitals in calendar year 2007); MINN. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN MINNESOTA 5, 9, 40, 41, 59, 63 (2008), *available at* http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf (reporting 121 adverse events in hospitals and four events in ambulatory surgical centers from October 7, 2006 to October 6, 2007); N.J. DEP'T OF HEALTH & SENIOR SERVS., PATIENT SAFETY INITIATIVE: 2006 SUMMARY REPORT 6 (2007), *available at* http://www.state.nj.us/health/ps/documents/ps_report_2006.pdf (reporting 450 adverse events in hospitals in calendar year 2006); POPULATION DIV., U.S. CENSUS BUREAU, ANNUAL ESTIMATES OF THE POPULATION FOR THE UNITED STATES, REGIONS, STATES, AND PUERTO RICO: APRIL 1, 2000 TO JULY 1, 2007 (2007), available at http://www.census.gov/popest/states/tables/NST-EST2007-01.xls (estimating the population of relevant states as of July 1, 2007); WASH. STATE DEP'T OF HEALTH, SERIOUS REPORTABLE EVENTS REPORTS, *available at* http://www.doh.wa.gov/hsqa/ocrh/video_conf/2007_8_15/Handouts/

have adopted or adapted the NQF list of serious reportable events in order to compare states with roughly similar reporting requirements. At least twelve states have incorporated all or most of the items on the NQF's list of serious reportable events.[58] However, one state (California) does not issue public reports, two states (the District of Columbia and Massachusetts) started collecting data on NQF events very recently, and three states (Illinois, Utah, and Vermont) do not appear to post public reports in an easily accessible location. As such, Figure 1 contains data for only six states.

For the six states included in the figure, the estimated rates of preventable medical errors vary dramatically. Indeed, the number of reported errors per 100,000 residents in New Jersey and Connecticut exceeds the number of reported errors per 100,000 residents in Indiana by an implausible factor of three.[59] We obtain qualitatively similar results when comparing the number of serious reportable events to the estimated number of hospital admissions in a given state in 2006.[60]

It is unlikely that the actual rates of medical error vary this dramatically across states; some segment of the variation is almost certainly due to lower rates of reporting in particular states. In exploring how to address underreporting, four facets of current states systems warrant attention: 1) differences in whether underreporting is penalized, 2) differences in the probability that underreporting

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SummaryAdverseEvents.pdf (reporting 180 serious reportable events in hospitals from June 2, 2006 to July 13, 2007); WYO. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN WYOMING HEALTHCARE FACILITIES: SECOND ANNUAL REPORT 2006-2007 (2007), at 7, *available at* http://wdh.state.wy.us/Media.aspx?mediaId=3248 (reporting 14 adverse events in hospitals from mid-2006 to mid-2007).

58. These states are California, Connecticut, the District of Columbia, Illinois, Indiana, Massachusetts (started August 2008), Minnesota, New Jersey, Utah, Vermont, Washington, and Wyoming. Note that Connecticut's list of "serious reportable events" includes several additional items not found on the NQF list.

59. The Connecticut data has been adjusted to include only reports of events included in the NQF list. Reports of "[p]erforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability," "[o]bstetrical events resulting in death or serious disability to the neonate," "[s]ignificant medication reactions resulting in death or serious disability," "[l]aboratory or radiologic test results not reported to the treating practitioner or reported incorrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency department," and "[n]osocomial infections resulting in death or serious injury" were omitted from this analysis. CONN. DEP'T OF PUB. HEALTH, *supra* note 57.

60. Specifically, we compare the number of events reported by a state to an estimate of the number of hospital admissions in that state in that year. *See* Kaiser Family Foundation, Hospital Admissions per 1,000 Population: 2006, http://www.statehealthfacts.org/comparerawjsp?ind=386&cat=8&sub=94&yr=61&typ=1&sort=a&o=a (last visited Dec. 13, 2008) (reporting data from American Hospital Association survey).

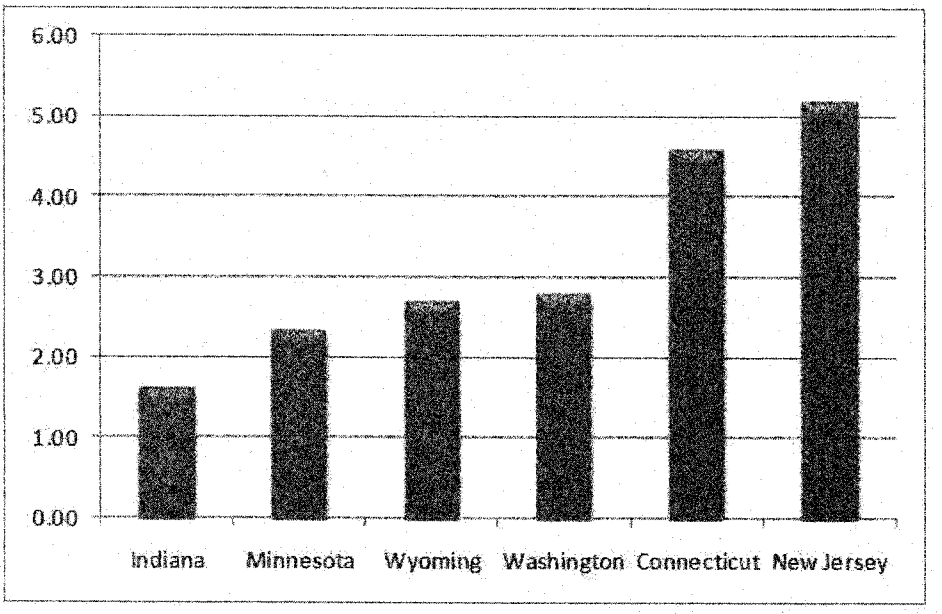

FIGURE 1. Number of "Serious Reportable Events" in Hospitals per 100,000 Residents (2006-2007)

will be detected by the regulating agency, 3) variation in facility acceptance of the reporting mechanism, and 4) variation in the extent to which physicians perceive that the reporting mechanism is designed to gather information rather than punish adverse events.

First, states differ with regard to the penalties for non-reporting. At least thirteen states have statutory or regulatory authority to impose financial penalties for failure to comply with reporting requirements.[61] In New Jersey, hospitals owe $1000 per day for failure to report a serious reportable adverse event, with a maximum penalty of $100,000 per event.[62] Similarly, facilities in Pennsylvania that fail to report a serious event may be subject to a $1000 per day administrative penalty, although this penalty may be adjusted at the discretion of the Department of Health.[63] Other jurisdictions impose far smaller financial penalties; for example, the District of Columbia imposes fines of $500 to $2500 for failure to report an adverse event.[64] In theory, states that routinely exercise their authority to impose financial penalties for failure to report should enjoy

61. These states are Colorado, the District of Columbia, Florida, Maine, Maryland, Massachusetts, New Jersey, Oregon, Pennsylvania, South Carolina, Utah, Vermont, and Wyoming.

62. N.J. ADMIN. CODE § 8:43E-3.4(a)(14) (2008).

63. 40 PA. CONS. STAT. § 1303.313 (2008).

64. D.C. CODE § 7-161(d)(2) (2008).

higher rates of compliance than states lacking such authority.[65]

Second, states differ with regard to whether they conduct audits of the records kept by the target medical facilities. Seven states provide at least limited statutory or regulatory authority for the governing agency to audit the records of facilities required to report medical errors.[66] Unfortunately, the extent to which such authority is employed is heavily contingent upon state appropriations, which lie beyond the scope of this study.[67] Anecdotal reports regarding the practices of leading states, however, may prove illuminating. A 2001 analysis by NASHP of medical error programs in New York and Florida found that "both states validate data by following up on media reports, identifying reportable incidents through the complaint process, conducting random on-site chart reviews, and attempting to match incident reports to hospital discharge data records."[68] The most recent report of the New York Patient Occurrence Reporting and Tracking System indicates that the New York Department of Health engages in "surveillance activities" and "retrospective chart review" to ensure that reporting occurs. "The Department [of Health] does impose citations and in some instances, fines for non-reporting or late reporting of statutorily mandated codes."[69] Although New York's definition of an adverse event is broader and far from synonymous with the NQF list of serious preventable events, it remains instructive that an impressive 31,154 reports were filed in 2004.[70] Most recently, in 2007, New York underwent a pilot phase of its program for hospital-acquired infection reporting. To assess whether hospitals were properly complying with the self-reporting requirements, Department of Health staff audited samples of medical records in onsite visits to ninety-five percent of New York hospitals from July 2007 to January 2008.[71]

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65. Certain states appear to financially penalize medical providers for lapses in safety, which may further reduce the willingness of providers to share information regarding preventable adverse events. California imposes a penalty of up to $50,000 for any situation "in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient." CAL. HEALTH & SAFETY CODE § 1280.3 (2008).

66. These states are Florida, Massachusetts, Minnesota, New Jersey, New York, Pennsylvania, and Vermont.

67. Although the magnitude of appropriations for various state adverse event reporting systems are not comprehensively catalogued in any single publication, the 2007 study by NASHP provides information regarding the funding source for each system. *See* ROSENTHAL & TAKACH, *supra* note 15.

68. ROSENTHAL, BOOTH & BARRY, *supra* note 46, at 13.

69. STATE OF N.Y. DEP'T OF HEALTH, NEW YORK PATIENT OCCURRENCE REPORTING AND TRACKING SYSTEM REPORT 14 (2005), *available at* http://www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2002-2004/docs/2002-2004_nyports_annual_report.pdf.

70. *Id.* at 2.

71. N.Y. STATE DEP'T OF HEALTH, HOSPITAL-ACQUIRED INFECTION REPORTING SYSTEM: PILOT

Third, health care facilities in different states may differ in the willingness of their staff to participate in the applicable reporting program. A facility's willingness to invest resources to consistently report all covered incidents may depend on the structure of the program. For instance, states that require facilities to report an incident within a short time span may foster a culture of compliance, whereas states that only require reporting on a semi-annual or annual basis may signal to participating facilities that the data generated are far from critical. Figure 2 provides an illustration of the disparities across states in deadlines for reporting incidents.[72] Moreover, medical providers may be more likely to comply with state reporting regimes that require the generation of "root cause analyses" that are actually reviewed and aggregated into useful reports that reveal trends and offer advice.[73] Indeed, a recent survey of physicians in Washington and Missouri revealed that "[p]hysicians [in the sample] were more likely to discuss serious errors, minor errors, and near misses with their colleagues than to report them to risk management or to a patient safety program."[74] Physicians in this survey offered several suggestions on how to increase their willingness to formally report error information: they generally desired a system that was confidential, nondiscoverable, and nonpunitive, and that did not require a substantial time commitment.[75] However, eighty-five percent of physicians surveyed also stressed the need for the information they submitted to be actually "used for system improvements."[76]

Fourth, despite the widespread availability of confidentiality provisions and protections against data discoverability, health care providers may remain fearful that liability will result from participation in an error reporting regime. This fear may stem from the origins of mandatory adverse event reporting programs, which were originally designed to shine a harsh light on poorly performing doctors and hospitals.[77] One method for allaying these fears is the use of

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YEAR – 2007, at 8 (2008), *available at* http://www.health.state.ny.us/nysdoh/hospital/reports/hospital_acquired_infections/2007/docs/hospital-acquired_infection-full_report.pdf.

72. Figure 2 only includes those states with deadlines of forty-five days or less.

73. Minnesota provides exemplary feedback to participating institutions. *See* MINN. STAT. § 144.7065(8) (2008) (requiring facilities to submit root cause analyses of reported events and plans of corrective action); MINN. DEP'T OF HEALTH, *supra* note 57 (providing summary information on common root causes of preventable adverse events and offering recommendations for the prevention of future adverse events, particularly wrong-site surgery and pressure ulcers).

74. Jane Garbutt et al., *Lost Opportunities: How Physicians Communicate About Medical Errors*, 27 HEALTH AFF. 246, 250 (2008).

75. *Id.* at 251.

76. *Id.*

77. *See* Kathryn E. Wood & David B. Nash, *Mandatory State-Based Error-Reporting Systems: Current and Future Prospects*, 20 AM. J. MED. QUALITY 298, 299 (2005).

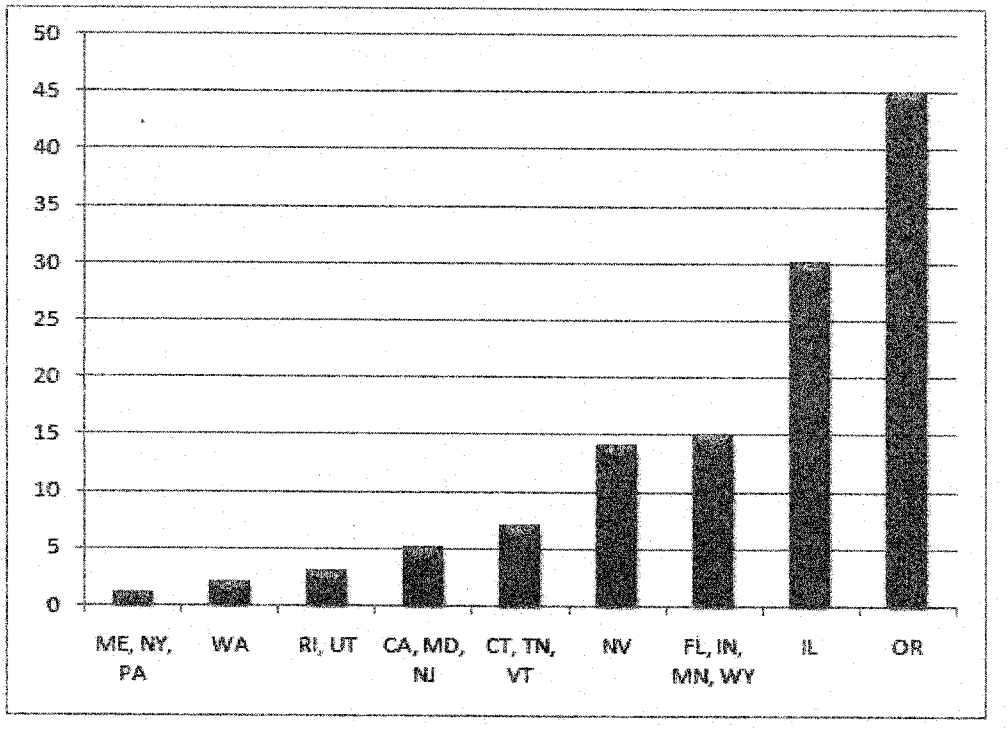

FIGURE 2. Maximum Number of Days for Reporting Facilities to File Incident Reports
Note: Figure only includes those states with deadlines of forty-five days or less following the incident or its discovery.

nonprofit "Patient Safety Organizations" for data collection, rather than a government body.[78] As mentioned above, our study reveals that at least three states (Florida, Nebraska, and Pennsylvania) rely on nonprofit organizations to receive and analyze at least some adverse event data.

B. Hospital-Acquired Infection Reporting

States are gradually converging on a set of serious, preventable adverse occurrences that must be reported. As noted above, twelve states have adopted or slightly altered the NQF's list of "serious reportable events." In addition, twelve states now require the reporting of certain health care-associated or hospital-acquired infections, and one state provides for optional reporting of hospital-acquired and health care-associated infections (HAIs).[79] Among medical errors,

78. *Id.*

79. The states requiring the reporting of hospital-acquired infections are Colorado, Connecticut, the District of Columbia, Illinois, Massachusetts, Nevada, New Jersey, New York, Oregon, Pennsylvania, Utah, and Washington. Indiana allows for optional reporting of hospital-

HAIs are likely the leading cause of injury and death; in a 2007 report, the CDC "estimated that 1.7 million hospital patients—4.5 of every 100 admissions—become infected each year, causing or contributing to the deaths of nearly 100,000 people."[80] However, given the preventability of HAIs, they may be low-hanging fruit in the response to preventable adverse events.

The Institute for Healthcare Improvement has addressed HAIs squarely in its ongoing "5 Million Lives Campaign," which advocates for hospitals to adopt twelve specific care improvements shown to reduce patient injury and death (including practices to prevent staph infections, central line infections, surgical site infections, and ventilator-associated pneumonia).[81]

C. Leading Edge: Pay-for-Performance Programs

Health care providers have seen increasing interest in pay-for-performance programs, which attempt to create financial incentives for the provision of higher-quality care and may impose financial penalties for medical errors. Our survey discovered that at least two states have established pilot programs based on pay-for-performance principles. Recent legislation in New York under the title of "Pay for Performance" expressed the state legislature's intent "to encourage and support regional demonstration projects involving multiple payors utilizing such metrics as the basis for providing financial incentives to providers to achieve increased quality and cost effectiveness."[82] The statute authorizes the Commissioner of Health to select up to five demonstration projects for state support, and one selection criterion is the "use of . . . metrics to measure and reward physician, clinic and hospital performance . . . ."[83] According to a 2008 statute, Pennsylvania will also institute a pay-for-performance program in

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acquired infections.

80. Inst. for Healthcare Improvement, What Zero Looks Like: Eliminating Hospital-Acquired Infections, http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/WhatZeroLooksLikeEliminatingHospitalAcquiredInfections.htm (last visited Nov. 15, 2008) (citing Klevens et al., *supra* note 6).

81. *See* Press Release, Inst. for Healthcare Improvement, IHI Launches National Campaign To Reduce Medical Harm in U.S. Hospitals, Building on Its Landmark 100,000 Lives Campaign (Dec. 12, 2006), *available at* http://www.ihi.org/NR/rdonlyres/A96E0639-A979-44F6-A0FF-20329E492F44/4230/5MillionLivespressreleaseupdatedDec26FINALFINAL.pdf; *see also* Inst. for Healthcare Improvement, Doing Better Spending Less, http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/ImprovementStories/DoingBetterSpendingLess.htm (last visited Nov. 15, 2008) (chronicling stories of improvements in intensive care); Inst. for Healthcare Improvement, Protecting Five Million Lives from Harm, http://www.ihi.org/IHI/Programs/Campaign (last visited Nov. 15, 2008).

82. N.Y. PUB. HEALTH LAW § 2999-b (2007).

83. *Id.* § 2999-e(1).

January 2009; the Department of Public Welfare will make a quality improvement payment to health care facilities that achieve at least a ten percent reduction in health care-associated infections relative to the preceding year.[84]

There is some evidence that pay-for-performance programs combined with reporting programs may make headway towards improving the quality of care. A 2007 study in the *New England Journal of Medicine* reported that among hospitals already engaged in voluntary public reporting of quality, those enrolled in a pay-for-performance demonstration project funded by CMS showed greater improvement on measures of quality over a two-year period.[85] Although the difference between the two groups was modest, the study provides some support for the idea that "financial incentives are capable of catalyzing quality-improvement efforts among hospitals already engaged in public reporting."[86] The IOM has heralded interest in pay-for-performance programs as a desirable trend for system-level change, noting in 2007 that "[a]lthough the magnitude of incentives necessary to achieve significant and sustainable change while avoiding adverse consequences is uncertain, steps can be taken now to begin to address the deficiencies of current payment systems and encourage progress toward significant quality improvement."[87] Notably, successful pay-for-performance regimes require confidence that underreporting can be kept at bay, even after the introduction of financial rewards that increase the incentives for underreporting.

IV. SURVEY LIMITATIONS

The results of this survey have several limitations. First, it was not possible to ensure that statutory or regulatory developments after September 2008 would be included. Second, in states where administrators from state agencies or departments of health did not respond to our requests for information, our results are limited to the detail provided in published sources. Third, it was not within the scope of this study to search for information beyond a formal description of the systems in place. For example, we did not have the capacity to contact health providers directly to learn how reporting systems are actually enforced in practice. Further, with some exceptions from states with publicly released data, we were not able to collect the actual number of reported errors for each state.

Despite these limitations, however, this survey is a timely and uniquely practice-oriented view of statewide medical error reporting systems, and we

84. 40 PA. CONS. STAT. § 1303.407 (2008).

85. Peter K. Lindenauer et al., *Public Reporting and Pay for Performance in Hospital Quality Improvement*, 356 NEW ENG. J. MED. 486 (2007).

86. *Id.* at 494.

87. INST. OF MED., REWARDING PROVIDER PERFORMANCE: ALIGNING INCENTIVES IN MEDICARE 2 (2007).

anticipate that practitioners, policymakers, patient safety advocates, and researchers alike will find these program descriptions useful.

CONCLUSION

Progress towards improved patient safety has continued apace since the IOM report, but continuing efforts to reform health systems must be based on solid data regarding the types of medical errors, the frequencies of such mistakes, and the steps being taken to address them. Statewide collection of medical error data could have far-reaching effects; however, the quality of the data will depend heavily on the systems that states use to gather this information. This survey provides an up-to-date look at the systems currently in use, with the hope that this comparison will aid all those working towards improvements in patient safety.

APPENDIX. NATIONAL QUALITY FORUM LIST OF "SERIOUS REPORTABLE EVENTS"[88]

1) Surgical Events:

A. Surgery performed on the wrong body part;

B. Surgery performed on the wrong patient;

C. Wrong surgical procedure performed on a patient;

D. Unintended retention of a foreign object in a patient after surgery or other procedure;

E. Intraoperative or immediately postoperative death in an ASA Class I [i.e., healthy] patient.

2) Product or Device Events:

A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility;

B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended;

C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.

3) Patient Protection Events:

A. Infant discharged to the wrong person;

B. Patient death or serious disability associated with patient elopement (disappearance);

C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.

4) Care Management Events:

A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration);

B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;

C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility;

88. NQF LIST, *supra* note 17, at 7-16.

D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility;
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates;
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility;
G. Patient death or serious disability due to spinal manipulative therapy;
H. Artificial insemination with the wrong donor sperm or wrong egg.

5) Environmental Events:

A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility;
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility;
D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility;
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.

6) Criminal Events:

A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;
B. Abduction of a patient of any age;
C. Sexual assault on a patient within or on the grounds of a healthcare facility;
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility.

TABLE: NATIONAL SURVEY OF LAWS

ALABAMA

A medical error reporting regime does not appear to exist for this state.

ALASKA

A medical error reporting regime does not appear to exist for this state.

ARIZONA

A medical error reporting regime does not exist for this state.[89]

ARKANSAS

A medical error reporting regime does not appear to exist for this state.

CALIFORNIA

1. GENERAL DESCRIPTION: Hospitals are required to report most of the "serious reportable events" listed by the NQF.
2. IS REPORTING MANDATORY? Yes.[90]
3. REPORT RECIPIENT(S): Department of Health Services.
4. IS REPORTING CONDUCTED ELECTRONICALLY? Unclear from statutes and regulations.
5. WHAT FACILITIES MUST PROVIDE REPORTS? General acute care hospitals, acute psychiatric hospitals, and special hospitals.[91]
6. WHAT INCIDENTS MUST BE REPORTED? "Adverse events" must be reported. Adverse events are defined to include twenty-seven of the twenty-eight "serious reportable events" listed by the NQF.[92]
7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Infections acquired in hospitals are not explicitly listed as a separate category, but could result from other "adverse events" (e.g., the use of contaminated drugs, devices, or biologics).

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89. E-mail from Edward Welsh, Manager, Cost Reporting & Discharge Data, Ariz. Dep't of Health Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 19, 2008, 19:31 EST) (on file with journal).

90. CAL. HEALTH & SAFETY CODE § 1279.1 (2008).

91. *Id.*

92. *See id.* § 1279.1(b)(1)-(6); *supra* Appendix. The National Quality Forum and California lists are nearly identical, with the exception that the California statute does not specifically include the event of artificial insemination with the wrong donor sperm or wrong egg as a reportable event.

8. DEADLINES: Hospitals must report adverse events within five days of the event.[93] If the error has produced an ongoing threat, hospitals must report the event within twenty-four hours.[94]

9. PENALTIES AND/OR ENFORCEMENT MECHANISMS: If a patient is in imminent danger, then the Department of Health Services will inspect the facility within forty-eight hours after receiving the report of an adverse event. If no imminent threat exists, then the investigation and report must be completed within forty-five days.[95] For any violation that causes an immediate threat to a patient, the Department of Health Services can assess a penalty of up to $50,000 per violation upon the facility. The Department can assess up to $17,500 per violation that does not lead to an immediate threat.[96] If a facility fails to report an adverse event, the Department may assess $100 per day for the failure to report within the five day period following the event.[97]

(a) Revocation of license? Yes. The Department of Health Services may provide consulting services for a facility to develop a corrective plan. If the facility does not implement the plan, the facility's license may be revoked. Additionally, if the facility and the Department of Health Services cannot agree on a corrective plan and safety remains an issue, the Department can order the closure of the facility or a reduction in its patient numbers.[98]

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? By 2009, information regarding reports of substantiated adverse events will be available to the public via non-electronic means.[99] By 2015, the Department of Health Services shall provide this information on its website.[100]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Unclear from statutes and regulations. Note that "[a]ll inspection reports and lists of deficiencies shall be open to public inspection when the state department has received verification that the health facility has received the report from the state department. All plans of correction shall be open to public inspection upon receipt by the state department."[101]

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

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93. CAL. HEALTH & SAFETY CODE § 1279.1 (2008).

94. *Id.*

95. *Id.* § 1279.2.

96. *Id.* § 1280.3.

97. *Id.* § 1280.4.

98. *Id.* § 1280.

99. *Id.* § 1279.3.

100. California Department of Public Health, http://www.cdph.ca.gov (last visited Nov. 15, 2008).

101. CAL. HEALTH & SAFETY CODE § 1280(e) (2008).

14. RELEVANT STATUTES AND REGULATIONS: CAL. HEALTH & SAFETY CODE §§ 1279-1280 (2008).
15. OTHER RESOURCES: N/A.
16. DATE REPORTING STARTED: Unknown.

COLORADO

1. GENERAL DESCRIPTION: Health care facilities must report listed occurrences to the Department of Public Health and Environment, which then investigates each report, summarizes its findings, and makes those summaries available to the public.[102] Health care facilities must also report hospital-acquired infections to the National Healthcare Safety Network and allow those data to be released to the Department of Public Health and Environment.[103]
2. IS REPORTING MANDATORY? Yes, for both listed occurrences and hospital-acquired infections.[104]
3. REPORT RECIPIENT(S): All health care facilities must report listed occurrences directly to the Department of Public Health and Environment.[105] A smaller group of health care facilities must report hospital-acquired infections to the National Healthcare Safety Network, and must also authorize the Department of Public Health and Environment "to have access to health-facility-specific data contained in the [N]ational [H]ealthcare [S]afety [N]etwork database."[106]
4. IS REPORTING CONDUCTED ELECTRONICALLY? For the reporting of listed occurrences, "[t]he board [of the Department of Health] by rule shall specify the manner, time period, and form in which the reports . . . shall be made."[107] Currently, occurrences must be reported within one business day by phone, followed by a written report to be returned by fax within five business days.[108] For the reporting of hospital-acquired infections, health facilities must report "in

102. COLO. REV. STAT. § 25-1-124 (2008).

103. *Id.* § 25-3-601 to -607.

104. *Id.* § 25-1-124(2) ("Each health care facility . . . shall report to the department the following occurrences."); *id.* § 25-3-602(1)(a), (3)(a) ("A health facility shall collect data on hospital acquired infection rates . . . [and] shall routinely submit its hospital-acquired infection data to the [N]ational [H]ealthcare [S]afety [N]etwork").

105. *Id.* § 25-1-124(2) (for listed occurrences). Within the department, it appears that reports are made to the Health Facilities and Emergency Medical Services Division. *See* Colo. Dep't of Pub. Health & Env't, Occurrence Reporting Program: Health Facilities, http://www.cdphe.state.co.us/hf/static/occforms.htm (last visited Nov. 15, 2008) [hereinafter CDPHE, Occurrence Reporting Program].

106. COLO. REV. STAT. § 25-3-602(3)(a)-(c) (2008); *id.* § 25-3-601(2) (defining "department"); *id.* § 25-3-601(3) (defining "[h]ealth facility").

107. *Id.* § 25-1-124(3).

108. *See* COLO. DEP'T OF PUB. HEALTH & ENV'T, OCCURRENCE REPORTING MANUAL 7 (2007), *available at* http://www.cdphe.state.co.us/hf/download/occman.pdf [hereinafter CDPHE, OCCURRENCE REPORTING MANUAL]; CDPHE, Occurrence Reporting Program, *supra* note 105.

accordance with [N]ational [H]ealthcare [S]afety [N]etwork requirements and procedures."[109] The National Healthcare Safety Network surveillance system is electronic.[110]

5. WHAT FACILITIES MUST PROVIDE REPORTS? "Each health care facility licensed pursuant to [Colo. Rev. Stat. § 25-3-101] or certified pursuant to [Colo. Rev. Stat. § 25-1.5-103(1)(a)]" must report listed occurrences.[111] "Health care facilities" include any "general hospital, hospital unit . . . psychiatric hospital, community clinic, rehabilitation center, convalescent center, community mental health center, acute treatment unit, facility for persons with developmental disabilities, habilitation center for brain-damaged children, chiropractic center and hospital, maternity hospital, nursing care facility, pilot project rehabilitative nursing facility, hospice care, assisted living residence . . . , dialysis treatment clinic, ambulatory surgical center, birthing center, or other facility of a like nature . . . ."[112]

"[I]f the Colorado attorney general, the division for developmental disabilities in the department of human services, a community centered board, an adult protection service, or a law enforcement agency" makes a report of any of the listed occurrences in a licensed long-term care facility, that report must also be provided to the department.[113] A "licensed long-term care facility" is defined as "a licensed community residential or group home, a licensed intermediate care facility for the mentally retarded, and a licensed facility for persons with developmental disabilities."[114]

Health care facilities must also report hospital-acquired infections to the National Healthcare Safety Network.[115] This reporting statute defines a "health care facility" as "a hospital, a hospital unit, an ambulatory surgical center, or a dialysis treatment clinic currently licensed or certified by the department pursuant to the department's authority . . . ."[116]

6. WHAT INCIDENTS MUST BE REPORTED? The statute requires reporting of the following events: "(a) Any occurrence that results in the death of a patient or resident of the facility and is required to be reported to the coroner pursuant to [Colo. Rev. Stat. § 30-10-606], as arising from an unexplained cause or under suspicious circumstances; (b) Any occurrence that results in any of the following serious injuries to a patient or resident: (I) Brain or spinal cord injuries; (II) Life-

109. COLO. REV. STAT. § 25-3-602(3)(a) (2008).

110. *See* Nat'l Healthcare Safety Network, Overview, http://www.cdc.gov/ncidod/dhqp/nhsn.html (last visited Nov. 15, 2008).

111. COLO. REV. STAT. § 25-1-124(2) (2008).

112. *Id.* § 25-3-101; *see also id.* § 25-1.5-103 (listing the same facility types with additional clarification).

113. *Id.* § 25-1-124(2.5).

114. *Id.*

115. *Id.* § 25-3-602(3)(a).

116. *Id.* § 25-3-601(3).

threatening complications of anesthesia or life-threatening transfusion errors or reactions; (III) Second- or third-degree burns involving twenty percent or more of the body surface area of an adult patient or resident or fifteen percent or more of the body surface area of a child patient or resident; (c) Any time that a resident or patient of the facility cannot be located following a search of the facility, the facility grounds, and the area surrounding the facility and there are circumstances that place the resident's health, safety, or welfare at risk or, regardless of whether such circumstances exist, the patient or resident has been missing for eight hours; (d) Any occurrence involving physical, sexual, or verbal abuse of a patient or resident . . . or . . . by another patient or resident, an employee of the facility, or a visitor to the facility; (e) Any occurrence involving neglect of a patient or resident . . . ; (f) Any occurrence involving . . . a pattern of or deliberately misplacing, exploiting, or wrongfully using, either temporarily or permanently, a patient's or resident's belongings or money without the patient's or resident's consent[;] (g) Any occurrence in which drugs intended for use by patients or residents are diverted to use by other persons; and (h) Any occurrence involving the malfunction or intentional or accidental misuse of patient or resident care equipment that occurs during treatment or diagnosis of a patient or resident and that significantly adversely affects or if not averted would have significantly adversely affected a patient or resident of the facility."[117]

A "hospital-acquired infection" is "a localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that was not present or incubating at the time of admission to the health facility."[118] An "infection" is "the invasion of the body by pathogenic microorganisms that reproduce and multiply, causing disease by local cellular injury, secretion of a toxin, or antigen-antibody reaction in the host."[119] Health care facilities must report hospital-acquired infections in each of the following categories: "(I) Cardiac surgical site infections; (II) Orthopedic surgical site infections; and (III) Central line-related bloodstream infections."[120] Individuals who collect data on hospital-acquired infections must be certified according to national certification standards, unless they are at hospitals with fifty or fewer beds.[121]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes, as defined above.[122]

8. DEADLINES: For listed occurrences, "[t]he board by rule shall specify the manner, time period, and form in which the reports required . . . shall be

117. *Id.* § 25-1-124(2).
118. *Id.* § 25-3-601(4).
119. *Id.* § 25-3-601(5).
120. *Id.* § 25-3-602(1)(a).
121. *Id.* § 25-3-602(1)(c).
122. *Id.* § 25-3-601 to -607.

made."[123] Currently, facilities must initially report occurrences within one business day, followed by a written report within five business days.[124] Health care facilities must report hospital-acquired infections "routinely" and "in accordance with [N]ational [S]afety [N]etwork requirements and procedures."[125]

9. PENALTIES AND ENFORCEMENT MECHANISMS: For the reporting of occurrences, "Effective December 1, 2001, if [a facility] report[s] late, [it] will receive one letter of warning. After that, any late report will result in a deficiency under State Licensure [R]egulation 3.2."[126] Failure to report hospital-acquired infections can result in "termination of licensure or other sanctions related to licensure" or "a civil penalty of up to one thousand dollars per violation for each day the health facility is in violation."[127]

(a) Revocation of license? Yes, for the failure to report hospital-acquired infections.[128] Late reports of occurrences constitute "deficiencies" under state licensure requirements.[129]

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Yes, for both listed occurrences and hospital-acquired infections. For occurrence reporting, "[t]he department shall investigate each report . . . . For each report investigated, the department shall prepare a summary of its findings, including the department's conclusions and whether there was a violation of licensing standards or a deficiency or whether the facility acted appropriately in response to the occurrence . . . . The department shall make the following information available to the public: (I) Any investigation summaries prepared . . . . (II) Any complaints against a health care facility that have been filed with the department and that the department has investigated . . . ; and (III) A listing of any deficiency citations issued against each health care facility . . . . The information released . . . shall not identify the patient or resident or the health care professional involved in the report."[130] Additionally, the department will report "to a law enforcement agency" any reports "involving physical, sexual, or verbal abuse of a patient or resident."[131]

For hospital-acquired infections, "the department shall [annually] submit to the health and human services committees of the house of representatives and of the senate a report summarizing the risk-adjusted health-facility data. The department shall post the report on its website . . . . The department shall issue

123. *Id.* § 25-1-124(3).

124. *See* CDPHE, OCCURRENCE REPORTING MANUAL, *supra* note 108, at 7; CDPHE, Occurrence Reporting Program, *supra* note 105.

125. COLO. REV. STAT. § 25-3-602(3)(a) (2008).

126. *See* CDPHE, OCCURRENCE REPORTING MANUAL, *supra* note 108, at 5.

127. COLO. REV. STAT. § 25-3-606 (2008).

128. *Id.*

129. *See* CDPHE, OCCURRENCE REPORTING MANUAL, *supra* note 108, at 5.

130. COLO. REV. STAT. § 25-1-124(5)-(6) (2008).

131. *Id.* § 25-1-124(8).

semi-annual informational bulletins summarizing all or part of the information submitted in the health-facility reports . . . . The annual report shall compare the risk-adjusted, hospital-acquired infection rates . . . for each individual health facility in the state . . . . A health-facility report or department disclosure may not contain information identifying a patient, employee, or licensed health care professional in connection with a specific infection incident."[132]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Reports of occurrences are not protected from use in regulatory proceedings. "Any report submitted . . . shall be strictly confidential; except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions. The information in such reports shall not be made public upon subpoena, search warrant, discovery proceedings, or otherwise, except as provided in [the subsection on public reporting]."[133]

Hospital-acquired infection reports are protected from legal discovery.[134] "[A]ll information and materials obtained and compiled . . . are confidential; are not subject to disclosure, discovery, subpoena, or other means of legal compulsion for release to any person . . . and may not be admitted as evidence or otherwise disclosed in a civil, criminal, or administrative proceeding."[135]

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations for occurrence reporting. However, there is immunity for individuals who contribute to the state's medical quality reporting program, which suggests that individuals who report medical errors may also be protected.[136] It appears that health care facility employees have immunity for reporting hospital-acquired infections. "Information reported by a health facility . . . and all related information and materials are subject to an absolute privilege and shall not be used in any form against the health facility, its agents, employees, partners, assignees, or independent contractors in any civil, criminal, or administrative proceeding, regardless of the means by which a person came into possession of the information . . . ."[137]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? Colorado has established a commission to create a comprehensive hospital information system for the management of hospital-related data and statistics.[138] The commissioners instituted a hospital report card survey in November 2007.[139] There is no evidence that payment systems are linked to quality reports.

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132. *Id.* § 25-3-603.

133. *Id.* § 25-1-124(4).

134. *Id.* § 25-3-605.

135. *Id.*

136. *See id.* § 25-3-109(6).

137. *Id.* § 25-6-605.

138. *Id.* § 25-3-702.

139. *Id.* § 25-3-703; Colorado Hospital Report Card, http://www.cohospitalquality.org/index.php (last visited Nov. 15, 2008).

14. RELEVANT STATUTES AND REGULATIONS: COLO. REV. STAT. § 25-1-124 (2008); COLO. REV. STAT. § 25-3-601 to -607 (2008).
15. OTHER RESOURCES: COLO. DEP'T OF PUB. HEALTH & ENV'T, OCCURRENCE REPORTING MANUAL (2007), *available at* http://www.cdphe.state.co.us/hf/download/occman.pdf.
16. DATE REPORTING STARTED: Occurrence reporting started April 24, 1997.[140] Reporting of hospital-acquired infections started July 31, 2007.[141]

CONNECTICUT

1. GENERAL DESCRIPTION: Hospitals and outpatient surgical facilities must report any "serious reportable event" as defined by the NQF, as well as several supplementary events defined by the Commissioner of Public Health.
2. IS REPORTING MANDATORY? Yes.[142]
3. REPORT RECIPIENT(S): Department of Public Health.[143]
4. IS REPORTING CONDUCTED ELECTRONICALLY? No. Initial reports are submitted in writing. However, if an adverse event is deemed "emergent," it must be reported immediately by telephone, followed by a written report.[144]
5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals and outpatient surgical facilities.[145]
6. WHAT INCIDENTS MUST BE REPORTED? Connecticut requires facilities to report all of the twenty-eight "serious reportable events" listed by the NQF.[146] A list of additional reportable adverse events is also compiled by the Commissioner of Public Health and adopted as regulations.[147] That list includes the following occurrences: "(1) Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability; (2) Obstetrical events resulting in death or serious disability to the neonate; (3) Significant medication reactions resulting in death or serious disability; (4) Laboratory or radiologic test results not reported to the treating practitioner or reported incorrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency

140. COLO. REV. STAT. § 25-1-124 (2008).
141. *Id.* § 25-3-602(3)(a).
142. CONN. GEN. STAT. § 19a-127n(b) (Supp. 2008).
143. *Id.*
144. CONN. AGENCIES REGS. § 19a-127n-2(c) (2008). An emergent report is "the report of an unexpected situation or sudden occurrence of a serious and urgent nature which requires immediate remedial action on the part of the facility to protect the health and safety of its patient population, or an event which is unusually serious in nature and has resulted in a patient's death or injury." *Id.* § 19a-127n-1(6).
145. CONN. GEN. STAT. § 19a-127n(b) (Supp. 2008).
146. *See id.* § 19a-127n(a)(1); *supra* Appendix.
147. CONN. GEN. STAT. § 19a-127n(a)(1) (Supp. 2008).

department; and (5) Nosocomial infections defined as reportable sentinel events by the Joint Commission on Accreditation of Healthcare Organizations."[148]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes. "Nosocomial infections defined as reportable sentinel events by the Joint Commission on Accreditation of Healthcare Organizations" are included in the Department of Public Health's supplemental list of reportable adverse events.[149]

8. DEADLINES: Facilities have seven days to report an adverse event to the Department of Public Health; facilities have thirty days to file a corrective action plan. Facilities may be investigated after a report is filed.[150]

9. PENALTIES AND ENFORCEMENT MECHANISMS: For violations, the Commissioner of Public Health can revoke a facility's license, subject it to suspension or censure, issue a letter of reprimand, place a facility on probation, and/or issue an order to compel compliance.[151]

(a) Revocation of license? Yes.[152]

(b) Audits? No.

10. ARE PUBLIC REPORTS ISSUED? No. The Department of Public Health investigates reports but does not disclose the results to the public. The Commissioner of Public Health shall report annually to the joint standing committee of the General Assembly "having cognizance on matters relating to public health."[153]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes. Any information collected for adverse event reports is confidential and not discoverable for a civil suit.[154]

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: CONN. GEN. STAT. § 19a-127n (2007); CONN. GEN. STAT. § 19a-494 (2007); CONN. AGENCIES REGS. § 19a-127n-2 (2008).

15. OTHER RESOURCES: N/A.

16. DATE REPORTING STARTED: October 1, 2002.[155]

DELAWARE

A medical error reporting regime does not appear to exist for this state.

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148. CONN. AGENCIES REGS. § 19a-127n-2(i) (2008).

149. *Id.*

150. CONN. GEN. STAT. § 19a-127n (Supp. 2008); CONN. AGENCIES REGS. § 19a-127n-2(c), 19a-127n-2(f) (2008).

151. CONN. GEN. STAT. § 19a-494 (Supp. 2008).

152. *Id.*

153. *Id.* § 19a-127n(d).

154. *Id.* § 19a-127n(e).

155. *Id.* § 19a-127n(b).

DISTRICT OF COLUMBIA

1. GENERAL DESCRIPTION: Health care facilities must report "adverse events" to the Department of Health on a semi-annual basis.
2. IS REPORTING MANDATORY? Yes.
3. REPORT RECIPIENT(S): The Department of Health; specifically the Senior Deputy for Health Regulation and Licensing Administration.[156]
4. IS REPORTING CONDUCTED ELECTRONICALLY? No, although the Department of Health expects to have "an interactive [w]eb-based reporting system" by 2009.[157]
5. WHAT FACILITIES MUST PROVIDE REPORTS? An individual or entity licensed or otherwise authorized under District of Columbia law to provide health care services, including "a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long-term care facility, behavioral health residential treatment facility, health clinic, clinical laboratory, health center, physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner."[158]
6. WHAT INCIDENTS MUST BE REPORTED? "Adverse events" must be reported. The D.C. Code defines an "adverse event" as "an event, occurrence, or situation involving the medical care of a patient by a health care provider that results in death or an unanticipated injury to the patient."[159] The Board of Medicine has "defined the statutory term 'adverse event' as the [twenty-eight] Never Events set forth by the National Quality Forum and one [Hospital-Acquired Infection]."[160]
7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? One type of hospital-acquired infection must be reported: "[n]osocomial infection defined as a central catheter associated laboratory confirmed primary bloodstream infection."[161]

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156. E-mail from John Greenhaugh, Senior Assistant Attorney Gen., Health Regulation & Licensing Admin., D.C. Dep't of Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Nov. 6, 2008, 14:42 EST) [hereinafter E-mail from Greenhaugh] (on file with journal).

157. *Id.*

158. D.C. CODE § 7-161(a)(2) (2008).

159. *Id.* § 7-161(a)(1).

160. E-mail from Greenhaugh, *supra* note 156.

161. D.C. Dep't of Health, Adverse Event Reporting Form, at 8, http://hpla.doh.dc.gov/hpla/frames.asp?doc=/hpla/lib/hpla/dc_adverse_event_reporting_form.pdf (last visited Nov. 15, 2008); *see also* E-mail from Greenhaugh, *supra* note 156.

8. DEADLINES: Health care facilities are required to provide reports regarding adverse events by January 1 and July 1 of each year.[162]
9. PENALTIES AND ENFORCEMENT MECHANISMS: If facilities fail to file reports, they are subject to fines ranging from $500 to $2500.[163]
(a) Revocation of license? Unclear from statutes and regulations.
(b) Audits? Unclear from statutes and regulations.
10. ARE PUBLIC REPORTS ISSUED? Yes, the Department of Health issues an annual report.[164]
11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[165]
12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.
13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.
14. RELEVANT STATUTES AND REGULATIONS: D.C. CODE § 7-161 (2008); 17-40 D.C. CODE MUN. REGS. § 4017.40 (Weil 2008).
15. OTHER RESOURCES: D.C. Dep't of Health, Adverse Event Reporting Form, http://hpla.doh.dc.gov/hpla/frames.asp?doc=/hpla/lib/hpla/dc_adverse_event_reporting_form.pdf (last visited Nov. 15, 2008).
16. DATE REPORTING STARTED: July 1, 2007.[166]

FLORIDA

1. GENERAL DESCRIPTION: Licensed health care facilities are required to establish internal risk management programs that include an investigation of the frequency and causes of specific types of adverse incidents. Certain adverse incidents must then be reported to the Agency for Health Care Administration and the Department of Health.
2. IS REPORTING MANDATORY? Yes.[167]
3. REPORT RECIPIENT(S): The Agency for Health Care Administration and the Department of Health. The Florida Patient Safety Corporation, a nonprofit entity, then reviews these adverse event reports in order to recommend "changes in practices and procedures . . . to improve health care quality and to prevent future adverse incidents."[168]
4. IS REPORTING CONDUCTED ELECTRONICALLY? Unclear from statutes and regulations.

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162. D.C. CODE § 7-161(d)(1) (2008).
163. *Id.* § 7-161(d)(2) (2008).
164. *Id.* § 7-161(c)(8); 17-40 D.C. CODE MUN. REGS. § 4017.40 (Weil 2008); E-mail from Greenhaugh, *supra* note 156.
165. D.C. CODE § 7-161(e)(1) (2008).
166. E-mail from Greenhaugh, *supra* note 156.
167. FLA. STAT. § 395.0197(4)(e) (2006); *id.* § 395.0197(7).
168. *Id.* § 381.0271(7)(a)(2).

5. WHAT FACILITIES MUST PROVIDE REPORTS? All licensed facilities must provide reports.[169] These facilities include the office practices of medical doctors[170] and osteopathic practitioners.[171]

6. WHAT INCIDENTS MUST BE REPORTED? "Adverse incidents" must be reported. The Florida statute defines an "adverse incident" as "an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred," and which falls into one of four categories. The first are incidents that result in one of the following injuries: "(1) Death; (2) Brain or spinal damage; (3) Permanent disfigurement; (4) Fracture or dislocation of bones or joints; (5) A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility; (6) Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or (7) Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident." The second category of incidents includes "the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition." The third category of incidents "require[s] the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process." The fourth type of adverse incidents results from "a procedure to remove unplanned foreign objects remaining from a surgical procedure."[172] Internal risk managers at licensed facilities must also investigate allegations of sexual misconduct.[173]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? No.

8. DEADLINES: Facilities have three business days to report adverse incidents to their own internal risk management programs.[174] Certain adverse events must then be reported to the Department of Health within fifteen days.[175]

9. PENALTIES AND ENFORCEMENT MECHANISMS: For non-willful violations of the reporting requirements, the Agency for Health Care Administration first seeks corrective action by the facility. If the facility fails to demonstrate this

169. *Id.* § 395.0197(1).

170. *Id.* § 458.351(1)-(2).

171. *Id.* § 459.026(1)-(2).

172. *Id.* § 395.0197(5).

173. *Id.* § 395.0197(9).

174. *Id.* § 395.0197(4)(e).

175. *Id.* § 395.0197(7) (listing which adverse incidents must be reported to the Agency for Health Care Administration).

correction within the timeframe established by the Agency, or if the Agency discovers a pattern of non-willful violations, the Agency may impose administrative fines, not to exceed $5000 for any individual violation. Penalties for repeated non-willful violations may not exceed $10,000 per violation. Penalties for intentional and willful violations may not exceed $25,000 per violation, per day, and may not exceed $250,000 total.[176]

(a) Revocation of license? Unclear from statutes and regulations.

(b) Audits? As part of its licensure process, the Agency for Health Care Administration is directed to review the internal risk management program at each licensed facility to determine whether the program is appropriately reporting adverse incidents.[177]

10. ARE PUBLIC REPORTS ISSUED? Each licensed facility must submit an annual report summarizing its adverse incident reports for the prior year. This annual report is confidential and is not available to the public.[178] However, on at least a quarterly basis, the Agency for Health Care Administration must publish "a summary and trend analysis of adverse incident reports . . . ."[179] These reports shall not include information that would identify the reporting facility or the practitioners involved.[180] Victims of adverse events have the right to their records and adverse event reports.[181]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[182]

12. IMMUNITY FOR REPORTERS? Yes.[183]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: FLA. STAT. § 381.0271 (2006); FLA. STAT. § 381.028 (2006); FLA. STAT. § 395.0197 (2006); FLA. STAT. § 458.351 (2006); FLA. STAT. § 459.026 (2006).

15. OTHER RESOURCES: N/A.

16. DATE REPORTING STARTED: Unknown.

GEORGIA

A medical error reporting regime does not appear to exist for this state.

176. *Id.* § 395.0197(12).

177. *Id.* § 395.0197(15).

178. *Id.* § 395.0197(5)(c); *id.* § 395.0197(6)(2).

179. *Id.* § 395.0197(8).

180. *Id.*

181. Patient's Right-to-Know About Adverse Medical Incidents Act, FLA. STAT. § 381.028 (2006).

182. FLA. STAT. § 395.0197(6)(c) (2006); FLA. STAT. § 395.0197(7)(h) (2006); *id.* § 395.0197(13)-(14).

183. *Id.* § 395.0197(4).

HAWAII

A medical error reporting regime does not appear to exist for this state.

IDAHO

A medical error reporting regime does not appear to exist for this state.

ILLINOIS

1. GENERAL DESCRIPTION: Hospitals and ambulatory surgical treatment centers are required to report twenty-four different "adverse health care event[s]" to the Department of Public Health. The reporting system "shall not be designed . . . to punish errors or to investigate or take disciplinary action against health care facilities, health care practitioners, or health care facility employees."[184]

2. IS REPORTING MANDATORY? Yes.[185]

3. REPORT RECIPIENT(S): Department of Public Health.[186]

4. IS REPORTING CONDUCTED ELECTRONICALLY? An electronic filing option is available,[187] and the Department of Public Health "will be strongly encouraging facilities to report electronically."[188]

5. WHAT FACILITIES MUST PROVIDE REPORTS? Any "health care facility," which is defined to include state hospitals, university hospitals, hospitals licensed under the Hospital Licensing Act or the University of Illinois Hospital Act, and ambulatory surgical treatment centers.[189]

6. WHAT INCIDENTS MUST BE REPORTED? The Illinois Adverse Health Care Reporting Act of 2005 requires facilities to report twenty-four of the twenty-eight "serious reportable events" listed by the NQF.[190] The four adverse events from the NQF list that have not been adopted by Illinois are 1) death or serious disability associated with failure to identify and treat hyperbilrubinemia in neonates, 2) stage 3 or 4 pressure ulcers acquired after admission to a health care facility, 3) patient death or serious disability due to spinal manipulative therapy, and 4) artificial insemination with the wrong donor sperm or egg.

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Pursuant to the Hospital Report Card Act, hospitals must prepare a quarterly report of

184. 410 ILL. COMP. STAT. 522/10-5 (2005).

185. *Id.* 522/10-15(a).

186. *Id.* 522/10-10 (defining "department").

187. *Id.* 522/10-30(d).

188. Facsimile from Mary Driscoll, Div. Chief of Patient Safety & Quality, Div. of Health Policy, Ill. Dep't of Pub. Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 22, 2008) [hereinafter Facsimile from Driscoll] (on file with journal).

189. 410 ILL. COMP. STAT. 522/10-10 (2005) (defining "health care facility").

190. *Id.* 522/10-15(b)-(g).

"[i]nfection-related measures for the facility,"[191] which includes "central line blood [s]tream infections."[192]

8. DEADLINES: Health care facilities must report adverse health care events within thirty days of discovery to the Department of Public Health.[193] Facilities must then conduct a root cause analysis and implement a corrective action plan within ninety days of the initial submission of the adverse event report.[194]

9. PENALTIES AND ENFORCEMENT MECHANISMS: The statute directs the Department of Public Health to impose sanctions against health care facilities that fail to comply with reporting system requirements.[195] The pending approval of an associated administrative rule will clarify the nature of those sanctions.[196]

(a) Revocation of license? Yes. If a hospital fails to comply with the Adverse Health Care Reporting Act of 2005, its license may be revoked.[197]

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Yes. The Department of Health issues an annual report with aggregate data.[198]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[199]

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: Adverse Health Care Reporting Act of 2005, 410 ILL. COMP. STAT. 522/10-5 to 522/10-50 (2005); Hospital Report Card Act, 210 ILL. COMP. STAT. 86/25(a)(2) (2008); ILL. ADMIN. CODE 255, §§ 250, 280 (2008).

15. OTHER RESOURCES: N/A.

16. DATE REPORTING STARTED: January 1, 2008.[200]

INDIANA

1. GENERAL DESCRIPTION: Administrative regulations require hospitals to implement a quality assessment and improvement program that includes the reporting of serious adverse events to the Indiana Department of Health.

2. IS REPORTING MANDATORY? Yes.[201]

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191. 210 *id.* 86/25(a)(2) (2008).
192. Facsimile from Driscoll, *supra* note 188.
193. 410 ILL. COMP. STAT. 522/10-15(a) (2005).
194. *Id.* 522/10-20.
195. *Id.* 522/10-30(b)(4).
196. Facsimile from Driscoll, *supra* note 188.
197. ILL. ADMIN. CODE tit. 255, § 280 (2008).
198. 410 ILL. COMP. STAT. 522/10-25 (2005); *id.* 522/10-35(4).
199. *Id.* 522/10-25.
200. *Id.* 522/10-30.
201. 410 IND. ADMIN. CODE 15-1.4-2 (2008); *Id.* 15-1.4-2.2(a).

3. REPORT RECIPIENT(S): Department of Health.[202]
4. IS REPORTING CONDUCTED ELECTRONICALLY? Unclear from statutes and regulations.
5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals.[203]
6. WHAT INCIDENTS MUST BE REPORTED? "Serious adverse events" must be reported. Adverse events are defined to include twenty-seven of the twenty-eight "serious reportable events" listed by the NQF.[204] The hospital must also have a "plan to address the internal review and reporting of unusual occurrences and disasters."[205]
7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? No. The reporting of hospital-acquired infections is optional.[206]
8. DEADLINES: Hospitals must submit reports to the Department of Health within fifteen days after the hospital quality assurance and improvement program becomes aware of the incident.[207]
9. PENALTIES AND ENFORCEMENT MECHANISMS: Unclear from statutes and regulations.
(a) Revocation of license? Unclear from statutes and regulations.
(b) Audits? Unclear from statutes and regulations.
10. ARE PUBLIC REPORTS ISSUED? Yes. The Department of Health issues an annual report.[208]
11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[209]
12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.
13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.
14. RELEVANT STATUTES AND REGULATIONS: IND. CODE § 16-40-5-4 to § 16-40-5-6 (Supp. 2008); 410 IND. ADMIN. CODE 15-1.2-1 (2008); 410 IND. ADMIN. CODE 15-1.4-2 (2008); 410 IND. ADMIN. CODE 15-1.4-2.2 (2008).
15. OTHER RESOURCES: N/A.
16. DATE REPORTING STARTED: Unknown.

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202. *Id.* 15-1.4-2; *Id.* 15-1.4-2.2(a).

203. *Id.* 15-1.4-2; *Id.* 15-1.4-2.2.

204. *See id.* 15-1.4-2.2(a); *supra* Appendix. The National Quality Forum and Indiana lists are nearly identical, with the exception that the Indiana regulation does not specifically include the event of artificial insemination with the wrong donor sperm or wrong egg as a reportable event.

205. 410 IND. ADMIN. CODE 15-1.2-1 (2008) (listing examples of unusual occurrences and disasters).

206. IND. CODE § 16-40-5-5(2) (Supp. 2008) (stating that health care facilities, health care professionals, and individuals may file reports of infections that were acquired in the health care facility).

207. 410 IND. ADMIN. CODE 15-1.4-2.2(c)(1)(B) (2008).

208. *Id.* 15-1.4-2.2(d).

209. IND. CODE § 16-40-5-6 (Supp. 2008).

IOWA

A medical error reporting regime does not appear to exist for this state.

KANSAS

1. GENERAL DESCRIPTION: Health care providers, medical care facility agents, and medical care facility employees must report incidents in which an action by a health care provider "(1) [i]s or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency."[210] Reports are first filed internally for review and then sent to the appropriate state licensing agency for "appropriate disciplinary measures."[211]

2. IS REPORTING MANDATORY? Yes.[212]

3. REPORT RECIPIENT(S): Health care providers, medical care facility agents, and medical care facility employees report incidents directly to "the chief of the medical staff, chief administrative officer or risk manager of the facility."[213] This individual then "refer[s] the report to the appropriate executive committee or professional practices peer review committee . . . ."[214] After investigating the report, the applicable committee must "report to the appropriate state licensing agency any finding by the committee that a health care provider acted below the applicable standard of care which action had a reasonable probability of causing injury to a patient, or in a manner which may be grounds for disciplinary action by the appropriate licensing agency, so that the agency may take appropriate disciplinary measures."[215]

4. IS REPORTING CONDUCTED ELECTRONICALLY? No.[216]

5. WHAT FACILITIES MUST PROVIDE REPORTS? Licensed medical care facilities, private psychiatric hospitals, state psychiatric hospitals, and certain state institutions for the mentally retarded.[217]

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210. KAN. STAT. ANN. § 65-4921(f) (2007); *id.* § 65-4923(a)(2).

211. *Id.* § 65-4923(a)(2).

212. *Id.* § 65-4923(a) ("If a health care provider, or a medical care facility agent or employee who is directly involved in the delivery of health care services, has knowledge that a health care provider has committed a reportable incident, such health care provider, agent or employee shall report such knowledge . . . .").

213. *Id.* § 65-4923(a)(2).

214. *Id.*

215. *Id.*

216. KAN. ADMIN. REGS. § 28-52-2(a) (2008) ("Each medical care facility shall identify a written form on which employees and health care providers shall report clinical care concerns to the risk manager, chief of staff, or administrator.").

217. KAN. STAT. ANN. § 65-4921(e) (2007) (defining "[m]edical care facility").

6. WHAT INCIDENTS MUST BE REPORTED? A "[r]eportable incident" is defined as "an act by a health care provider which: (1) Is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency."[218]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Unclear from statutes and regulations.

8. DEADLINES: At least once every three months, the review and executive committee of the medical facility must submit a report to the secretary of health and environment "summarizing the reports received" for the applicable time period.[219] "The report shall include the number of reportable incidents reported, whether an investigation was conducted and any action taken."[220]

9. PENALTIES AND ENFORCEMENT MECHANISMS: "No person or entity shall be subject to liability in a civil action for failure to report as required" under the reporting program.[221]

> **(a) Revocation of license?** Yes. "The license of a person or entity required to report . . . may be revoked, suspended or limited, or the licensee subjected to public or private censure, by the appropriate state licensing agency if the licensee is found . . . to have willfully and knowingly failed to make any [required] report."[222]
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> **(b) Audits?** Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Yes. Annual reports are issued.[223]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes. "The reports and records made pursuant to [this reporting program] . . . shall be confidential and privileged."[224] "Such reports and records shall not be subject to discovery, subpoena or other means of legal compulsion for their release to any person or entity and shall not be admissible in any civil or administrative action other than a disciplinary proceeding by the appropriate state licensing agency."[225] Witnesses or participants in meetings of the executive or review committees of affected medical facilities shall not "be compelled to testify in any civil, criminal or administrative action, other than a disciplinary proceeding by the appropriate licensing agency, as to any committee discussions or proceedings."[226]

12. IMMUNITY FOR REPORTERS? Yes. "No employer shall discharge or otherwise discriminate against any employee for making any report" required by

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218. *Id.* § 65-4921(f).
219. *Id.* § 65-4923(d).
220. *Id.*
221. *Id.* § 65-4927(a).
222. *Id.* § 65-4927(b).
223. ROSENTHAL AND TAKACH, *supra* note 15, at 14.
224. KAN. STAT. ANN. § 65-4925(a) (2007).
225. *Id.*
226. *Id.* § 65-4925(b).

the applicable statute.[227] The statute provides for the recovery of damages by aggrieved employees for monetary losses attributable to wrongful discharge.[228] Further, "[a]ny person or entity which, in good faith, reports or provides information or investigates any health care provider [under this reporting program] . . . shall not be liable in a civil action for damages or other relief arising from the reporting."[229]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: KAN. STAT. ANN. § 65-4921 to -4929 (2007); KAN. ADMIN. REGS. § 28-52-1 to -4 (2008).

15. OTHER RESOURCES: N/A.

16. DATE REPORTING STARTED: 1986.[230]

KENTUCKY

A medical error reporting regime does not exist for this state.[231]

LOUISIANA

A medical error reporting regime does not appear to exist for this state.

MAINE

1. GENERAL DESCRIPTION: Health care facilities must notify the Division of Licensing and Certification within the Bureau of Medical Services of the occurrence of any "sentinel event."

2. IS REPORTING MANDATORY? Yes. Sentinel event reporting is mandatory.

3. REPORT RECIPIENT(S): The Division of Licensing and Certification within the Bureau of Medical Services.[232]

4. IS REPORTING CONDUCTED ELECTRONICALLY? Yes.[233]

5. WHAT FACILITIES MUST PROVIDE REPORTS? All health care facilities "defined under Title 34-B, chapter 1 or a health care facility licensed by the division," except for facilities "licensed as a nursing facility or licensed under chapter 1665."[234] This includes general and specialty hospitals, ambulatory

227. *Id.* § 65-4928(a).

228. *Id.* § 65-4928(b).

229. *Id.* § 65-4926.

230. *Id.* §§ 65-4921 to -4929.

231. Letter from J. Thomas Badgett, Chief Med. Officer, Ky. Cabinet for Health & Family Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 21, 2008) (on file with journal).

232. ME. REV. STAT. ANN. tit. 22 §§ 8752(2), 8753 (2008).

233. *Id.* § 8754(2).

234. *Id.* §§ 8752(2), 8753 (defining "health care facility").

surgical centers, end-stage renal disease facilities or units, and intermediate care facilities for persons with mental retardation.[235]

6. WHAT INCIDENTS MUST BE REPORTED? Any of the following sentinel events that are "determined to be unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition or that results from the elopement of a hospitalized inpatient who lacks the capacity . . . to make decisions:" 1) an "unanticipated death" or "a major permanent loss of function that is not present when the patient is admitted to the health care facility;" 2) "[s]urgery on the wrong patient or wrong body part;" 3) "[h]emolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;" 4) "[s]uicide of a patient in a health care facility where the patient receives inpatient care;" 5) "[i]nfant abduction or discharge to the wrong family;" 6) "[r]ape of a patient."[236]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Hospital-acquired infections are not explicitly listed as a separate category of sentinel events, but could qualify as "adverse events" in instances where the infection results in unanticipated death or a major permanent loss of function.

8. DEADLINES: The Division of Licensing and Certification must be notified the next business day after the sentinel event or its discovery. The health care facility then files a written report within forty-five days of the occurrence.[237]

9. PENALTIES AND ENFORCEMENT MECHANISMS: If a health care facility knowingly violates reporting requirements, it is subject to a civil penalty of up to $5000 per unreported episode. That fine must be recovered in a civil action. Fines are deposited in a special account to support sentinel event reporting and education.[238]

(a) Revocation of license? Unclear from statutes and regulations.

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Yes. The Division of Licensing and Certification develops an annual report for the legislature, health care facilities, and the public. The annual report includes summary data of the number and types of sentinel events of the prior calendar year by type of health care facility, rates of change, other analyses, and an outline of areas to be addressed for the upcoming year.[239]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[240]

12. IMMUNITY FOR REPORTERS? Yes.[241]

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235. ME. DEP'T OF HEALTH & HUMAN SERVS., SENTINEL EVENT ANNUAL REPORT TO THE LEGISLATURE: CY 2006 (2007), http://maine.gov/dhhs/dlrs/medical_facilities/archive/SE_Annual_Report_2007.doc.

236. ME. REV. STAT. ANN. 22 tit. §§ 8752(4), 8753 (2008) (defining "sentinel events").

237. *Id.* § 8753(2).

238. *Id.* § 8755.

239. *Id.* § 8754(4).

240. *Id.* § 8754(3).

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? Unclear from statutes and regulations.
14. RELEVANT STATUTES AND REGULATIONS: ME. REV. STAT. ANN. tit. 22, §§ 8751-8756 (2008); 10-144-112 ME. CODE R. § VI (Weil 2008); 10-144-118 ME. CODE R. § 5.C.7 (Weil 2008); 10-144-125 ME. CODE R. § 4.B. (Weil 2008); 10-144-126 ME. CODE R. § 4.F. (Weil 2008).
15. OTHER RESOURCES: NAT'L ACAD. FOR STATE HEALTH POLICY, AN ACT TO REDUCE MEDICAL ERRORS AND IMPROVE PATIENT HEALTH: A CASE STUDY FROM MAINE (2002), http://www.nashp.org/Files/Mandatory_reporting_ME.pdf; ME. DEP'T OF HEALTH & HUMAN SERVS., SENTINEL EVENT ANNUAL REPORT TO THE LEGISLATURE: CY 2006 (2007), http://maine.gov/dhhs/dlrs/medical_facilities/archive/SE_Annual_Report_2007.doc.
16. DATE REPORTING STARTED: May 2003.[242]

MARYLAND

1. GENERAL DESCRIPTION: Hospitals must report all "level 1 adverse events" to the Department of Health and Mental Hygiene[243] and conduct root cause analyses of these events.
2. IS REPORTING MANDATORY? Reporting is only mandatory for "level 1" events, as defined below.
3. REPORT RECIPIENT(S): Department of Health and Mental Hygiene.[244]
4. IS REPORTING CONDUCTED ELECTRONICALLY? Unclear from statutes and regulations.
5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals.[245]
6. WHAT INCIDENTS MUST BE REPORTED? Hospitals must report "level 1 adverse event[s]" to the Department of Health and Mental Hygiene. An "adverse event" is an "unexpected occurrence related to an individual's medical treatment and not related to the natural course of the patient's illness or underlying disease condition."[246] A "[l]evel 1 adverse event" means "an adverse event that results in death or serious disability,"[247] and hospitals must report these events to the Department of Health and Mental Hygiene. A "[l]evel 2 adverse event" is "an adverse event that requires a medical intervention to prevent death or serious disability."[248] A "[n]ear-miss" is a "situation that could have resulted in an

241. *Id.* § 8753(4).
242. Id. § 8751.
243. MD. CODE REGS. 10.07.06.04(B)(1) (2008); *id.* 10.07.06.09.
244. *Id.* 10.07.06.02(3) (defining "department"); *id.* 10.07.06.09.
245. *Id.* 10.07.06.01.
246. *Id.* 10.07.06.02(2).
247. *Id.* 10.07.06.02(4).
248. *Id.* 10.07.06.02(5). A "[l]evel 3 adverse event" is "an adverse event that does not result in death or serious disability and does not require any medical intervention to prevent death or serious

adverse event but did not, either by chance or through timely intervention"; hospitals are encouraged to report "near-misses."[249] In addition to identifying "any immediate corrective action to prevent reoccurrence," the hospital is also required to complete a root cause analysis for any level 1 or 2 adverse event (or near-miss that warrants a root cause analysis).[250] Root cause analyses for level 1 adverse events must be submitted to the Department of Health and Mental Hygiene.

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Hospital-acquired infections are not explicitly listed as a separate category, but could qualify as "level 1 adverse events" if they result in death or serious disability.

8. DEADLINES: Hospitals must report level 1 adverse events within five days of the hospital's knowledge of the event. The hospital is then required to submit a root cause analysis and action plan within sixty days of its knowledge of the event.[251]

9. PENALTIES AND ENFORCEMENT MECHANISMS: If a hospital fails to implement a patient safety program that fulfills the requirements of the applicable regulations, then the Secretary of Health and Mental Hygiene may revoke the hospital's license or assess a fine of $500 per day.[252]

(a) Revocation of license? Yes.[253]

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Yes, an annual report is produced by the Hospital Patient Safety Program that provides aggregate data on level 1 adverse events in Maryland hospitals.[254]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[255]

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: MD. CODE ANN., HEALTH-GEN. § 19-304 (2005); MD. CODE REGS. 10.07.06.01-16 (2008) (Hospital Patient Safety Program); *see also* MD. CODE ANN., HEALTH-GEN. § 19-305 (2005) (requiring residential treatment centers to notify a resident's family or guardian of adverse events and changes in condition).

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disability." *Id.* 10.07.06.02(6).

249. *Id.* 10.07.06.02(8).

250. *Id.* 10.07.06.05. Level 3 adverse events and certain near-misses should still be evaluated by the hospital to determine any patterns or trends, although they need not be reported to the Department of Health and Mental Hygiene. *Id.* 10.07.06.07.

251. *Id.* 10.07.06.09(A-B).

252. MD. CODE ANN., HEALTH-GEN. § 19-304 (2005); MD. CODE REGS. 10.07.06.16 (2008).

253. MD. CODE REGS. 10.07.06.16(A) (2008).

254. *See, e.g.*, MD. DEP'T OF HEALTH & MENTAL HYGIENE, MARYLAND HOSPITAL PATIENT SAFETY PROGRAM ANNUAL REPORT: FISCAL YEAR 2007, http://www.dhmh.state.md.us/ohcq/download/reports/mhpsp_07_report.pdf.

255. MD. CODE REGS. 10.07.06.09(C) (2008).

15. OTHER RESOURCES: MD. DEP'T OF HEALTH & MENTAL HYGIENE, MARYLAND HOSPITAL PATIENT SAFETY PROGRAM ANNUAL REPORT: FISCAL YEAR 2007, http://www.dhmh.state.md.us/ohcq/download/reports/mhpsp_07_report.pdf.

16. DATE REPORTING STARTED: March 15, 2004.[256]

MASSACHUSETTS

1. GENERAL DESCRIPTION: Health care facilities must report "major incidents" to the Board of Registration in Medicine.[257] Health care facilities must also report "serious incidents" to the Division of Health Care Quality within the Department of Public Health's Bureau of Health Care Safety and Quality.[258] Starting on August 10, 2008, hospitals and ambulatory surgical centers are also required to report the NQF's "serious reportable events"[259] and hospital-acquired infections to the Health Care Quality and Cost Council within the Executive Office of Health and Human Services.[260]

In January 2004, Massachusetts launched the Betsy Lehman Center for Patient Safety and Medical Error Reduction. The center is meant to serve as a clearinghouse for the development and dissemination of best practices for patient safety. The Massachusetts General Laws mandate that the Center "coordinate state participation in any appropriate state or federal reports or data collection efforts relative to patient safety and medical error reduction. The center shall analyze available data, research and reports for information that would improve education and training programs that promote patient safety."[261]

2. IS REPORTING MANDATORY? Yes.

3. REPORT RECIPIENT(S): Board of Registration in Medicine; Department of Public Health; Health Care Quality and Cost Council.

4. IS REPORTING CONDUCTED ELECTRONICALLY? Unclear from statutes and regulations.[262]

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256. *Id.* 10.07.06.03(A) (specifying date on which "patient safety program" associated with reporting of Level 1 adverse events must be implemented).

257. 243 MASS. CODE REGS. 3.08(2) (2008). The regulation alternates between the terms "major accident" and "major incident." The Division of Health Care Quality of the Massachusetts Department of Public Health indicated that "major incident" is the proper term. Letter from Nancy Murphy, Policy Analyst, Div. of Health Care Quality, Mass. Dep't of Pub. Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 17, 2008) [hereinafter Letter from Murphy] (on file with journal).

258. 105 MASS. CODE REGS. 130.331(2008); Letter from Murphy, *supra* note 257.

259. *See supra* Appendix.

260. 2008 Mass. Legis. Serv. ch. 305 (West); Letter from Murphy, *supra* note 257.

261. MASS. GEN. LAWS ch. 6A, § 16E (2006).

262. 243 MASS. CODE REGS. 3.08(3) (2008) ("When reporting a major incident, health care facilities shall use the Board's form prescribed for that purpose.").

5. WHAT FACILITIES MUST PROVIDE REPORTS? "Health care facilit[ies]" must report "major incidents." A health care facility is defined as "any entity licensed pursuant to [Mass. Gen. Laws ch. 111, § 51 (2006) (Hospitals, institutions for unwed mothers, or clinics)]; any nursing home, within the meaning of [Mass. Gen. Laws ch. 111, § 203(d) (2006)]; any state, county or municipal hospital; any entity maintaining more than one primary or episodic walk-in center; and any health maintenance organization within the meaning of [Mass. Gen. Laws ch. 176G, § 1 (2006)]."[263] Hospitals must report "serious incidents" in addition to major incidents.[264]

6. WHAT INCIDENTS MUST BE REPORTED? Health care facilities must report "major incidents" to the Board of Registration in Medicine. Major incidents are defined as "(a) Maternal deaths that are related to delivery"; "(b) Death in the course of, or resulting from, elective ambulatory procedures"; "(c) Any invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity or body part"; and "(d) All deaths or major or permanent impairments of bodily functions . . . that are not ordinarily expected as a result of the patient's condition on presentation."[265] Major incidents of type (d) are not necessarily errors. The regulation seeks to identify any outcomes that are rare relative to the normal progression of a disease or condition.[266]

In addition, hospitals must report "serious incidents" to the Department of Public Health, which are defined as: "(1) Fire; (2) Suicide; (3) Serious criminal acts; (4) Pending or actual strike action by its employees, and contingency plans for operation of the hospital; (5) Serious physical injury to a patient resulting from an accident or unknown cause."[267]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? "Beginning in July 2008, pursuant to hospital licensure regulatory amendments, hospitals must participate in and report healthcare-associated infections to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). The Department [of Public Health] will have access to certain data for the purposes of monitoring and public reporting. Public reports will be available on the Health Care Quality and Cost Council's consumer health information website beginning in March 2009. The Betsy Lehman Center will have access to certain data for review and development of recommendations regarding future public reporting."[268]

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263. *Id.* 3.02.

264. 105 *id.* 130.331.

265. 243 *id.* 3.08(2).

266. *Id.* 3.08(2)(d).

267. 105 *id.* 130.331(A).

268. Letter from Murphy, *supra* note 257; *see also* 2008 Mass. Legis. Serv. ch. 305 (West).

8. DEADLINES: Health care facilities must file "major incident" reports with the Board of Registration in Medicine on a quarterly basis.[269] Hospitals must immediately report via telephone any "serious incident" to the Department of Public Health. A hospital must also file written reports within one week for "any other serious incidents occurring on the premises covered by its license . . . which seriously affect the health and safety of its patients."[270]

9. PENALTIES AND ENFORCEMENT MECHANISMS: "If any insurer or health care provider fails to submit required data to the [Health Care Quality and Cost Council] on a timely basis, the council shall provide written notice to the insurer or health care provider. An insurer or health care provider that fails, without just cause, to provide the required information within [two] weeks following receipt of the written notice may be required to pay a penalty of $1,000 for each week of delay; provided, however, that the maximum annual penalty under this section shall be $50,000."[271]

(a) Revocation of license? Participation in the Patient Care Assessment (PCA) program operated by the Board of Registration in Medicine is a condition of both hospital and physician licensure. However, the "PCA Committee is not punitive or adversarial in nature; it does not discipline physicians or regulate their licensure."[272]

(b) Audits? The Board of Registration in Medicine and the Department of Public Health have "access and audit authority over Qualified Patient Care Assessment Program information and records during normal business hours."[273] The Board's authority to conduct external audits is limited to "all incident reports, patient complaints, employee training materials, credentialing items, Patient Care Assessment Coordinator reports, and other items [the hospitals] are charged with generating."[274] The Board is not, however, entitled to "access and audit authority" over a hospital's Peer Review Committee "proceedings, reports, and records" unless necessary for the Board during its "investigation of a complaint [regarding a physician] . . . ."[275] Health care facilities are also required to conduct internal reviews of "a percentage of patients' medical records . . . shortly after discharge" to "reveal . . . adverse or potentially adverse patient occurrences that might not otherwise be evident."[276] The "Patient Care Assessment Coordinator" at the health care facility, who is

269. 243 MASS. CODE REGS. 3.08(3) (2008).

270. 105 *id.* 130.331.

271. 2008 Mass. Legis. Serv. ch. 305 (West).

272. Commonwealth of Mass., Bd. of Registration in Med., Patient Care Assessment, http://www.massmedboard.org/pca (last visited Nov. 15, 2008).

273. 243 MASS. CODE REGS. 3.07(3)(k) (2008).

274. Beth Israel Hosp. Ass'n v. Bd. of Registration in Med., 515 N.E.2d 574, 580 (Mass. 1987).

275. *Id.* at 579 n.11.

276. 243 MASS. CODE REGS. 3.07(3)(c) (2008).

charged with "implement[ing] . . . a facility's Qualified Patient Care Assessment Program," is also responsible for creating "a random chart audit system to assure compliance with the incident reporting requirements."[277]

10. ARE PUBLIC REPORTS ISSUED? Yes, the Board of Registration in Medicine releases an annual report regarding "major incidents" reported to its Patient Care Assessment Division.[278] Serious "incident reports (with protected health information redacted) are public information once a review is completed and the case is closed."[279]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[280]

12. IMMUNITY FOR REPORTERS? Yes. "No person filing a complaint [against a licensed physician] or . . . assisting the [Board of Registration in Medicine] at its request in any manner in discharging its duties and functions shall be liable in any cause of action arising out of the receiving of such information or assistance, provided the person making the complaint or reporting or providing such information or assistance does so in good faith and without malice."[281]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? Unclear from statutes and regulations.

14. RELEVANT STATUTES AND REGULATIONS: MASS. GEN. LAWS ch. 111, §§ 203-205 (West 2003 & Supp. 2008); MASS. GEN. LAWS ch. 112, § 5 (Supp. 2008); 243 MASS. CODE REGS. 3.07-3.08 (2008).

15. OTHER RESOURCES: COMMONWEALTH OF MASS., BD. OF REGISTRATION IN MED., PATIENT CARE ASSESSMENT DIVISION ANNUAL REPORT (2005), http://www.massmedboard.org/pca/pdf/pca_annual_report_2005.pdf.

16. DATE REPORTING STARTED: 1987.[282]

MICHIGAN

"Michigan does not require the mandatory reporting of medical errors, nor [is] information as to near misses or potential adverse events systematically gathered by [the] Department [of Community Health]."[283] Nevertheless, "the concerns of medical errors have and will continue to receive attention across Michigan's

277. *Id.* 3.07(3)(d)(3).

278. *See, e.g.*, COMMONWEALTH OF MASS., BD. OF REGISTRATION IN MED., PATIENT CARE ASSESSMENT DIVISION ANNUAL REPORT (2005), http://www.massmedboard.org/pca/pdf/pca_annual_report_2005.pdf.

279. Letter from Murphy, *supra* note 257.

280. MASS. GEN. LAWS ANN. ch. 111, § 204 (West 2003 & Supp. 2008); *id.* § 205 (West 2003).

281. *Id.* ch. 112, § 5 (Supp. 2008).

282. 243 MASS. CODE REGS. 3.07(3) (2008); *see also* COMMONWEALTH OF MASS., BD. OF REGISTRATION IN MED., *supra* note 278.

283. Letter from Janet Olszewski, Dir., Mich. Dep't of Cmty. Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 8, 2008) [hereinafter Letter from Olszewski] (on file with journal).

entire continuum of health care. In 2006, the Michigan State Commission on Patient Safety recommended to the Governor a statewide voluntary, confidential, non-punitive health care error and near-miss reporting system. In response to the federal Patient Safety and Quality Improvement Act of 2005, the Michigan Health & Hospital Association recently established a new Patient Safety Organization . . . that will collect and analyze data about medical errors and near misses in Michigan hospitals."[284] Finally, 108 hospitals have voluntarily committed to participating in a project organized by the Health & Hospital Association to reduce hospital-acquired infections that will entail the collection of data on hospital-acquired infections.[285]

MINNESOTA

1. GENERAL DESCRIPTION: Minnesota has implemented a comprehensive reporting regime that requires all hospitals and outpatient surgical centers to report the occurrence of any of the twenty-eight "serious reportable events" designated by the NQF.

2. IS REPORTING MANDATORY? Yes.[286]

3. REPORT RECIPIENT(S): Commissioner of Health.

4. IS REPORTING CONDUCTED ELECTRONICALLY? Electronic reporting is available but not required.[287]

5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals and outpatient surgical centers.[288]

6. WHAT INCIDENTS MUST BE REPORTED? The Minnesota Adverse Health Care Events Reporting Act requires the reporting of all of the twenty-eight "serious reportable events" listed by the NQF.[289] The Commissioner of Health is directed to monitor implementation efforts in other states and offer recommendations to the legislature for the modification of this list in order to keep the reporting system "as . . . uniform as possible with similar systems in other states."[290]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Hospital-acquired infections are not explicitly listed as a separate category, but could result from other "adverse events" (e.g., the use of contaminated drugs, devices, or biologics).

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284. *Id.*

285. Mich. Health & Hosp. Ass'n, Keystone: HAI, http://www.mhakeystonecenter.org/hai_overview.htm (last visited Nov. 15, 2008); *see also* Letter from Olszewski, *supra* note 283.

286. MINN. STAT. § 144.7065 (Supp. 2008) (detailing "facility requirements to report, analyze, and correct").

287. *Id.* § 144.7065(9).

288. *Id.* § 144.7063(3) (defining "facility").

289. *Id.* § 144.7065(2)-(7); *see also supra* Appendix.

290. MINN. STAT. § 144.7069 (Supp. 2008).

8. DEADLINES: Adverse health care events should be reported "as soon as is reasonably and practically possible, but no later than fifteen (15) working days after discovery of the event."[291] A root cause analysis of the event and a plan of corrective action are due to the Commissioner of Health within sixty days of the event.[292]

9. PENALTIES AND ENFORCEMENT MECHANISMS: The reporting system includes "sanctions against facilities for failure to comply with [its] requirements." Violations of reporting system requirements may entail "failure to file a timely adverse event report," failure to conduct a root cause analysis," and failure "to implement a corrective action plan . . . ."[293]

> **(a) Revocation of license?** Yes. "If a facility fails to develop and implement a corrective action plan or report to the commissioner why corrective action is not needed, the commissioner may suspend, revoke, fail to renew, or place conditions on the license under which the facility operates."[294]
>
> **(b) Audits?** While the statute does not indicate whether the Commissioner of Health is authorized to conduct random audits of health care facility records, it does require the Commissioner to review the reports from various licensing boards (e.g., the Board of Medical Practice, the Board of Pharmacy) and determine whether the events listed therein have been previously reported under the Adverse Health Care Events Reporting Act. If an event has not been reported, the facility knew or reasonably should have known about the occurrence of that event, and the event was reportable under section 144.7065, then the facility will be considered out of compliance with the reporting act and will be subject to investigation by the Department of Health under the Vulnerable Adult Act or the Maltreatment of Minors Act.[295] In addition, the Department of Health website indicates that the Department reviews all death records to determine whether deaths were related to reportable adverse events.[296]

10. ARE PUBLIC REPORTS ISSUED? Yes. The Commissioner of Health is required to publish an annual report regarding the adverse event reporting system.[297] These annual reports release data at the level of individual facilities.[298]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[299]

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291. *Id.* § 144.7065(1).

292. *Id.* § 144.7065(8).

293. *Id.* § 144.7067.

294. *Id.* § 144.7067(3)(b).

295. *Id.* § 144.7068.

296. Minn. Dep't of Health, Frequently Asked Questions: Adverse Events, http://www.health.state.mn.us/patientsafety/ae/faq.html (last visited Nov. 15, 2008).

297. MINN. STAT. § 144.7067(2)(4) (Supp. 2008).

298. *See, e.g.*, MINN. DEP'T OF HEALTH, *supra* note 73.

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.
13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? Unclear from statutes and regulations.
14. RELEVANT STATUTES AND REGULATIONS: Minnesota Adverse Health Care Events Reporting Act of 2003, MINN. STAT. §§ 144.7063-144.7069 (Supp. 2008); MINN. STAT. § 145.64 (Supp. 2008).
15. OTHER RESOURCES: MINN. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN MINNESOTA (2008), http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf.
16. DATE REPORTING STARTED: July 1, 2003.[300]

MISSISSIPPI

A medical error reporting regime does not appear to exist for this state.

MISSOURI

A medical error reporting regime does not appear to exist for this state.

MONTANA

A medical error reporting regime does not exist for this state.[301]

NEBRASKA

1. GENERAL DESCRIPTION: Nebraska's error reporting regime is set forth in the Patient Safety Improvement Act. The act allows certain nonprofit organizations ("patient safety organizations") to collect data on a host of specified types of medical errors from health care providers that agree to participate. Participating health care providers voluntarily agree to report medical errors, prepare root cause analyses, and implement action plans. The act is "not administered by . . . the Department of Health and Human Services, and such reporting is not required of licensed health professionals."[302]
2. IS REPORTING MANDATORY? No. Reporting is voluntary.

299. MINN. STAT. § 145.64 (Supp. 2008).

300. MINN. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN MINNESOTA: FIRST ANNUAL PUBLIC REPORT 3 (2005), http://www.health.state.mn.us/patientsafety/ae/aereport0105.pdf.

301. Facsimile from Roy Kemp, Deputy Adm'r (QAP), Mont. Dep't of Pub. Health & Human Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 27, 2008) (on file with journal).

302. Letter from Becky Wisell, Adm'r, Office of Med. & Specialized Health, Neb. Dep't of Health & Human Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 16, 2008) [hereinafter Letter from Wisell] (on file with journal).

3. REPORT RECIPIENT(S): "Patient safety organizations" that are nonprofit as defined by section 501(c)(3) of the Internal Revenue Code.[303] The Act specifies rules for the composition of the board of a patient safety organization.[304]
4. IS REPORTING CONDUCTED ELECTRONICALLY? Unclear from statutes and regulations.
5. WHAT FACILITIES MUST PROVIDE REPORTS? A provider under the Act is either: "(1) A facility licensed under the Health Care Facility Licensure Act; or (2) A health care professional licensed under the Uniform Credentialing Act."[305] Providers elect whether to participate.[306]
6. WHAT INCIDENTS MUST BE REPORTED? Covered events include the following: "(a) Surgery or procedures performed on the wrong patient or the wrong body part of a patient; (b) Foreign object accidentally left in a patient during a procedure or surgery; (c) Hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities; (d) Sexual assault of a patient during treatment or while the patient was on the premises of a facility; (e) Abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant; (f) Suicide of a patient in a setting in which the patient received care twenty-four hours a day; (g) Medication error resulting in a patient's unanticipated death or permanent or temporary loss of bodily function, including (i) [circumstances necessitating] treatment intervention, [resulting in] temporary harm, (ii) [circumstances necessitating] initial-prolonged hospitalization, [resulting in] temporary harm, (iii) permanent patient harm, and (iv) near death event in circumstances unrelated to the natural course of the illness or underlying condition of the patient, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, but excluding reasonable differences in clinical judgment on drug selection and dose; (h) Patient death or serious disability associated with the use of adulterated drugs, devices, or biologics provided by the provider; (i) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended; and (j) Unanticipated death or major permanent loss of function associated with . . . nosocomial infection."[307] Patient safety organizations, upon reviewing indicators recommended by the Joint Commission on Accreditation of Healthcare

303. NEB. REV. STAT. § 71-8714 (Supp. 2007).
304. *Id.* § 71-8715.
305. *Id.* § 71-8709 (defining "provider").
306. *Id.* § 71-8716(2).
307. *Id.* § 71-8717(1).

Organizations, can add or subtract from the list of reportable patient safety events, and those changes shall be binding on providers who elect to participate.[308] This list shares several elements with the list provided by the NQF, but the lists are not identical.

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Only to the extent that the infection results in death or major permanent loss of function.[309]

8. DEADLINES: Providers report aggregate totals of each type of event on an annual basis. For each reported event, a root cause analysis and action plan must be conducted within forty-five days. A copy of that action plan must be sent to the relevant patient safety organization within thirty days of its creation.[310]

9. PENALTIES AND ENFORCEMENT MECHANISMS: This voluntary program does not feature penalties or enforcement mechanisms.

(a) Revocation of license? N/A.

(b) Audits? N/A.

10. ARE PUBLIC REPORTS ISSUED? Yes. "A patient safety organization shall release to the public non-identifiable aggregate trend data identifying the number and types of patient safety events that occur. A patient safety organization shall publish educational and evidenced-based information from the summary reports, which shall be available to the public, that can be used by all providers to improve the care they provide."[311]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[312]

12. IMMUNITY FOR REPORTERS? Yes, unless reporting was done "with actual malice, fraudulent intent, or bad faith."[313]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: Patient Safety Improvement Act of 2005, NEB. REV. STAT. §§ 71-8701 to -21 (Supp. 2007).

15. OTHER RESOURCES: N/A.

16. DATE REPORTING STARTED: Unknown.

NEVADA

1. GENERAL DESCRIPTION: Medical facilities, through their "patient safety officers," report all sentinel events to the State Health Division of the Department of Health and Human Services.[314]

2. IS REPORTING MANDATORY? Yes.[315]

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308. *Id.* § 71-8717(2).

309. *Id.* § 71-8717(1)(j) (requiring reporting of "[u]nanticipated death or major permanent loss of function associated with health care associated nosocomial infection").

310. *Id.* § 71-8718.

311. *Id.* § 71-8720.

312. *Id.* §§ 71-8710 to -13.

313. *Id.* § 71-8721.

314. NEV. ADMIN. CODE § 439.902 (2008) (defining "division").

3. REPORT RECIPIENT(S): Medical facility employees report sentinel events to the "patient safety officer" designated by the facility. The patient safety officer then reports the sentinel events to the State Health Division of the Department of Health and Human Services.[316]
4. IS REPORTING CONDUCTED ELECTRONICALLY? No. "Reports are submitted via fax and/or [United States Postal Service] Certified Mail. As funds become available, future plans include implementing a web-based system."[317]
5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals, obstetric centers, surgical centers for ambulatory patients, and independent centers for emergency medical care.[318]
6. WHAT INCIDENTS MUST BE REPORTED? Medical facilities are responsible for reporting the occurrence of all "sentinel events."[319] A sentinel event is defined as "an unexpected occurrence involving facility-acquired infection, death or serious physical or psychological injury or the risk thereof, including, without limitation, any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. The term includes loss of limb or function."[320] The reporting form used by medical facilities contains a list of reportable events. "The list is based on the NQF Never Events, Joint Commission [on Accreditation of Healthcare Organizations] reportable sentinel events and statutory requirements."[321]
7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes.[322]
8. DEADLINES: Any person employed by a medical facility must report sentinel events to the facility's patient safety officer within twenty-four hours of becoming aware of the event. The patient safety officer then has thirteen days to report the sentinel event to the health division.[323] If the patient safety officer is the individual to discover the sentinel event, that officer has fourteen days to

315. NEV. REV. STAT. § 439.835 (2005 & Supp. 2008).

316. *Id.*

317. E-mail from Lynn O'Mara, Health Planning Program Manager, Bureau of Health Statistics, Planning & Emergency Response, Nev. State Health Div., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Nov. 7, 2008, 14:56 EST) [hereinafter E-mail from O'Mara] (on file with journal).

318. NEV. REV. STAT. § 439.805 (2005 & Supp. 2008) (defining "medical facility").

319. *Id.* § 439.835.

320. *Id.* § 439.830 (defining "sentinel event").

321. E-mail from O'Mara, *supra* note 317.

322. NEV. REV. STAT. § 439.802 (2005 & Supp. 2008) (defining "facility acquired infection"). "Only 'unexpected occurrences' of facility acquired events are required to be reported as sentinel events." Unexpected occurrences are defined as occurrences that are unrelated "to the patients underlying condition or the natural course of the patient's illness." E-mail from O'Mara, *supra* note 317.

323. NEV. REV. STAT. § 439.835 (2005 & Supp. 2008).

report its occurrence to the State Health Division.[324] Within forty-five days of becoming aware of a sentinel event, the patient safety officer must submit a second, more detailed report to the division, including an analysis of factors contributing to the event and a description of any corrective actions undertaken by the medical facility.[325] A representative from the medical facility must provide notice to any patient involved in a sentinel event within seven days of "discovering or becoming aware of a sentinel event . . . ."[326]

9. PENALTIES AND ENFORCEMENT MECHANISMS: "Currently, there are no penalties for non-reporting . . . ."[327]

(a) Revocation of license? No.

(b) Audits? No. The Health Division does not currently have the authority to conduct audits.[328]

10. ARE PUBLIC REPORTS ISSUED? In the future, public reports will be issued. "[T]o the extent of legislative appropriation and authorization," the health division is obligated to contract with a "quality improvement organization, as defined in 42 C.F.R. § 400.200," to produce a quarterly report regarding the "analysis of aggregated trends of sentinel events . . . ."[329] However, "No appropriations have been authorized due to fiscal constraints."[330] "[T]he Health Division expects to publish a public report that covers Jan. 1, 2005 – Dec. 31, 2007, for the 2009 Legislative Session."[331]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[332]

12. IMMUNITY FOR REPORTERS? Yes.[333] Nevada also provides legal protection against retaliation for reporters of sentinel events.[334]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? "There are no related pay-for-performance programs currently" nor are any such programs under consideration.[335]

14. RELEVANT STATUTES AND REGULATIONS: NEV. REV. STAT. §§ 439.800-890 (2005 & Supp. 2008); NEV. REV. STAT. §§ 630.293-96, 630.505-07 (LEXIS 2008); NEV. ADMIN. CODE §§ 439.900-915 (2008).

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324. *Id.*

325. NEV. ADMIN. CODE § 439.915(2) (2008).

326. NEV. REV. STAT. § 439.855 (2005 & Supp. 2008).

327. E-mail from O'Mara, *supra* note 317.

328. *Id.*

329. NEV. REV. STAT. § 439.845 (2005 & Supp. 2008).

330. E-mail from O'Mara, *supra* note 317.

331. *Id.*

332. NEV. REV. STAT. § 439.840(2) (2005 & Supp. 2008); *id.* § 439.860.

333. *Id.* § 439.880.

334. NEV. REV. STAT. ANN. §§ 630.293, 630.296, 630.505, 630.507 (LEXIS 2008).

335. E-mail from O'Mara, *supra* note 317.

15. OTHER RESOURCES: Nev. State Health Div., Sentinel Event Report, http://health.nv.gov/sentinel/Forms/UpdatedForms105/SER_Section_One_Man_Oct05.pdf (last visited Nov. 15, 2008).
16. DATE REPORTING STARTED: January 1, 2005.[336]

NEW HAMPSHIRE

New Hampshire has "established a commission to review and analyze quality of care issues including, but not limited to, medical errors, unexpected adverse outcomes, and near misses, and to propose changes to improve health care."[337] New Hampshire regulations also provide for physician practices to develop and implement "quality assurance program[s] to monitor, evaluate and improve the quality and appropriateness of the care provided to patients, so that important problems and trends in the delivery of care are identified and steps are taken to correct problems and to take advantage of opportunities to improve care."[338]

NEW JERSEY

1. GENERAL DESCRIPTION: Health care facilities must report "serious preventable adverse events" to the Department of Health and Senior Services.[339]
2. IS REPORTING MANDATORY? Yes.[340]
3. REPORT RECIPIENT(S): The Department of Health and Senior Services (or the Department of Human Services in the case of a state psychiatric hospital).[341] The health care facility is also obligated to inform a patient or resident (or the patient/resident's guardian or representative) of any "serious preventable adverse event."[342]
4. IS REPORTING CONDUCTED ELECTRONICALLY? No. Facilities are currently expected to submit event reports via fax.[343] However, "[t]he Department [of Health and Senior Services] anticipates the development of an Internet web-based electronic reporting system."[344]
5. WHAT FACILITIES MUST PROVIDE REPORTS? Licensed health care facilities and state psychiatric hospitals.[345]
6. WHAT INCIDENTS MUST BE REPORTED? All "serious preventable adverse event[s]" must be reported to the Department of Health and Senior Services.[346] A

336. *Id.*
337. N.H. REV. STAT. ANN. § 151-G:1 (2008).
338. N.H. CODE ADMIN. R. ANN. HE-P 401.03 (2008).
339. N.J. STAT. ANN. § 26:2H-12.25(c) (West 2007).
340. *Id.*
341. *Id.*; N.J. ADMIN. CODE § 8:43E-10.6(a) (2008).
342. N.J. ADMIN. CODE § 8:43E-10.7 (2008).
343. *Id.* § 8:43E-10.6(d).
344. *Id.* § 8:43E-10.6(n).
345. N.J. STAT. ANN. § 26:2H-12.25(a) (West 2007) (defining "health care facility").

serious preventable adverse event is defined as "an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility."[347] An "[a]dverse event" is defined as "an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable."[348] A "[p]reventable event" is "an event that could have been anticipated and prepared against, but occurs because of an error or other system failure."[349] Health care professionals are also encouraged, but not required, to report near-misses, preventable events, and adverse events.[350] Regulations specifically enumerate events that qualify as "serious preventable adverse events." This list generally matches the twenty-eight "serious reportable events" listed by the NQF.[351]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes. The Health Care Facility-Associated Infection Reporting and Prevention Act requires general hospitals to report information related to health care-associated infections to the Department of Health and Senior Services.[352] In April 2008, the Department of Health and Senior Services proposed new rules to implement this authority.[353]

8. DEADLINES: Health care facilities must notify the Department of Health and Senior Services (or the Department of Human Services, if applicable) of any event subject to mandatory reporting within five business days of discovering the event.[354] If inadequate information exists for a complete report by the deadline, facilities may submit an initial partial report.[355]

9. PENALTIES AND ENFORCEMENT MECHANISMS: The Commissioner of Health and Senior Services may impose the following enforcement remedies against a health care facility for violations of licensure regulations or other statutory requirement: "[c]ivil monetary penalty"; "[c]urtailment of admissions"; "[a]ppointment of a receiver or temporary manager"; "[p]rovisional license"; "[s]uspension of a license"; "[r]evocation of a license"; and an "[o]rder to Cease

346. *Id.* § 26:2H-12.25(4)(c).

347. *Id.* § 26:2H-12.25(a).

348. *Id.*

349. *Id.*

350. *Id.* § 26:2H-12.25(e)(1).

351. *See* N.J. ADMIN. CODE §§ 8:43E-10.6(f)-(j) (2008); *supra* Appendix. The National Quality Forum and New Jersey lists are nearly identical, with the exception that the New Jersey regulations do not specifically include the event of artificial insemination with the wrong donor sperm or wrong egg as a reportable event and the New Jersey regulations do not cover criminal events.

352. N.J. STAT. ANN. § 26:2H-12.41 (West 2007). *See generally* Health Care Facility-Associated Infection Reporting and Prevention Act, *id.* §§ 26:2H-12.39 to .45.

353. 40 N.J. Reg. 1958(a) (Apr. 21, 2008).

354. N.J. ADMIN. CODE § 8:43E-10.6(b) (2008)

355. *Id.*

and Desist operation of an unlicensed health care facility."[356] Regulations require the assessment of civil monetary penalties for failure to report serious preventable adverse events.[357] The Department of Health and Senior Services shall assess penalties of $1000 per day for general hospitals for each day following the date the report was due, with a maximum penalty of $100,000 per event.[358] The penalty falls to $250 per day for all other facilities, with a maximum penalty of $25,000 per event.[359] The Department must also assess penalties against facilities that fail to disclose serious preventable adverse events to patients or residents. If a facility fails to report an event to a patient or resident, and the facility also has not reported that event to the Department, the facility can be fined $1000. If the facility fails to report an event to a patient or resident, but did report that event to the Department in a timely manner, the facility can be fined $5000.[360] The Department has discretion to decrease these penalties based on the compliance history of the facility and measures taken by the facility to mitigate the effect of the violation.[361]

(a) Revocation of license? Yes.[362]

(b) Audits? The Department of Health and Senior Services has authority to "conduct periodic or special inspections of licensed health care facilities" to "ascertain whether the facility complies with all applicable State and Federal licensure regulations and statutes."[363] "The Department may evaluate all aspects of patient care, and operations of a health care facility, including the inspection of medical records; observation of patient care where consented to by the patient; inspection of all areas of the physical plant under the control or ownership of the licensee; and interview of the patient or resident, his or her family or other individuals with knowledge of the patient or care rendered to him or her."[364] Moreover, employees and health care professionals may submit anonymous reports to the Department of Health and Senior Services (or the Department of Human Services) "regarding preventable adverse events that are otherwise not subject to mandatory reporting."[365]

10. ARE PUBLIC REPORTS ISSUED? Yes. "The Commissioner of Health and Senior Services and the Commissioner of Human Services shall compile their findings and recommendations for operational changes related to patient safety in

356. *Id.* § 8:43E-3.1.
357. *Id.* § 8:43E-3.4(a)(14).
358. *Id.* § 8:43E-3.4(a)(14)(i).
359. *Id.* § 8:43E-3.4(a)(14)(ii).
360. *Id.* § 8:43E-3.4(a)(15).
361. *Id.* § 8:43E-3.4(b).
362. *Id.* § 8:43E-3.1.
363. *Id.* § 8:43E-2.1.
364. *Id.*
365. *Id.* § 8:43E-10.8.

health care facilities, based on information reported to the commissioners pursuant to the 'Patient Safety Act.'"[366] The commissioners issue an annual report to the Governor and the Legislature, available to the public via the Internet.[367] Information regarding hospital-acquired infections is available to the public via an annual Hospital Performance Report.[368]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[369] However, information related to the reporting of "serious preventable adverse events" shall be shared with the Attorney General. The Department of Human Services and the Attorney General shall use this information to "exercise oversight" with a "primary emphasis on assuring effective corrective action by the facility or health care professional, reserving punitive enforcement or disciplinary action for those cases in which the facility or the professional has displayed recklessness, gross negligence or willful misconduct . . . ."[370]

12. IMMUNITY FOR REPORTERS? Reports may be filed anonymously,[371] but immunity is not explicitly provided by statute or regulation.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? Not yet. The Commissioner's office within the Department of Health and Senior Services reports that pay-for-performance programs are currently under discussion.[372]

14. RELEVANT STATUTES AND REGULATIONS: Patient Safety Act, N.J. STAT. ANN. §§ 26:2H-12.23 to -12.25a (West 2007); N.J. ADMIN. CODE §§ 8:43E-10.1 to -10.11 (2008).

15. OTHER RESOURCES: N.J. DEP'T OF HEALTH & SENIOR SERVS., PATIENT SAFETY INITIATIVE: 2006 SUMMARY REPORT (2007), http://www.state.nj.us/health/ps/documents/ps_report_2006.pdf.

16. DATE REPORTING STARTED: 2004.[373]

NEW MEXICO

A medical error reporting regime does not exist for this state.[374]

366. N.J. STAT. ANN. § 26:2H-12.25a (West 2007).

367. *Id.*

368. *Id.* §§ 26:2H-12.41, 12.43.

369. *Id.* § 26:2H-12.25(f)-(g); N.J. ADMIN. CODE § 8:43E-10.9 (2008).

370. N.J. STAT. ANN. § 26:2H-12.25(f) (West 2007).

371. Facsimile from Ruth Charbonneau, Dir. of the Office of Legal & Regulatory Affairs, Office of the Comm'r, N.J. Dep't of Health & Senior Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 24, 2008) (on file with journal).

372. *Id.*

373. N.J. STAT. ANN. § 26:2H-12.23 (West 2007).

374. Facsimile from Alfredo Vigil, Cabinet Sec'y, N.M. Dep't of Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 18, 2008) (on file with journal).

NEW YORK

1. GENERAL DESCRIPTION: New York has established three separate programs related to medical error reporting: 1) a long-standing hospital-based program, 2) a more recent office-based reporting program, and 3) a hospital-acquired infection reporting program that completed its pilot year on December 31, 2007.

2. IS REPORTING MANDATORY? 1) Yes;[375] 2) Unclear from statutes and regulations; 3) Yes.[376]

3. REPORT RECIPIENT(S):

1) Hospital-based incidents should be reported to the Department of Health's Office of Health Systems Management.[377]

2) Department of Health.[378]

3) Department of Health.[379]

4. IS REPORTING CONDUCTED ELECTRONICALLY?

1) Unclear from statutes and regulations.

2) Unclear from statutes and regulations.

3) Yes.[380]

5. WHAT FACILITIES MUST PROVIDE REPORTS?

1) All hospitals.[381]

2) Accrediting agencies for office-based surgical practices.[382]

3) General hospitals.[383]

6. WHAT INCIDENTS MUST BE REPORTED?

1) Within the hospital setting, the following incidents must be reported: "patients' deaths in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards. Injuries and impairments of bodily functions, in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards and that necessitate additional or more complicated treatment regimens or that result in a significant change in patient status, shall also be considered reportable under this subdivision . . . ."[384]

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375. N.Y. PUB. HEALTH LAW § 2805-*l*(1) (McKinney 2007).

376. *Id.* § 2819(2)(a).

377. N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8(a) (2008).

378. N.Y. PUB. HEALTH LAW § 2998e(1) (McKinney Supp. 2008).

379. N.Y. COMP. CODES R. & REGS. tit. 10, § 405.11(c) (2008).

380. N.Y. PUB. HEALTH LAW § 2819(5)(c) (McKinney 2007).

381. *Id.* § 2805-*l*(1).

382. *Id.* § 2998-e(1) (McKinney Supp. 2008).

383. *Id.* § 2819(2)(a) (McKinney 2007).

384. N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8(b)(1) (2008); N.Y. PUB. HEALTH LAW §

2) "Adverse events for all office-based surgical practices accredited by the accrediting agencies."[385]

3) Hospital-acquired infections. A "hospital acquired infection" is defined as "any localized or systemic patient condition that: (a) resulted from the presence of an infectious agent . . . and (b) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission."[386]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes.[387]

8. DEADLINES:

1) "Hospitals shall report such incidents within 24 hours of when the incident occurred or when the hospital has reasonable cause to believe that such an incident has occurred and shall take no more than seven calendar days to determine whether an incident . . . is reportable."[388] "The hospital shall give written notification within seven calendar days of the initial notification."[389] The reporting hospital shall then conduct an investigation within thirty days and "provide a copy of its investigative report to the area administrator within 24 hours of its completion"[390]

2) Unclear from statutes and regulations.

3) "Each hospital shall regularly report to the department the hospital infection data it has collected. The department shall establish data collection and analytical methodologies that meet accepted standards for validity and reliability. In no case shall the frequency of reporting be required to be more frequently than once every six months, and reports shall be submitted not more than sixty days after the close of the reporting period."[391]

9. PENALTIES AND ENFORCEMENT MECHANISMS: Unclear from statutes and regulations.

(a) Revocation of license? Unclear from statutes and regulations.

(b) Audits?

1) Unclear from statutes and regulations.

2) Unclear from statutes and regulations.

3) Yes. "To assure the accuracy of the self-reported hospital-acquired infection data and to assure that public reporting fairly reflects what

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2805-*l*(2) (McKinney Supp. 2008).

385. N.Y. PUB. HEALTH LAW § 2998-e(1) (McKinney Supp. 2008).

386. *Id.* § 2819(1) (McKinney 2007).

387. *See generally id.* § 2819; N.Y. COMP. CODES R. & REGS. tit. 10, § 405.11 (2008).

388. N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8(a) (2008).

389. *Id.*

390. N.Y. PUB. HEALTH LAW § 2805-l(3) (McKinney Supp. 2008); N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8(d) (2008).

391. N.Y. PUB. HEALTH LAW § 2819(3) (McKinney 2007).

actually is occurring in each hospital, the department shall develop and implement an audit process."[392]

10. ARE PUBLIC REPORTS ISSUED?

1) Unclear from statutes and regulations.

2) Unclear from statutes and regulations.

3) "The commissioner shall establish a state-wide database of all reported hospital-acquired infection information for the purpose of supporting quality improvement and infection control activities in hospitals. The database shall be organized so that consumers, hospitals, healthcare professionals, purchasers and payers may compare individual hospital experience with that of other individual hospitals as well as regional and state-wide averages and, where available, national data."[393] On or before May 1 of each year, the Commissioner of Health shall submit a report to the governor and the legislature with infection rates for each hospital, analysis of trends, and recommendations for safety and quality improvement.[394] This report is available to the public.[395]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?

1) Unclear from statutes and regulations.

2) Unclear from statutes and regulations.

3) Yes.[396]

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? Recent legislation authorized the Commissioner of Health to select up to five demonstration projects pertaining to one of six categories, including the "use of . . . metrics to measure and reward physician, clinic and hospital performance . . . ."[397]

14. RELEVANT STATUTES AND REGULATIONS: N.Y. PUB. HEALTH LAW § 2819 (McKinney 2007) (hospital-acquired infection reporting); N.Y. COMP. CODES R. & REGS. tit. 10, § 405.11 (2008) (hospital-acquired infection reporting); N.Y. PUB. HEALTH LAW § 2805-l (McKinney Supp. 2008) (hospital incident reporting); N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8 (2008) (hospital incident reporting); N.Y. PUB. HEALTH LAW §§ 2995-2998 (McKinney 2007) (initiative to create a statewide health information system).

15. OTHER RESOURCES: N/A.

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392. *Id.* § 2819(7).

393. *Id.* § 2819(4).

394. *Id.* § 2819(5).

395. *Id.*

396. *Id.* § 2998-e(2) (McKinney Supp. 2008).

397. *Id.* § 2999-e(1) (McKinney 2007).

16. DATE REPORTING STARTED: Hospitals have been required to report medical errors to the Department of Health since 1985.[398] Unknown for hospital-acquired infections.

NORTH CAROLINA

A medical error reporting regime does not appear to exist for this state, with the exception of a statute governing the reporting of medication-related errors in the nursing home setting.[399]

NORTH DAKOTA

A medical error reporting regime does not exist for this state.[400]

OHIO

1. GENERAL DESCRIPTION: The Director of Health has authority to require health care providers to submit reports regarding quality of care and safety information. Reporting is required for a discrete list of health safety events.
2. IS REPORTING MANDATORY? Yes.[401]
3. REPORT RECIPIENT(S): Director of Health.
4. IS REPORTING CONDUCTED ELECTRONICALLY? Reports may be conducted electronically.[402]
5. WHAT FACILITIES MUST PROVIDE REPORTS? All health care facilities, including hospitals.[403]
6. WHAT INCIDENTS MUST BE REPORTED? Any unexpected complications or adverse events, including death or serious injury, that result from an operation or procedure must be reported. In addition, eleven specific quality measures must be reported, and providers must report any incidents that might have influenced the facility's overall data.[404] Although eleven quality measures are reported by hospitals, "only two of them apply to medical error: Iatrogenic Pneumothorax and Postoperative Respiratory Failure."[405]

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398. ROSENTHAL, BOOTH & BARRY, *supra* note 46, at Appendix A.

399. N.C. GEN. STAT. § 131E-128.5 (2007).

400. Facsimile from Terry L. Dwelle, Health Officer, N.D. Dep't of Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 18, 2008) (on file with journal).

401. OHIO ADMIN. CODE 3701:14-02(A) (2008).

402. *Id.* 3701:14-02(E).

403. *Id.* 3701:14-02(A) (hospitals).

404. *See* Ohio Dep't of Health, Appendix: Annual Hospital Disclosure Quality Measures Reporting Form, http://www.odh.ohio.gov/ASSETS/6F3AAB79274E41998783040C96103A3F/FR14_02app.pdf (last visited Nov. 15, 2008).

405. E-mail from Kaliyah Shaheen, Div. of Quality Assurance, Ohio Dep't of Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 10, 2008, 12:37

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? The Director of Health has authority to require that this data be reported, but it is unclear from statutes and regulations whether this is required.
8. DEADLINES: April 1 and October 1 of each year.[406]
9. PENALTIES AND ENFORCEMENT MECHANISMS: If the patient does not suffer any harm, the Director of Health may assess a $50,000 penalty. If more than one patient is harmed, the Director of Health may impose a penalty of $50,000 to $100,000. If a patient suffers permanent injury, the Director of Health may impose a penalty of $100,000 to $150,000. If a patient dies as a result of unexpected complications or an adverse event, the Director of Health may impose a $150,000 to $250,000 penalty. If a health care facility does not correct any regulatory violations, the Director of Health may fine the facility an additional $250,000.[407]

(a) Revocation of license? The Director may revoke a license if he or she deems it necessary.

(b) Audits? The Director of Health may audit any information submitted regarding unexpected complications and adverse events.[408]

10. ARE PUBLIC REPORTS ISSUED? No. However, within ninety days of submission, the Director of Health must make the submitted information available for sale "to any interested person or governmental entity."[409]
11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[410]
12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.
13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.
14. RELEVANT STATUTES AND REGULATIONS: OHIO REV. CODE ANN. § 3727.33 (LexisNexis 2008); OHIO ADMIN. CODE 3701:14-02 (2008); OHIO ADMIN. CODE 3701:83-05 (2008); OHIO ADMIN. CODE 3701:83-12 (2008).
15. OTHER RESOURCES: N/A.
16. DATE REPORTING STARTED: April 1, 2007.[411]

OKLAHOMA

A medical error reporting regime does not appear to exist for this state.

OREGON

1. GENERAL DESCRIPTION: Two programs exist. The first is operated through the Oregon Patient Safety Commission and includes serious adverse events. The

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EST) (on file with journal).

406. OHIO ADMIN. CODE 3701:14-02(A) (2008).
407. *Id.* 3701:83-05.2.
408. OHIO REV. CODE ANN. § 3727.331 (LexisNexis 2008).
409. OHIO ADMIN. CODE 3701:14-02(G) (2008).
410. OHIO REV. CODE ANN. § 2305.24 (LexisNexis 2008).
411. OHIO ADMIN. CODE 3701:14-02(A) (2008).

second is operated through the Health Care Acquired Infection Advisory Committee and includes health care-acquired infections.
2. IS REPORTING MANDATORY? Reporting to the Patient Safety Commission is voluntary. Reporting to the Health Care Acquired Infection Advisory Committee is mandatory.
3. REPORT RECIPIENT(S): Patient Safety Commission; Health Care Acquired Infection Advisory Committee.
4. IS REPORTING CONDUCTED ELECTRONICALLY? Unclear from statutes and regulations.
5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals voluntarily report to the Patient Safety Commission.[412]
6. WHAT INCIDENTS MUST BE REPORTED? "Serious [a]dverse [e]vent[s]" must be reported to the Patient Safety Commission.[413] A "[r]eportable [s]erious [a]dverse [e]vent . . . means any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury."[414] An appendix to the applicable regulations, available from the Patient Safety Commission, specifies twenty-three events as "serious adverse events" that are also listed by the NQF.[415] Hospitals are also encouraged to report less serious adverse events to the Commission.[416]
7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes. Health care-acquired infections must be reported to the Health Care Acquired Infection Advisory Committee beginning in 2009. The specific types of infections that must be reported are set forth in the main authorizing rule.[417]
8. DEADLINES: Voluntary reports made to the Patient Safety Commission must be made within forty-five days of the event. Mandatory reports of health care acquired infections must be made to the Health Care Acquired Infection Advisory Committee on a quarterly basis.[418]
9. PENALTIES AND ENFORCEMENT MECHANISMS: Reporting to the Patient Safety Commission is voluntary and not subject to penalty. Civil penalties of $500 a day shall be levied against any health care facility that is found to be in

412. OR. ADMIN. R. 325-010-0000 to -0045 (2008).
413. *Id.* 325-010-0005(4).
414. *Id.* 325-010-0001(8).
415. *See* Or. Patient Safety Comm'n, Appendix A: Reportable Hospital Serious Adverse Events, http://www.oregon.gov/OPSC/docs/Division10Rules-final-2-1-06.pdf (last visited Nov. 15, 2008); *supra* Appendix. Oregon's appendix does not include the criminal events listed by the National Quality Forum, nor does it include artificial insemination with the wrong donor sperm or wrong egg. The Oregon list also includes "[a]ny perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams" as a reportable event. Or. Patient Safety Comm'n, *supra*.
416. OR. ADMIN. R. 325-010-0030 (2008).
417. *Id.* 409-023-0010.
418. *Id.* 409-023-0020.

violation of the reporting requirements imposed by the Health Care Acquired Infection Advisory Committee.[419]

(a) Revocation of license? Unclear from statutes and regulations.

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Public reports are issued listing all hospitals that voluntarily report information to the Patient Safety Commission. The Health Care Acquired Infection Advisory Committee will begin releasing public reports of summarized data in 2010.

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Unclear from statutes and regulations.

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: OR. ADMIN. R. 325-010-0000 to -0045 (2008) (setting forth the Oregon Patient Safety Commission); OR. ADMIN. RULES 409-023-0000 *et seq.* (2008) (setting forth the Health Care Acquired Infection Reporting and Public Disclosure Committee).

15. OTHER RESOURCES: N/A.

16. DATE REPORTING STARTED: Unknown for the reporting of serious adverse events to the Oregon Patient Safety Commission. Mandatory reporting of health care-acquired infections to the Health Care Acquired Infection Advisory Committee starts on January 1, 2009.

PENNSYLVANIA

1. GENERAL DESCRIPTION: Hospitals, ambulatory surgical facilities, birthing centers, and abortion centers of a certain size must report medical errors (both "serious events" and "near misses") to the Patient Safety Authority.[420] Serious events and infrastructure failures must also be reported to the Department of Health. Hospitals must report hospital-acquired infections to the National Health Safety Network.

2. IS REPORTING MANDATORY? Yes.[421]

3. REPORT RECIPIENT(S): Health care providers must provide data to nonprofit organizations designated by the Patient Safety Authority. These organizations, which are under contract with the Patient Safety Authority, must file annual reports with the legislature summarizing this information.[422] Currently, the Patient Safety "Authority has contracts with ECRI Institute – a Pennsylvania-based non-profit health services research agency [–] and the Institute for Safe

419. *Id.* 409-023-0035.

420. E-mail from Laurene M. Baker, Dir. of Commc'n, Pa. Patient Safety Auth., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 9, 2008, 13:29 EST) [hereinafter E-mail from Baker] (on file with journal).

421. 40 PA. CONS. STAT. § 1303.308 (Supp. 2008).

422. *Id.* § 1303.304.

Medication Practices [ISMP], a Pennsylvania-based non-profit medication error research organization. Analysts from ECRI Institute and ISMP . . . analyze the data and provide guidance to the Pennsylvania healthcare facilities through the Pennsylvania Patient Safety Advisory."[423]

4. IS REPORTING CONDUCTED ELECTRONICALLY? Yes, reports are filed electronically through a secure web-based system known as the Pennsylvania Patient Safety Reporting System.[424]

5. WHAT FACILITIES MUST PROVIDE REPORTS? All licensed hospitals, ambulatory surgical facilities, birthing centers, and abortion centers that perform one hundred or more procedures per year must report "[s]erious [e]vents" and "near misses" to the Patient Safety Authority. These facilities must also report "[s]erious [e]vents" and "[i]nfrastructure failures" to the Department of Health.[425]

6. WHAT INCIDENTS MUST BE REPORTED? As noted above, serious events and incidents must be reported to the Patient Safety Authority, and serious events and infrastructure failures must be reported to the Department of Health. A serious event is defined as "an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient."[426] An incident is defined as "[a]n event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient."[427] Finally, an infrastructure failure is defined as "[a]n undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation of significant disruption of a service which could seriously compromise patient safety."[428]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes. "[A]ll hospitals must report healthcare acquired infections as Serious Events through the National Health Safety Network (NHSN) operated by the Centers for Disease Control and Prevention (CDC) reporting system . . . . [T]he Patient Safety Authority, the . . . Department of Health . . . and the Pennsylvania Healthcare Cost Containment Council . . . have access to the data reported through NHSN."[429] In April 2009, nursing homes will start to report infections.[430]

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423. E-mail from Baker, *supra* note 420.

424. *Id.*

425. 40 PA. CONS. STAT. § 1303.404 (Supp. 2008); E-mail from Baker, *supra* note 420.

426. 40 PA. CONS. STAT. § 1303.302 (Supp. 2008).

427. E-mail from Baker, *supra* note 420.

428. *Id.*

429. *Id.*

430. *Id.*

8. DEADLINES: Medical facilities must report the occurrence of a serious event to the Department and the Authority within twenty-four hours of the medical facility's confirmation of the occurrence of the serious event.[431]

9. PENALTIES AND ENFORCEMENT MECHANISMS: Failure to report a serious event or infrastructure failure, "or to develop and comply with the patient safety plan or to notify the patient . . . shall be a violation of the Health Care Facilities Act," which can result in an audit or even revocation of license.[432] Facilities that fail to report a serious event may also be subject to a $1000 per day administrative penalty at the discretion of the Department.[433]

(a) Revocation of license? Yes.[434]

(b) Audits? Audits appear to occur in response to a known failure to report a serious event or infrastructure failure.[435]

10. ARE PUBLIC REPORTS ISSUED? Yes. The "Pennsylvania Patient Safety Authority must file an Annual Report to the General Assembly that includes: a schedule of the year's meetings; a list of contracts entered into pursuant to Section 303 of Act 13, including the amounts awarded to each contractor; a summary of the fund receipts and expenditures, including a financial statement and balance sheet; the number of Serious Events and Incidents reported by medical facilities on a geographical basis; the information derived from the data collected, including any recognized trends concerning patient safety; the number of anonymous reports filed and reviews conducted by the Authority; the number of referrals to licensure boards for failure to report under this chapter; recommendations for statutory or regulatory changes which may help improve patient safety in the Commonwealth."[436] This report is public and posted on the Patient Safety Authority's website.[437]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[438]

12. IMMUNITY FOR REPORTERS? Yes.[439]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? Yes. Starting January 1, 2009, the Department of Public Welfare will make a quality improvement payment to health care facilities that achieve at least a ten percent reduction in health care-acquired infection.[440]

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431. 40 PA. CONS. STAT. § 1303.313 (Supp. 2008).

432. E-mail from Baker, *supra* note 420.

433. 40 PA. CONS. STAT. § 1303.313 (Supp. 2008).

434. E-mail from Baker, *supra* note 420.

435. *See id.*

436. *Id.*

437. Commonwealth of Pennsylvania Patient Safety Authority, http://www.psa.state.pa.us (last visited Nov. 15, 2008).

438. 40 PA. CONS. STAT. § 1303.407 (2008); *Id.* § 1303.311 (Supp. 2008).

439. *Id.* § 1303.308(c) (Supp. 2008).

440. *Id.* § 1303.407 (2008).

14. RELEVANT STATUTES AND REGULATIONS: 40 PA. CONS. STAT. §§ 1303.103 to .407 (2008 & Supp. 2008).
15. OTHER RESOURCES: N/A.
16. DATE REPORTING STARTED: June 2004.[441]

RHODE ISLAND

1. GENERAL DESCRIPTION: All health care providers are required to inform the Department of Health of injuries to patients and certain specified events.[442]
2. IS REPORTING MANDATORY? Yes.
3. REPORT RECIPIENT(S): The Division of Facilities within the Department of Health.
4. IS REPORTING CONDUCTED ELECTRONICALLY? No. Reports are made telephonically.[443]
5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals.[444]
6. WHAT INCIDENTS MUST BE REPORTED? Injury to patients constitutes any of the following: "(1) Brain injury; (2) Mental impairment; (3) Paraplegia; (4) Quadriplegia; (5) Any type of paralysis; (6) Loss of use of limb or organ; (7) Hospital stay extended due to serious or unforeseen complications; (8) Birth injury; (9) Impairment of sight or hearing; (10) Surgery on the wrong patient; (11) Subjecting a patient to a procedure other than that ordered or intended by the patient's attending physician; (12) Any other incident that is reported to their malpractice insurance carrier or self-insurance program; (13) Suicide of a patient during treatment or within five (5) days of discharge from an inpatient or outpatient unit (if known); (14) Blood transfusion error; and (15) Any serious or unforeseen complication, that is not expected or probable, resulting in an extended hospital stay or death of the patient."[445] The following incidents must also be reported: "(i) Fires or internal disasters in the facility which disrupt the provisions of patient care services or cause harm to patients or personnel; (ii) Poisoning involving patients of the facility; (iii) Infection outbreaks as defined by the department in regulation; (iv) Kidnapping and inpatient psychiatric elopements and elopements by minors; (v) Strikes by personnel; (vi) Disasters or other emergency situations external to the hospital environment which adversely affect facility operations; [or] (vii) Unscheduled termination of any services vital to the continued safe operation of the facility or to the health and safety of its patients and personnel." "[A]buse, neglect and mistreatment of patients"[446] must also be reported.

441. E-mail from Baker, *supra* note 420.
442. R.I. GEN. LAWS § 23-17-40 (2001).
443. *Id.* § 23-17-40(a).
444. *Id.* § 23-17-40.
445. *Id.* § 23-17-40(d).
446. *Id.* § 23-17-40(2).

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Only to the extent they are covered by one of the injury categories listed above.
8. DEADLINES: Injuries in the first list must be reported within twenty-four hours.[447] Incidents in the second list must be reported within seventy-two hours of their occurrence or as soon as the hospital has reasonable cause to believe that an incident has occurred.[448]
9. PENALTIES AND ENFORCEMENT MECHANISMS: Unclear from statutes and regulations.
(a) Revocation of license? Unclear from statutes and regulations.
(b) Audits? Unclear from statutes and regulations.
10. ARE PUBLIC REPORTS ISSUED? The Department of Health "shall issue an annual report by March 31 each year providing aggregate summary information on the events and incidents reported by hospitals.[449]
11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Unclear from statutes and regulations.
12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.
13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.
14. RELEVANT STATUTES AND REGULATIONS: R.I. GEN. LAWS § 23-17-40 (2001).
15. OTHER RESOURCES: N/A.
16. DATE REPORTING STARTED: Unknown.

SOUTH CAROLINA

1. GENERAL DESCRIPTION: All licensing hospitals and institutional general infirmaries must report accidents or incidents that result in death or serious injury to the Division of Health Licensing within the Department of Health and Environmental Control.[450]
2. IS REPORTING MANDATORY? Yes.[451]
3. REPORT RECIPIENT(S): The Division of Health Licensing in the Department of Health and Environmental Control.[452]
4. IS REPORTING CONDUCTED ELECTRONICALLY? No. Facilities must issue reports "in writing."[453]

447. *Id.* § 23-17-40.
448. *Id.* § 23-17-40(c).
449. *Id.* § 23-17-40(h).
450. S.C. CODE ANN. REGS. 61-16 § 206.2 (2008).
451. *Id.*
452. *Id.*; *see also id.* § 101(A) (defining "[t]he [d]epartment").
453. *Id.* § 206.2.

5. WHAT FACILITIES MUST PROVIDE REPORTS? Licensed hospitals, general hospitals, institutional general infirmaries, chronic hospitals, publicly owned health centers, diagnostic and treatment centers, and rehabilitation facilities.[454]
6. WHAT INCIDENTS MUST BE REPORTED? A record of "each accident and/or incident occurring in the facility, including medication errors and adverse drug reactions" must be retained by the facility.[455] Only those incidents that result "in death or serious injury, e.g., broken limb, shall be reported, in writing, to the Division of Health Licensing . . . ."[456] The Department of Health and Environmental Control also requires licensed hospitals and institutional general infirmaries "to annually complete a questionnaire named 'Joint Annual Report.'"[457]
7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Hospital-acquired infections must only be reported to the extent that they qualify as an accident or incident resulting in death or serious injury.[458]
8. DEADLINES: Reports must be made within ten days of the occurrence of the accident or incident.[459]
9. PENALTIES AND ENFORCEMENT MECHANISMS: The Department of Health and Environmental Control has the authority to "deny, suspend, or revoke licenses or assess a monetary penalty for violations" of the incident report provisions.[460] In determining whether to penalize a facility, the Department "will consider the following factors: specific conditions and their impact or potential impact on health, safety or welfare; efforts by the facility to correct; overall conditions; history of compliance; [and] any other pertinent conditions."[461] The size of a monetary penalty may range from $200 to $5000, depending on the frequency of violations by a facility within a two-year period and classification of the violation (i.e., Class I, II, or III).[462]

(a) Revocation of license? Yes.[463]

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Unclear from statutes and regulations.
11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Unclear from statutes and regulations.
12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.
13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

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454. *Id.* § 101(D) (defining "[f]acilities"); *id.* § 206.2.
455. *Id.* § 206.2.
456. *Id.* § 206.2.
457. *Id.* § 206.3; S.C. CODE ANN. § 61-16-101(D) (2008) (defining "[f]acilities").
458. *See* S.C. CODE ANN. REGS. 61-16, § 206.2 (2008).
459. *Id.*
460. *Id.* 61-16, § 105.
461. *Id.*
462. *Id.*
463. *Id.*

14. RELEVANT STATUTES AND REGULATIONS: S.C. CODE ANN. REGS. 61-16 (2008).
15. OTHER RESOURCES: N/A.
16. DATE REPORTING STARTED: Unknown.

SOUTH DAKOTA

A medical error reporting regime does not appear to exist for this state.

TENNESSEE

1. GENERAL DESCRIPTION: All licensed health care facilities must report "unusual events" to the Department of Health.
2. IS REPORTING MANDATORY? Yes.[464]
3. REPORT RECIPIENT(S): Department of Health.[465] "The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility."[466]
4. IS REPORTING CONDUCTED ELECTRONICALLY? Yes. "Tennessee receives reports via fax, mail, and electronic means."[467]
5. WHAT FACILITIES MUST PROVIDE REPORTS? All licensed health care facilities, including hospitals[468] and nursing homes.[469]
6. WHAT INCIDENTS MUST BE REPORTED? "Unusual events" must be reported to the Department of Health. Unusual events are "unexpected occurrence[s] or accident[s] resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition."[470]

"[C]ircumstances that could result in an unusual event include, but are not limited to: 1. medication errors; 2. aspiration in a non-intubated patient related to conscious/moderate sedation; 3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax; 4. volume overload leading to pulmonary edema; 5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient; 6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological

464. TENN. COMP. R. & REGS. 1200-8-1.11(8) (2007).
465. *Id.*
466. *Id.* 1200-8-1.11(8)(j).
467. E-mail from Ann Thompson, Dir. of Licensure, Bureau of Health Licensure & Regulation, Div. of Health Care Facilities, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 6, 2008, 18:05 EST) [hereinafter E-mail from Thompson] (on file with journal).
468. TENN. COMP. R. & REGS. 1200-8-1.11 (2007).
469. *Id.* 1200-8-6.11.
470. *Id.* 1200-8-1.11(8)(a).

deficit with motor weakness; 7. burns of a second or third degree; 8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions; 9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include: (i) procedure related injury requiring repair or removal of an organ; (ii) hemorrhage; (iii) displacement, migration or breakage of an implant, device, graft or drain; (iv) post operative wound infection following clean or clean/contaminated case; (v) any unexpected operation or reoperation related to the primary procedure; (vi) hysterectomy in a pregnant woman; (vii) ruptured uterus; (viii) circumcision; (ix) incorrect procedure or incorrect treatment that is invasive; (x) wrong patient/wrong site surgical procedure; (xi) unintentionally retained foreign body; (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence; (xiii) criminal acts; (xiv) suicide or attempted suicide; (xv) elopement from the facility; (xvi) infant abduction, or infant discharged to the wrong family; (xvii) adult abduction; (xviii) rape; (xix) patient altercation; (xx) patient abuse, patient neglect, or misappropriation of resident/patient funds; (xxi) restraint related incidents; or (xxii) poisoning occurring within the facility."[471]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Not as a separate category, but a "post operative wound infection following clean or clean/contaminated implant, device, graft or drain" is considered a "procedure related incident" that may result in an "unusual event."[472]

8. DEADLINES: After a facility learns of an unusual event, it has seven days to report the incident to the Department of Health.[473] The facility must also file a corrective action report with the Department of Health within forty days of identifying an unusual event.[474]

9. PENALTIES AND ENFORCEMENT MECHANISMS: "Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction . . . may be grounds for disciplinary action,"[475] including suspension or revocation of a facility's license.[476]

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471. *Id.* Additional incidents that must be reported, but do not quality as medical errors, include "strike by staff at the facility; external disaster impacting the facility; disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires." E-mail from Thompson, *supra* note 467.

472. TENN. COMP. R. & REGS. 1200-8-1.11(8)(a)(9)(iv) (2007).

473. *Id.* 1200-8-1.11(8).

474. *Id.* 1200-8-1.11(8)(d).

475. *Id.* 1200-8-1.11(8)(i); *see also* TENN. CODE ANN. § 68-11-207 (2007).

476. TENN. CODE ANN. § 68-11-207 (2007).

(a) Revocation of license? Yes, "the board may suspend or revoke the license" of the facility.[477]

(b) Audits? Audits are not addressed in the applicable statutes or regulations.[478]

10. ARE PUBLIC REPORTS ISSUED? Yes. "During the second quarter of each year, the Department [of Health] shall provide the Board [for Licensing Health Care Facilities] an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year."[479]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[480]

12. IMMUNITY FOR REPORTERS? Immunity for reporters is not addressed in the applicable statutes or regulations.[481]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: TENN. COMP. R. & REGS. 1200-8-1.11 (2007); TENN. COMP. R. & REGS. 1200-8-6.11 (2007).

15. OTHER RESOURCES: N/A.

16. DATE REPORTING STARTED: Tennessee personnel are "uncertain of the reporting start date."[482]

TEXAS

1. GENERAL DESCRIPTION: Each hospital must develop a "Patient Safety Program" that entails an annual report to the Department of Health regarding the aggregate number of certain specified types of medical errors.

2. IS REPORTING MANDATORY? Yes.

3. REPORT RECIPIENT(S): Department of Health.

4. IS REPORTING CONDUCTED ELECTRONICALLY? Unclear from statutes and regulations.

5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals.[483]

6. WHAT INCIDENTS MUST BE REPORTED? Medical errors must be reported. A medical error is defined as "[t]he failure of a planned action to be completed as intended, the use of a wrong plan to achieve an aim, or the failure of an unplanned action that should have been completed, that results in an adverse event."[484] In their annual reports to the Department of Health, hospitals are only

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477. *Id.*; E-mail from Thompson, *supra* note 467.

478. E-mail from Thompson, *supra* note 467.

479. TENN. COMP. R. & REGS. 1200-8-1.11(8)(k) (2007).

480. *Id.* 1200-8-1.11(8)(f).

481. E-mail from Thompson, *supra* note 467.

482. *Id.*

483. *See generally* 25 TEX. ADMIN. CODE § 133.48(a) (2008). Similar regulations govern other types of health care facilities in Texas.

484. *Id.* § 133.48(a)(1)(A).

required to report the aggregate numbers of the following events: "(i) a medication error resulting in a patient's unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient; (ii) a perinatal death unrelated to a congenital condition in an infant with a birth weight greater that 2,500 grams; (iii) the suicide of a patient in a setting in which the patient received care 24 hours a day; (iv) the abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant; (v) the sexual assault of a patient during treatment or while the patient was on the premises of the hospital or facility; (vi) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities; (vii) a surgical procedure on the wrong patient or on the wrong body part of a patient; (viii) a foreign object accidentally left in a patient during a procedure; and (ix) a patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended."[485] "The hospital is not required to include any information other than the total number of occurrences of each of [these] events."[486]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? No.

8. DEADLINES: Within forty-five days of discovering a reportable event, hospitals must complete a root cause analysis and develop an action plan to reduce the risk of similar events in the future.[487] On an annual basis, each hospital must provide the Department of Health with a report detailing the number of occurrences of each of the events listed above.[488]

9. PENALTIES AND ENFORCEMENT MECHANISMS: Unclear from statutes and regulations.

(a) Revocation of license? Unclear from statutes and regulations.

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Unclear from statutes and regulations.

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Unclear from statutes and regulations.

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: 25 TEX. ADMIN. CODE §133.48 (2008).

15. OTHER RESOURCES: N/A.

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485. *Id.* § 133.48(b)(1)(A).

486. *Id.* § 133.48(6).

487. *Id.* § 133.48(5).

488. *Id.* § 133.48(6).

16. DATE REPORTING STARTED: Unknown.

UTAH

1. GENERAL DESCRIPTION: All hospitals must file reports of any "patient safety sentinel event" within seventy-two hours to the Department of Health and must file an action plan within sixty calendar days of a determination that a patient safety sentinel error occurred.
2. IS REPORTING MANDATORY? Yes.[489]
3. REPORT RECIPIENT(S): Department of Health.
4. IS REPORTING CONDUCTED ELECTRONICALLY? Action plans may be submitted in paper or electronic format.[490]
5. WHAT FACILITIES MUST PROVIDE REPORTS? General acute hospitals, critical access hospitals, ambulatory surgical centers, psychiatric hospitals, orthopedic hospitals, rehabilitation hospitals, chemical dependency/substance abuse hospitals and long-term acute care hospitals.[491]
6. WHAT INCIDENTS MUST BE REPORTED? "Patient safety sentinel events" must be reported. This term is defined as "an event which has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition or is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."[492] The Utah Administrative Code defines patient safety sentinel events to include twenty-seven of the twenty-eight "serious reportable events" listed by the NQF.[493] In addition, Utah regulations include five additional events not found in the NQF list: "(iv) "unanticipated death of a full-term newborn; . . . (ix) Prolonged fluoroscopy with cumulative dose greater than 1500 rads to a single field; (x) Radiotherapy to the wrong body region; (xi) Radiotherapy greater than 25% above the prescribed radiotherapy dose; and (xii) Death or major permanent loss of function related to a health care acquired infection."[494]
7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes, facilities must report hospital-acquired infections resulting in death or major permanent loss of function.[495] Hospitals must also report each case of "[c]entral line associated blood stream infection."[496]

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489. UTAH ADMIN. CODE. r. 380-200-1 (2008).
490. *Id.* 380-200-5(2).
491. *Id.* 380-200-2 (defining "facility").
492. *Id.*
493. *See id.* 380-200-3(2)(a)-(f); *supra* Appendix. The National Quality Forum list includes artificial insemination with the wrong donor sperm or wrong egg as a reportable event, whereas the Utah regulations do not.
494. UTAH ADMIN. CODE. r. 380-200-3(2)(d) (2008).
495. *Id.* 380-200-3(2)(d)(xii).
496. *Id.* 386-705-2 (2008); *id.* 386-705-3.

8. DEADLINES: Hospitals must file a report of any patient safety sentinel event within seventy-two hours to the Department of Health[497] and must file an action plan within sixty calendar days of a determination that a patient safety sentinel event occurred.[498] The Department has discretion to grant extensions.[499]
9. PENALTIES AND ENFORCEMENT MECHANISMS: Any facility that violates the sentinel event reporting requirements may be assessed "a civil money penalty not to exceed the sum of $5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor . . . ."[500]

(a) Revocation of license? Unclear from statutes and regulations.

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Unclear from statutes and regulations.
11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[501]
12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.
13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.
14. RELEVANT STATUTES AND REGULATIONS: UTAH CODE ANN. § 26-33-103 (2007); UTAH CODE ANN. § 26-33A-104 (2007); UTAH CODE ANN. § 26-33A-111 (2007); Patient Safety Sentinel Event Reporting, UTAH ADMIN. CODE. r. 380-200-1 to -7 (2008); UTAH ADMIN. CODE. r. 386-705-2 to -3. (2008).
15. OTHER RESOURCES: N/A.
16. DATE REPORTING STARTED: Unknown.

VERMONT

1. GENERAL DESCRIPTION: Hospitals must report all of the "serious reportable events" specified by the NQF to the Department of Health within seven calendar days.
2. IS REPORTING MANDATORY? Yes.[502]
3. REPORT RECIPIENT(S): Department of Health.[503] In addition, hospitals are required to "disclose to patients, or, in the case of a patient death, an adult member of the immediate family, at a minimum, adverse events that cause death or serious bodily injury."[504]
4. IS REPORTING CONDUCTED ELECTRONICALLY? No.[505]

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497. *Id.* 380-200-3(1).
498. *Id.* 380-200-5(1).
499. *Id.* 380-200-7(1).
500. *Id.* 380-200-9.
501. *Id.* 380-200-6(1).
502. VT. STAT. ANN. tit. 18, § 1915(2) (Supp. 2007).
503. *Id.*; 13-140-068 VT. CODE R. § 1.5(5) (LEXIS 2008) (defining "[d]epartment").
504. VT. STAT. ANN. tit. 18, § 1915(1)(D) (Supp. 2007); *see also* 13-140-068 VT. CODE R. § 2.4 (LEXIS 2008).
505. 13-140-068 VT. CODE R. § 1.7(2) (LEXIS 2008) ("Each hospital shall submit reports

5. WHAT FACILITIES MUST PROVIDE REPORTS? Hospitals licensed by the Board of Health.[506]

6. WHAT INCIDENTS MUST BE REPORTED? The statute specifies that administrative rules "shall list reportable adverse events, which shall include the 'serious reportable events' published by the National Quality Forum."[507] Adverse events are defined broadly as "any untoward incident, therapeutic misadventure, iatrogenic injury, or other undesirable occurrence directly associated with care or services provided by a health care provider or health care facility."[508] Hospitals are also required to report the occurrence of any "intentional unsafe act."[509]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Hospital-acquired infections are not explicitly listed as a separate category, but could result from other reportable adverse events (e.g., the use of contaminated drugs, devices, or biologics).

8. DEADLINES: "Each hospital shall submit an initial report as soon as reasonably possible and no later than seven (7) calendar days after discovery or recognition of the reportable adverse event."[510] A causal analysis and corrective action plan are due "no later than sixty (60) calendar days from the submission of the initial report."[511]

9. PENALTIES AND ENFORCEMENT MECHANISMS: "[T]he commissioner [of the Department of Health] may impose on a hospital that knowingly violates [the reporting requirements] . . . a civil administrative penalty of no more than $10,000.00 or, in the case of a continuing violation, a civil administrative penalty of no more than $100,000.00 or one-tenth of one percent of the gross annual revenues of the health care facility, whichever is greater."[512] "The Department may use all enforcement powers granted to it . . . to ensure compliance with the requirements . . . ."[513]

(a) Revocation of license? Unclear from statutes and regulations.

(b) Audits? Yes. "The Patient Safety Surveillance and Improvement System will conduct routine periodic reviews to evaluate a hospital's

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required by this rule to the Patient Safety Surveillance and Improvement System using a secure transmission method, such as to and from a secure fax number, certified mail or other documented delivery system or, if established by the Department, through the secure reporting system.").

506. *See id.* § 1.3 (LEXIS 2008).

507. VT. STAT. ANN. tit. 18, § 1914(b) (Supp. 2007); *see also* 13-140-068 VT. CODE R. § 2.5 (LEXIS 2008).

508. VT. STAT. ANN. tit. 18, § 1912(1) (Supp. 2007).

509. *Id.* § 1916; 13-140-068 VT. CODE R. § 3.1 (LEXIS 2008).

510. 13-140-068 VT. CODE R. § 2.6(1)(A) (LEXIS 2008).

511. *Id.* § 2.6(1)(B).

512. VT. STAT. ANN. tit. 18, § 1918(b) (Supp. 2007).

513. 13-140-068 VT. CODE R. § 1.10 (LEXIS 2008).

compliance . . . ."[514] The system will specifically review "the implementation of hospital policies and procedures."[515] Hospitals are required to "provide the Patient Safety Surveillance and Improvement System with access to all information requested relating to and for the purpose of evaluating compliance . . . including . . . [a]ll original medical records, documents and databases in any format; . . . [i]nterviews with hospital staff; . . . [o]bservation of any area of the facility."[516]

10. ARE PUBLIC REPORTS ISSUED? Unclear from statutes and regulations.

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[517]

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: VT. STAT. ANN. tit. 18, §§ 1912–1919 (Supp. 2007); 13-140-068 VT. CODE R. §§ 1.1–4.2 (LEXIS 2008).

15. OTHER RESOURCES: N/A.

16. DATE REPORTING STARTED: Unknown.

VIRGINIA

A medical error reporting regime does not appear to exist for this state.

WASHINGTON

1. GENERAL DESCRIPTION: Medical facilities must report adverse events to the Department of Health. Adverse events are defined in accordance with the NQF's 2002 guidelines.

2. IS REPORTING MANDATORY? Yes.[518]

3. REPORT RECIPIENT(S): The Department of Health.[519]

4. IS REPORTING CONDUCTED ELECTRONICALLY? A qualified, independent entity is directed to "establish an internet-based system for medical facilities and the health care workers of a medical facility to submit notifications and reports of adverse events and incidents, which shall be accessible twenty-four hours a day, seven days a week."[520] At the present time, medical facilities report NQF adverse event confirmations within forty-eight hours via fax or a toll free hotline. Hospitals participating in the Healthcare Associated Infections program report through a different system.[521]

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514. *Id.* § 4.1(1).

515. *Id.*

516. *Id.* § 4.1(3).

517. VT. STAT. ANN. tit. 18, § 1917(a) (Supp. 2007); 13-140-068 VT. CODE R. § 1.6(1) (LEXIS 2008).

518. WASH. REV. CODE § 70.56.020(2) (Supp. 2008).

519. *Id.* § 70.56.020(2); *id.* § 70.56.010(5) (defining "department").

520. *Id.* § 70.56.040(2).

521. E-mail from Linda Furkay, Patient Safety-Adverse Event Officer, Cmty. Health Sys.

5. WHAT FACILITIES MUST PROVIDE REPORTS? All medical facilities must report adverse event notifications.[522] A medical facility is defined as "a childbirth center, hospital, psychiatric hospital, or correctional medical facility." Beginning in 2009, an ambulatory surgical facility shall be considered a medical facility for purposes of this reporting program.[523] At this time, only hospitals are included in the Healthcare Associated Infections Reporting.[524]

6. WHAT INCIDENTS MUST BE REPORTED? Medical facilities must notify the Department of Health regarding the confirmation of any "adverse event."[525] Adverse events are defined to include "the list of serious reportable events adopted by the [N]ational [Q]uality [F]orum in 2002, in its consensus report on serious reportable events in health care. The [D]epartment [of Health] shall update the list, through adoption of rules, as subsequent changes are made by the [N]ational [Q]uality [F]orum."[526]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes. Starting July 1, 2008, hospitals were required to collect data related to health care-associated infections for central-line associated bloodstream infections acquired in the intensive care unit. Beginning January 1, 2009, hospitals shall collect data on ventilator-associate pneumonia, and beginning January 1, 2010, hospitals shall collect data on surgical site infections, deep sternal wound infection in cardiac surgeries (including coronary artery bypass graft), total hip and knee replacement surgeries, and abdominal or vaginal hysterectomies.[527] Hospitals must submit these data to the Department of Health via the National Healthcare Safety Network at the Centers for Disease Control and Prevention.[528] Outbreaks or suspected outbreaks of disease that occur or are treated in a health care facility may also be reportable under the state's notifiable disease law.[529]

8. DEADLINES: Medical facilities must notify the Department of Health of adverse events within forty-eight hours of confirmation of the event.[530] A subsequent report containing a root cause analysis and a corrective action plan

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Office, Wash. State Dep't of Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 24, 2008, 09:58 EST) [hereinafter E-mail from Furkay] (on file with journal).

522. WASH. REV. CODE § 70.56.020(2) (Supp. 2008).

523. *Id.* § 70.56.010(10); E-mail from Furkay, *supra* note 521.

524. E-mail from Furkay, *supra* note 521.

525. WASH. REV. CODE § 70.56.020(2) (Supp. 2008).

526. *Id.* § 70.56.010(1).

527. *Id.* § 43.70.056(2)(a).

528. *Id.* § 43.70.056(2)(b).

529. E-mail from Furkay, *supra* note 521; *see also* WASH. ADMIN. CODE § 246-101-001 to -120. (2008).

530. WASH. REV. CODE § 70.56.020(2) (Supp. 2008).

must be submitted within forty-five days of the initial confirmation of the event.[531]

9. PENALTIES AND ENFORCEMENT MECHANISMS: "The intent of the law is quality improvement and there are no sanctions or citations in the law."[532] If the Department of Health discovers that an event is not reported, the "department shall direct the facility to report or to undertake an investigation of the event."[533]

(a) Revocation of license? No.

(b) Audits? No.

10. ARE PUBLIC REPORTS ISSUED? The Department of Health is directed to contract with a "qualified, independent entity to receive notifications and reports of adverse events and incidents." This entity must produce an annual report for the governor and legislature regarding the "number of adverse events and incidents reported by medical facilities, in the aggregate, on a geographical basis, and a summary of actions taken by facilities in response to the adverse events or incidents" as well as "recommendations to medical facilities on a facility-specific or on a statewide basis regarding changes, trends, and improvements in health care practices and procedures for the purpose of reducing the number and severity of adverse events or incidents."[534] This report must be publicly available on the Department of Health's website.[535] Starting December 1, 2009, and each December 1 thereafter, the Department of Health must also "prepare and publish a report on its website that compares the health care-associated infection rates at individual hospitals in the state using the data reported in the previous calendar year . . . ."[536]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? No. "The notification of an adverse event . . . shall be subject to public disclosure and not exempt from disclosure . . . . Any public disclosure of an adverse event notification must include any contextual information the medical facility chose to provide" with its original report to the Department of Health.[537] However, health care-associated infection reports are protected from discovery.[538]

12. IMMUNITY FOR REPORTERS? Unclear from statutes and regulations.

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: WASH. REV. CODE § 43.70.056 (Supp. 2008); WASH. REV. CODE §§ 70.56.010 to .050 (Supp. 2008).

15. OTHER RESOURCES: N/A.

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531. *Id.* § 70.56.020(2)-(4).

532. E-mail from Furkay, *supra* note 521.

533. WASH. REV. CODE § 70.56.020(5) (Supp. 2008).

534. *Id.* § 70.56.040(1)-(3).

535. *Id.* § 70.56.040(3)(c).

536. *Id.* § 43.70.056(3)(d).

537. *Id.* § 70.56.050(b).

538. *Id.* § 43.70.056(2)(e)(ii).

16. DATE REPORTING STARTED: June 5, 2006.[539]

WEST VIRGINIA

A medical error reporting regime does not appear to exist for this state.

WISCONSIN

A medical error reporting regime does not appear to exist for this state.

WYOMING

1. GENERAL DESCRIPTION: All health care facilities must report "safety events" to the Department of Health.

2. IS REPORTING MANDATORY? Yes, until June 30, 2010.[540]

3. REPORT RECIPIENT(S): Department of Health.[541]

4. IS REPORTING CONDUCTED ELECTRONICALLY? The Department of Health "may design the reporting system so that a facility may file by electronic means . . . [and] shall encourage a facility to use the electronic filing option when that option is feasible for the facility."[542]

5. WHAT FACILITIES MUST PROVIDE REPORTS? Every licensed health care facility.[543]

6. WHAT INCIDENTS MUST BE REPORTED? "Safety events" must be reported, which are defined as "unexpected occurrence[s] involving death or serious physical or psychological injury or the risk thereof . . . ."[544] In 2007, safety events were defined to include twenty-seven of the twenty-eight "serious reportable events" listed by the NQF.[545] In 2008, the state legislature eliminated the statutory list of safety events and replaced that section of the statute with authorization for the Department of Health to issue rules or regulations identifying reportable events "using a standard taxonomy generally accepted in

539. E-mail from Furkay, *supra* note 521.

540. WYO. STAT. ANN. § 35-2-912(b) (2007). This statute has been repealed, effective June 30, 2010.

541. *Id.* (requiring report of safety events to the "department"); *id.* § 35-2-901(a)(vi) (defining "department").

542. *Id.* § 35-2-912(c).

543. *Id.* § 35-2-912(b); *id.* § 35-2-901(a)(x) (defining "health care facility" as "any ambulatory surgical center, assisted living facility, adult day care facility, adult foster care home, alternative eldercare home, birthing center, boarding home, freestanding diagnostic testing center, home health agency, hospice, hospital, intermediate care facility for the mentally retarded, medical assistance facility, nursing care facility, rehabilitation facility and renal dialysis center").

544. *Id.* § 35-2-912(a).

545. *See id.* § 35-2-912(a)(i)-(vi); *supra* Appendix. The National Quality Forum and Wyoming lists are nearly identical, with the exception that the Wyoming statute does not specifically include the event of artificial insemination with the wrong donor sperm or wrong egg as a reportable event.

the health care industry as indicated by endorsement of the [N]ational [Q]uality [F]orum or similar health care quality control organization."[546]

7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Hospital-acquired infections are not explicitly listed as a separate category, but could result from other "safety events."

8. DEADLINES: Any person employed by the health care facility shall notify the patient safety officer of the facility within twenty-four hours of becoming aware of a patient safety event. The patient safety officer must then report the event to the Department of Health within fifteen days of receiving notification.[547]

9. PENALTIES AND ENFORCEMENT MECHANISMS: Any person who violates the reporting requirements or violates orders issued pursuant to those requirements "shall be deemed guilty of misdemeanor, and shall be punished except as otherwise provided therein by a fine or not more than one thousand dollars ($1,000.00), or by imprisonment for not more than one (1) year or by both such fine and imprisonment."[548]

(a) Revocation of license? Yes, at the Department's discretion.[549]

(b) Audits? Unclear from statutes and regulations.

10. ARE PUBLIC REPORTS ISSUED? Yes. On an annual basis, the Department of Health "shall prepare and publish a report and analysis of all reported safety events for the previous year, including a trend analysis and recommendations for systemic improvements that are likely to enhance patient safety and health care."[550] This report is available to the public and is forwarded to the governor, the health care commission, and Wyoming's Joint Labor, Health, and Social Services Interim Committee.[551]

11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY? Yes.[552] Moreover, safety event reports shall not identify the health care professionals, facility employees, or patients involved.[553]

12. IMMUNITY FOR REPORTERS? Yes.[554]

13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED? No.

14. RELEVANT STATUTES AND REGULATIONS: WYO. STAT. ANN. § 35-2-912 (2007); 35-2-912 WYO. CODE R. §§ 1 to 14 (Supp. 2008).

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546. WYO. STAT. ANN. § 35-2-912(a) (2008).

547. *Id.* § 35-2-912(b)(i).

548. *Id.* § 35-1-106.

549. *Id.* § 35-2-905(a) (stating that "the division may . . . deny, suspend or revoke a license . . . if a licensee: (i) violates any provision of this act . . .").

550. *Id.* § 35-2-912(f).

551. *Id.*

552. *Id.* § 35-2-912(e).

553. *Id.* § 35-2-912(c).

554. *Id.* § 35-2-910(a) (stating that "any person who . . . participates in the reporting, collection, evaluation, or use of quality management information . . . shall be immune from suit in any civil action . . .").

15. OTHER RESOURCES: WYO. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN WYOMING HEALTHCARE FACILITIES: SECOND ANNUAL REPORT 2006-2007, *available at* http://wdh.state.wy.us/Media.aspx?mediaId=3248.
16. DATE REPORTING STARTED: June 30, 2005.[555]

555. *Id.* § 35-2-912(b).