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# ARTICLES

# Prescriptions sans Frontières (or How I Stopped Worrying About Viagra on the Web but Grew Concerned About the Future of Healthcare Delivery)

Nicolas P. Terry, J.D.\*

#### INTRODUCTION

Internet-based prescribing and dispensing are poised to become major components of healthcare delivery in the United States: In 2003, eighteen percent of online U.S. households purchased prescription drugs online, a number expected to grow to twenty-seven percent in 2004.<sup>1</sup> Together, this infusion of technology and the broader trend toward increased prescribing<sup>2</sup> are changing the landscape of American healthcare, and the manner in which the legal system interacts with these controversial millennial delivery models will shape the future of healthcare.

This Article explores the policy issues and legal or regulatory structures currently applied to prescribing and dispensing. Much of the controversy surrounding Internet prescribing and dispensing can be

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<sup>1.</sup> Eric G. Brown with Bradford J. Homes et al., Forrester's Top 10 Healthcare Predictions for 2004 (Dec. 15, 2003), at

http://www.forrester.com/ER/Research/Brief/0,1317,33444,00.html.

<sup>2.</sup> See, e.g., Press Release, Health Affairs, Doctors Prescribing More Drugs? (July 9, 2002), http://www.healthaffairs.org/press/In\_The\_News\_070902.htm.

attributed to the unsavory origins of these initiatives: Many of the early providers have been illegal or marginally legal businesses.<sup>3</sup> This Article argues that the threat posed by rogue prescribing and dispensing does not justify the level, style, and mechanics of current regulation. The Article further argues that current and emerging regulation may chill the development of lawful, efficient, necessary, and patient-friendly services and recommends alternate approaches.

Part I of the Article sets out the key distinguishing features of the aforementioned initiatives and suggests that simple confusion between different and emergent models seem to be misleading legislators and regulators and imperiling patient choice. Part II discusses current regulation of Internet prescribing and dispensing and addresses the areas that most concern regulators. In the process, it examines the regulation of Internet prescribing by state licensing boards and the controversy surrounding transnational prescription dispensing.

Parts III and IV of the Article then look beyond the current forms of Internet prescribing and dispensing to identify the stakeholders and critically analyze the regulatory themes that populate the landscape. These themes, including those labeled as uneasy federalism, under-regulation, and over-regulation, help us better understand the ways our legal and regulatory systems create disincentives to the adoption of new technologies or business models. Part V of the Article describes the steps necessary to maintain rigorous control over healthcare quality while avoiding disincentives to the provision of the next generation of effective and efficient healthcare. More importantly, it suggests positive steps (both legal and structural) necessary to create a prescribing and dispensing environment that is lawful, patient-friendly, and progressive in integrating e-health solutions into standard care practices.

#### I. BACKGROUND: ISSUES AND TERMINOLOGY

To better understand the impact of regulation on Internet prescribing and dispensing, it is important to appreciate the broader and highly varied landscape of technologically-mediated healthcare. It is also critical to distinguish between the overlapping and frequently confusing labels applied in the relatively immature e-health domain.

In the early twentieth-century there were recorded attempts at what we now call remote imaging or PACS (Picture Archiving and Communications

<sup>3.</sup> See discussion infra notes 18-20, 27-29 and accompanying text.

Systems).<sup>4</sup> However, the first successful iterations of telemedicine<sup>5</sup> were primarily audio educational teleconferences in the 1950s.<sup>6</sup> By the 1960s, rudimentary telemedicine networks had added video, leading to the first remote consultations.<sup>7</sup> As POTS (Plain Old Telephone System) gave way to faster ISDN (Integrated Services Digital Networks) and subsequent high-speed networks, increasingly sophisticated data, such as charts and x-rays, were added to the telemedical consultation mix.<sup>8</sup>

Telemedicine began as a narrow construct—a consultation-based model of diagnosis and occasionally treatment.<sup>9</sup> In the traditional telemedicine model a primary (or originating) physician uses technology (be it phone, e-mail, or interactive video) to connect to a consulting (or remote) physician; the primary physician may provide the consulting physician with access to a patient's chart, x-ray, or other medical information.

Technological developments have allowed telemedicine to move beyond its early intrastate models to interstate and international projects.<sup>10</sup>

4. Travis Wheeler, In the Beginning... Telemedicine and Telepsychiatry, 2 TELEMEDICINE TODAY 2 (1994).

5. In this Part, I describe telemedicine's original meaning—i.e., the consultative interaction between a patient, an on-site health professional, and a distant physician. See *infra* text accompany note 9. In recent years, telemedicine has increasingly been used as an umbrella term, encompassing a broad range of technologically-mediated interactions. See *infra* note 10 and text accompanying note 12. I posit that continued use of a narrow definition of telemedicine is preferable for its specificity, and other terms, such as telehealth, are more appropriate as broadly inclusive references. See *infra* text accompanying note 13.

6. Wheeler, *supra* note 4, at 2. Audio educational teleconferences were first used in psychiatry. See Tracy D. Gunter et al., *Misinformed Regulation of Electronic Medicine Unfair to Responsible Telepsychiatry*, 31 J. ACAD. PSYCHIATRY L. 10 (2003).

7. Wheeler, supra note 4, at 4.

8. See TELEMEDICINE: A GUIDE TO ASSESSING TELECOMMUNICATIONS FOR HEALTH CARE 34-38 (Marilyn J. Field ed., 1996) [hereinafter TELEMEDICINE GUIDE].

9. Id. at 44-46.

10. Much of the technological innovation in telemedical services, particularly in the use of microwave and satellite technologies, has been driven by the military and NASA. *Id.* at 39. Increasingly, traditional bricks-and-mortar healthcare entities have invested heavily in imaging technologies which enable store-and-forward type applications. *See, e.g., Teleradiology FAQ*, Hospital for Special Surgery, *at* http://www.imaginghss.org/patient/dripat\_faq\_telerradio.htm (last visited Apr. 15, 2004); *The Apollo Telepathology System*, Apollo Telemedicine, *at* http://www.apollotelemedicine.com/solutions/telepathology (last visited Apr. 15, 2004). These applications provide their physicians and consultants with widespread remote access to patient data. *See, e.g.*, Scott A. Edelstein, *Careful Telemedicine Planning Limits* 

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Once it became possible for the remote physician to observe and communicate directly with the patient, telemedicine practice began to deemphasize the importance and role of the "local" physician; in many instances, nurses, nurse practitioners, and IT technicians may now substitute for the local physician.<sup>11</sup>

More recently, the "telemedicine" label has been applied to fully disintermediated models—that is, where there is no on-site health professional and technology alone links patients to distant healthcare providers. For example,

in telehome medicine (technologically-mediate home care) patients interact with monitoring or diagnostic appliances that transmit results to healthcare professionals.<sup>12</sup> Rather than stretching the scope of "telemedicine" to include the full range of remote diagnosis and treatment, store-and-forward technologies, telehome medicine and other disintermediated models, "telehealth"<sup>13</sup> is a broader term that more easily captures all of this. However, the fact that telehealth is an appropriate term to describe these related technologies should not suggest that they necessarily merit collective regulatory treatment.

Extending well beyond the scope of terms like telemedicine or even telehealth, "e-health" is now the accepted reference for the many varied modes of technologically-mediated healthcare.<sup>14</sup> E-health includes telehealth and also encompasses Internet-based prescribing and dispensing, e-prescribing,<sup>15</sup> health advice websites, online continuing medical education and health care procurement.<sup>16</sup> E-health stretches beyond Internet-based commercial activities (commonly referred to as "e-commerce") to include technologically-mediated healthcare more generally. It includes the accelerating incorporation of technology into traditional bricks-and-mortar healthcare—from reimbursement and

11. TELEMEDICINE GUIDE, supra note 8, at 44-46.

12. Id.

13. According to Nebraska law, "Telehealth means the use of telecommunications technology by a healthcare practitioner to deliver healthcare services within his or her scope of practice at a site other than the site where the patient is located . . . ." NEB. REV. STAT. § 71-8503 (2002).

14. See Nicolas P. Terry, Structural and Legal Implications of e-Health, 33 J. HEALTH L. 606 n.1 (2000); see also G. Eysenbach, Editorial, What Is e-Health?, 3 J. MED. INTERNET RES. e20 (2001), http://www.jmir.org/2001/2/e20/.

15. Infra note 17 discusses the definition of e-prescribing.

16. See Terry, supra note 14.

Costly Liability Exposure, HEALTHCARE FIN. MGMT., Dec. 1999,

http://articles.findarticles.com/p/articles/mi\_m3257/is\_12\_53/ai\_58185760.

insurance transactions, to longitudinal electronic medical records, to computerized physician order entry (CPOE) systems, to surgery robots—to improve the quality or efficiency of healthcare. Ironically, e-health is unlikely to remain a meaningful label: The rapid deployment of technologies in the health arena, fuelled by the need to reduce medical and medication adverse events and the urgent imperative to remove administrative costs, will rapidly blur the distinction between traditional healthcare delivery and e-health.

Internet prescribing is a particularly important subset of e-health. It is the practice of providing access to prescription drugs when the primary contact between patient and prescriber is Internet or email-based.<sup>17</sup> Many of the businesses involved in such practices are completely disconnected from any model of responsible medical practice.<sup>18</sup> They frequently dabble in controlled substances or maintain a "side business" to perform credit

17. Care must be taken to distinguish the term "e-prescribing" (electronic prescribing) from Internet prescribing which may result in electronic prescriptions. In its simplest forms, e-prescribing consists of handheld devices that improve prescription writing or dispensing; they are frequently used by physicians in hospitals. (Admittedly, given e-prescribing's narrow definition, its use of the prefix "e-" is anomalous; elsewhere the prefix "e-" indicates reliance on internet functionality, as in "e-commerce," or technological-mediation more generally, as in "e-health.")

There are direct cost-savings associated with e-prescribing's use of electronic interfaces, and the use of such interfaces will expand exponentially as the full HIPAA electronic data interchange (EDI) and longitudinal patient records come online. *See* Nicolas P. Terry, *An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 AM. J. L. & MED. 361, 365-66, 370 (2001). At present, however, the dominant reason for adopting such technologies lies in their potential for reducing medical error. *See generally* CAL. HEALTH CARE FOUND., E-PRESCRIBING (2001), http://www.chcf.org/documents/hospitals/EPrescribing.pdf; CAL. HEALTH CARE FOUND., IMPROVING DRUG PRESCRIBING PRACTICES IN THE OUTPATIENT SETTING: A MARKET ANALYSIS

IMPROVING DRUG PRESCRIBING PRACTICES IN THE OUTPATIENT SETTING: A MARKET ANALYSIS (2002), http://www.chcf.org/documents/ihealth/ImprovingDrugPrescribing.pdf.

Electronic prescription refers to the movement away from requiring a conventional written prescription provided to a patient by a physician that is then manually transmitted to a pharmacy. State laws increasingly allow for a purely electronic prescription and resultant transmittal. *See, e.g.*, MASS. GEN. LAWS ch. 94C, § 23 (Supp. 2004) ("A prescription may be transmitted electronically with the electronic signature and electronic instructions of the prescriber, and shall be transmitted directly from the prescriber to the pharmacy designated by the patient without alteration of the prescription information, except that third-party intermediaries may act as conduits to route the prescription from the prescriber to the pharmacy.").

18. See, e.g., Gilbert M. Gaul & Mary Pat Flaherty, Doctors Medicate Strangers on Web; Some Physicians Face Own Troubles, WASH. POST, Oct. 21, 2003, at A1.

card fraud or other scams.<sup>19</sup> Others are far greyer and make for the most difficult policy and regulatory choices. These superficially professional sites involve online "diagnosis" prior to prescribing. Subsequently, they generate a prescription that they dispense or, more likely, is dispensed through an Internet-based fulfillment partner.<sup>20</sup> What they have in common is best described as an opportunistic physician-patient "relationship" that is entered into for a single purpose (and often a solitary transaction)—the purchase of a specific drug.

Internet dispensing is a potentially far larger business than Internet prescribing, and much of the existing traffic is facially lawful, premised on a valid U.S. prescription that is far more likely to have been written by a patient's primary care provider than by a Perl script<sup>21</sup> on a website. In 2001. legal Internet and mail-order dispensing accounted for only \$28 billion of the \$164 billion in drug sales, but it is the fastest growing segment of the pharmacy industry and is predicted to double each year in the near term.<sup>22</sup> These legal Internet-based pharmacies and prescription fulfillment businesses, such as Drugstore.com, (often referred to in the press as "epharmacies") are desperate to differentiate themselves from their less reputable brethren<sup>23</sup> and to recapture the business they are losing to Canadian pharmacies.<sup>24</sup> They possess multiple state pharmacy licenses and, frequently, Pharmacy Verified Internet Practice Sites (VIPPS) accreditation. Formalism aside, these legal Internet-based pharmacies are distinguishable by reference to their business model; they do not offer prescribing services but fill prescriptions that, while frequently electronically transmitted, are written by a traditional healthcare provider.

Overlapping conceptually with these legal Internet-based pharmacies are Pharmacy Benefits Managers (PBMs), prescription fulfillment services that increasingly are part of the managed care bundle. A growing number of health plans and employers seek to control pharmaceutical costs by contracting with a PBM, such as Medco Health or ExpressScripts, to

<sup>19.</sup> Mary Pat Flaherty & Gilbert M. Gaul, Lax System Allows Criminals To Invade the Supply Chain, WASH. POST, Oct. 22, 2003, at A1.

<sup>20.</sup> See infra text accompanying notes 408-415.

<sup>21.</sup> For examples of the use of Perl scripts generally, see The CGI Resource Index, *at* http://cgi.resourceindex.com/Programs\_and\_Scripts/Perl/ (last visited July 29, 2004).

<sup>22.</sup> See Bob Tedeschi, As Baby Boomers Grow Older, Online Prescription Drug Sales Are Showing Steady Growth, N.Y. TIMES, Dec. 16, 2002, at C16.

<sup>23.</sup> See Gilbert M. Gaul & Mary Pat Flaherty, Warnings Target Rogue Drug Sites, WASH. POST, Oct. 24, 2003, at A7.

<sup>24.</sup> See Bob Tedeschi, As the Debate Continues, Opinions Are Divided over the Merits of Allowing Online Drug Purchases from Canada, N.Y. TIMES, Mar. 8, 2004, at C4.

manage the fulfillment side of the patient benefits package.<sup>25</sup> The larger PBMs have their own online pharmacies or have contracted with Internetbased pharmacies for prescription fulfillment, threatening the heretofore dominant role of bricks-and-mortar pharmacies.<sup>26</sup>

In contrast to the legal Internet-based pharmacies, illegal pharmacies generally employ a composite model in which prescribing and dispensing businesses overlap. For example, it is not uncommon to see a portal-style advice site that drives users first to an online diagnosis and then on to Internet dispensing.<sup>27</sup> Some Internet addresses that seem to be cohesive, one-stop diagnosis and prescribing businesses in fact have outsourced to separate fulfillment businesses.<sup>28</sup> Even though the domain names for these businesses may "look" American (i.e., dot.com), it is likely that a large percentage are based offshore.<sup>29</sup>

#### **II. REGULATING INTERNET PRESCRIBING AND DISPENSING**

It is not disputed that Internet prescribing and dispensing require close regulation and that some market participants may merit criminal prosecution. Unfortunately, to date, the regulatory routes chosen tend to be conceptually awkward and operationally flawed; so, too, have been the medical community's efforts to self-regulate. An unfortunate byproduct of

27. Indeed, Internet businesses may register multiple domain names, feeding their single business from multiple or transient storefronts.

28. See, e.g., Anelia K. Dimitrova & Tony Leys, Government Closes Dubuque Pharmacy over Internet Orders, DES MOINES REG., Sept. 13, 2003, at 1A (describing how federal and state agents shut down a neighborhood pharmacy suspected of fulfilling orders for a Virgin Islands-based Internet company).

29. For example, Buymeds.com is based in the Virgin Islands but fulfills its orders through U.S. bricks-and-mortar pharmacies. *See Pharmacy Linked to Internet Sales Ordered Closed*, USA TODAY, Sept. 12, 2003, *available at* 

http://www.usatoday.com/tech/news/techpolicy/2003-09-12-pharmacy\_x.htm?csp=15.

<sup>25.</sup> In some cases, HMOs have opted to develop their own in-house Internet prescription fulfillment services, instead of contracting with a PBM. For a summary of HMO activity and models, see *Health Plan Strategies for Pharmacy Benefit Management*, MANAGED CARE WK., Jan. 13, 2003, *at* http://www.aishealth.com/DrugCosts/HMOstrategies.html. For the technological structure and other details of Medco, a major PBM, see Alan Cohen, *Online Prescriptions*, PC MAG., Aug. 19, 2003, at 68,

http://www.pcmag.com/article2/0,4149,1204843,00.asp.

<sup>26.</sup> See The Internet's Drug Lords, INDUSTRY STANDARD, Apr. 10, 2000, http://www.thestandard.com/article/0,1902,13407,00.html; Associated Press, Retail Pharmacies Fight for Share in Medicare Bill (Oct. 21, 2003), available at http://www.foxnews.com/ story/0,2933,100595,00.html.

this imperfect regulation may be the chilling of responsible practices.

#### A. Traditional Licensure

The monopoly granted to physicians to prescribe and pharmacists to dispense vests the regulation of pharmaceutical distribution in the hands of state licensure systems.<sup>30</sup> The modern legal history of medical practice acts, licensure, and discipline began in the 1870s with the enactment of state statutes governing the licensing of physicians<sup>31</sup> and pharmacies.<sup>32</sup> The role of the state was sanctioned in 1889, when the Supreme Court denied a due process challenge to a West Virginia medical practice act which required state licensure of physicians.<sup>33</sup> From this point onward, the state police power has been widely recognized as the source of licensure regulation—since then only states have licensed physicians.<sup>34</sup> Pharmacy licensure also remains resolutely state-based, although the reciprocity process and standardized examinations administered by the National Association of Boards of Pharmacies (NABP) have pushed the profession closer to national standards.<sup>35</sup>

Physician mobility in the early part of the twentieth century led to

32. CARL T. MARCOS, PHARMACY AND THE LAW 42 (1984). Licensure statutes began to appear in the 1870s; they continue to focus on drug preparation and premises. *Id.* 

Id. at 122.

<sup>30.</sup> See, e.g., AZ. STAT. § 32-1961(A) (2000).

<sup>31.</sup> Medical licensure statutes enforced by state medical boards have existed for over two hundred years, and historical antecedents aimed at quackery and overcharging date back almost four hundred years. However, after the Civil War, licensure went into decline in the hands of local medical societies and inferior medical schools. Thus, the modern history of practice acts and licensure statutes did not truly begin until Texas enacted such legislation in 1873. ROBERT C. DERBYSHIRE, MEDICAL LICENSURE AND DISCIPLINE IN THE UNITED STATES 3-12 (1969); see Texas State Bd. of Med. Examiners, *Board of Medical Examiners' History, at* http://www.tsbme.state.tx.us/boards/mbhis.htm (last visited Apr. 12, 2004).

<sup>33.</sup> Dent v. Virginia, 129 U.S. 114 (1889) (upholding 1882 W. Va. Act 93, §§ 9, 15). The Court explained:

The power of the State to provide for the general welfare of its people authorizes it to prescribe all such regulations as, in its judgment, will secure or tend to secure them against the consequences of ignorance and incapacity as well as of deception and fraud.... The nature and extent of the qualifications required must depend primarily upon the judgment of the State as to their necessity.

<sup>34.</sup> See Kevin Outterson, Health Care, Technology and Federalism, 103 W. VA. L. REV. 503, 505-09 (2001).

<sup>35.</sup> MARCOS, supra note 32, at 27.

discussions of reciprocity and national (or uniform) licensure-issues that the Federation of State Medical Boards has nurtured, albeit inconclusively, since its founding in 1912.<sup>36</sup> Today, a modern rationale for state as opposed to national licensure seems difficult to identify. The supposed premise for state licensure is the desirability of regulatory heterogeneity based on geographically distinct economic, religious, or other social policies. Malpractice law,<sup>37</sup> national health quality regulators, accreditation systems, and even state boards themselves<sup>38</sup> have recognized that medical practice. as well as its training, testing, and literature, is national in scope.<sup>39</sup> Healthcare workers and consumers are highly mobile and large integrated healthcare providers have more in common with national or multinational corporations than the local hospitals of an earlier age. Protection of the public is a laudable goal, but not one that requires the Balkanization of the medical profession.<sup>40</sup> Contemporary state licensure justifies local professional fiefdoms, perpetuates parochialism, and encourages anticompetitive protectionism.<sup>41</sup>

The current state medical board systems and analogous pharmacy systems have two key functions: gate-keeping via licensure and quality

<sup>36.</sup> DERBYSHIRE, *supra* note 31, at 8-9. Some progress was made, however, with the establishment of the Federation Credentials Verification Service in 1996. *See* Federation Credentials Verification Service, *at* http://www.fsmb.org/fcvs\_program/cvrhome.htm. *See also* FED'N OF STATE MED. BDS., REPORT OF THE SPECIAL COMMITTEE ON LICENSE PORTABILITY (2002),

http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/license%20\_por tability.htm (last visited Apr. 19, 2004); *infra* text accompanying note 464.

<sup>37.</sup> See, e.g., Sheeley v. Memorial Hosp., 710 A.2d 161 (R.I. 1998); Hall v. Hilbun, 466 So. 2d 856 (Miss. 1985); Morrison v. MacNamara, 407 A.2d 555 (D.C. 1979).

<sup>38.</sup> See, e.g., Gabri v. Rhode Island Bd. of Med. Licensure & Discipline, No. 97-4344, 1998 R.I. Super. LEXIS 36 (approving use of expert testimony to determine a national standard in sexual misconduct hearing).

<sup>39.</sup> On the role of the federal government in healthcare delivery, see Outterson, *supra* note 34, at 515-20.

<sup>40.</sup> There is even less contemporary rational for making the licensure of physicians state-based than there is for having state bar requirements for lawyers. State laws, customary practices, and client expectations do in fact vary across state lines. The same cannot be said for human physiology. *See, e.g.*, Supreme Court of Virginia v. Friedman, 487 U.S. 59, 68 (1988) (holding that state bar residency requirement violated privileges and immunities clause, but apparently approving of state requirements designed to demonstrate familiarity with state law).

<sup>41.</sup> See DERBYSHIRE, supra note 31, at 13-31; STANLEY J. GROSS, OF FOXES AND HEN HOUSES: LICENSING AND THE HEALTH PROFESSIONS 9 (1984).

control via standard-setting and discipline.<sup>42</sup> Arguably, medical licensure alone reveals more about qualifications than quality. The pace of quality assurance is instead set by federal and accreditation-based reporting and institutional peer review, as well as managed care contracting, which identifies pools of approved providers for patients.<sup>43</sup> Although, for example, state medical boards have followed state malpractice law by adopting national standards for quality and ethics,<sup>44</sup> the requirement of licensure and the concept of disciplinary jurisdiction continue to be interpreted, implicitly or explicitly, as fundamentally intrastate concepts.<sup>45</sup> Thus, the presence of the physician and patient in separate states (interstate practice)—as is frequently the case with technologicallymediated care—implicates discrete and frequently asymmetrical regulatory systems.<sup>46</sup>

State medical boards are not only hostile to interstate practice, but also tend to be skeptical of non-traditional forms of practice,<sup>47</sup> putting even intrastate practice that is technologically-mediated at disciplinary risk. Such disciplinary scrutiny likely has its roots in customary standards, professional conservatism, or even softly articulated protectionism. Nonetheless, state licensure statutes have been able to accommodate two modest technologyinduced changes in the practice of medicine. First, when patients travel out of state and then realize they have left their medications behind, they may phone or email their physician for a replacement prescription.<sup>48</sup>

42. See, e.g., Sugarman v. Bd. of Registration in Med., 662 N.E.2d 1020, 1023 (Mass. 1996) (noting the broad authority of medical boards "to sanction physicians for conduct which undermines public confidence in the integrity of the medical profession").

43. See GROSS, supra note 41, at 16-21. See generally Nicolas P. Terry, When the "Machine That Goes 'Ping'" Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries, 46 ST. LOUIS U. L.J. 37 (2002).

44. See supra note 37 and accompanying text.

45. The conceptual and operational basis of state licensure and disciplinary jurisdiction is the idea of the "practice of medicine"—a term of art referring to legally permitted provisions of allopathic medicine. Implicitly or explicitly, that foundational concept is interpreted to mean the practice of medicine *in a given state. See, e.g.*, KY. REV. STAT. ANN. §311.560(1) (Michie 2001); CAL. BUS. & PROF. CODE § 2052(a) (West 2003).

46. This dynamic becomes even more complicated once the location of web or mail servers in additional states is considered. *See, e.g.*, United States v. Kammersell, 7 F. Supp. 2d 1196 (C.D. Utah 1998), *aff'd* 196 F.3d 1137 (10th Cir. 1999) (allowing indictment for interstate transmission of a threat between intrastate actors because of the routing of threatening email through server in remote state).

48. See, e.g., ALA. CODE § 34-24-505(a) (1975) (emergencies); id. § 34-24-505(b)

<sup>47.</sup> See infra notes 434-442 and accompanying text.

Second, inherent to all professions is the practice of consultation—the formal or informal (that is, remunerated or unremunerated) discussion of a case between professionals. It is now accepted that this will occur among physicians across technological media.<sup>49</sup>

# B. Telemedicine Regulation

Traditional telemedicine-the use of communication technology to facilitate long-distance consultation-was readily accepted under state regulatory systems. There are several possible explanations for the absence of controversy. First, it may be that most telemedicine consults have historically been intrastate in nature. Second, cost factors have constrained the number of such consults because of the limited reimbursement offered by private payers, Medicaid, or Medicare.<sup>50</sup> Third, where there is no relationship between the patient in one state and a consulting physician in another state because the consulting physician has a relationship only with the originating physician, then such a consultation-potentially interstate and telemedical-arguably does not qualify as the "practice of medicine" and therefore does not require regulation.<sup>51</sup> Furthermore, many state licensing statutes included narrow exceptions to the requirement of licensure tailored to some geographically indeterminate physician-patient interactions.<sup>52</sup> Fourth (and related to the general lack of reimbursement), it may be that the majority of telemedicine initiatives have been statefunded and carried out by state actors-hardly politically feasible targets for even the most regulatory active or technophobic state medical boards.

Although traditional telemedicine was readily accepted without provoking change in existing state regulatory systems, more recent developments—particularly Internet-based changes—have resulted in

51. See Irvin v. Smith, 31 P.3d 934 (Kan. 2001) (holding that a physician who gives an informal opinion at the request of a treating physician does not owe a duty to the patient).

52. See, e.g., KY. REV. STAT. ANN. § 311.560(2) (b) (1) (Michie 2003) (exempting from the state licensure requirement physicians who are licensed and reside in another state and whose only practice in Kentucky is infrequent consultation on medicine or osteopathy); see also 225 ILL. COMP. STAT. ANN. 60/49.5 (West 2003).

<sup>(</sup>infrequent consultations).

<sup>49.</sup> See, e.g., AMA President Talks to IBD About Guidelines for Information Technology Use, June 3, 2002, http://www.ama-assn.org/ama/pub/article/1615-6309.html (reporting AMA President statement that "[t]here's going to be cautious adoption of freestanding, online consultations. What's clearly going to happen is an extension of telemedicine, where doctors are messaging between themselves.").

<sup>50.</sup> See Edelstein, supra note 10.

legislative reforms, changes in regulatory attitudes, and shifts in enforcement practices. There are several possible explanations for these changes. First, there is an atmosphere of distrust of all things Internet among medicine's professional leadership. Notwithstanding the patient safety movement's focus on technological solutions to medical and medication errors and patient demand for email contact with physicians, the Internet and related technologies are a source of frustration for most physicians. For example, patient access to under-regulated<sup>53</sup> direct-toconsumer (DTC) information provided by pharmaceutical company websites is viewed as suspect and adversely affecting physician-patient dialogue.<sup>54</sup> Further, many physicians deeply resent the federal e-health flagship initiative—the privacy regulations promulgated under the Health Insurance Portability and Accountability Act<sup>55</sup>—and view it as an expensive example of overreaching regulation.<sup>56</sup>

Second, technological innovations have allowed us to move past the paradigmatic telemedicine consult to more advanced direct telemedical examinations of the patient by the remote physician.<sup>57</sup> An IT technician or nurse may be the only "local" professional<sup>58</sup> sharing physical space with the patient. Moreover, on the near horizon is the increased deployment of telehome appliances that enable the patient to communicate directly with

53. See Christopher Rowland, Lawmakers Assail FDA, Say Agency Fails To Get Tougher on Drug-ad Claims, BOSTON GLOBE, Jan. 30, 2004,

http://www.boston.com/business/globe/articles/2004/01/30/lawmakers\_assail\_fda/. 54. Physicians, many of whom feel that visits are already overly compressed and

burdened by the requirements of managed care, complain that DTC advertising makes patients more difficult to deal with and make visits even more time-consuming. *See* SUSANNAH FOX & DEBORAH FALLOWS, PEW INTERNET & AMERICAN LIFE PROJECT, INTERNET HEALTH RESOURCES (2003) [hereinafter FOX & FALLOWS],

http://207.21.232.103/pdfs/PIP\_Health\_Report\_July\_2003.pdf; Paul R. Helft et al., American Oncologists' Views of Internet Use by Cancer Patients: A Mail Survey of American Society of Clinical Oncology Members, 21 J. CLINICAL ONCOLOGY 942 (2003).

55. Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. §§ 160, 164 (2003).

56. See, e.g., South Carolina Med. Ass'n v. Thompson, 327 F.3d 346 (4th Cir. 2003) (upholding HIPAA against impermissible delegation and vagueness challenges brought by medical associations and physicians); see also infra text accompanying note 253.

57. Some specialties, such as psychiatry, used these techniques earlier than other specialties and continue to utilize them more frequently. Similarly, certain sub-populations, such as those in correctional facilities, have been particularly likely to receive direct telemedical services. *See, e.g.*, Kate Murphy, *Telemedicine Getting a Test in Efforts To Cut Costs of Treating Prisoners*, N.Y. TIMES, June 8, 1998, at D1.

58. See infra text accompanying note 496.

health providers through consumer-friendly interfaces; such appliances have no need for a "local" professional other than an IT technician to hook the device into the patient's broadband connection or nursing home network. Such medical practices cannot be characterized as "consultations" and thus cannot gain cover from the established exceptions in the medical practice acts; from the perspective of state regulators, these telehealth innovations must be addressed in a more direct (and generally disfavored) manner.

Third, telemedicine has been caught in the crossfire between regulators and Internet prescribers.<sup>59</sup> Just as the regulation of cloning and harvesting of fetal and embryo tissue influences responsible stem cell research,<sup>60</sup> the regulatory attack on Internet prescribing likely chills telemedicine. A large number of states have rewritten their licensure rules to bring Internet prescribing within the importing state's disciplinary ambit and, in the process, have added new definitions of telemedicine which impose state regulations on what heretofore were legally "safe" consulting relationships. For example, several jurisdictions have amended their licensing laws to specifically include "imported" electronic diagnosis or treatment.<sup>61</sup> Contemporary regulation of telemedicine, however, is anything but uniform. For example, the updated definitions of telemedicine in Arizona<sup>62</sup> and California<sup>63</sup> capture both intrastate and interstate consultations. In contrast, the Montana statute applies telemedicine-specific regulation only to interstate exchanges between physician and patient,<sup>64</sup> and the West Virginia definition of the "practice of

<sup>59.</sup> Regulating the Internet certainly presents certain challenges: As I have argued elsewhere, "[The] lack of physicality, the decoupling of physician from jurisdiction-delimited practice, severely challenges state licensing systems that apply to healthcare professionals." Terry, *supra* note 14, at 607. However, state regulators have responded in different ways; some have increased the enforcement of physician practice requirements and standards, while others have developed novel regulation of pharmacy practice. *See generally infra* Section II.C.

<sup>60.</sup> See generally Timothy Stoltzfus Jost, Rights of Embryo and Foetus in Private Law, 50 AM. J. COMP. L. 633, 644-45 (2002). However, California specifically distinguishes between disapproved tissue transactions, CAL. HEALTH & SAFETY CODE § 125117 (West 2004), and encouraged stem cell research, CAL. HEALTH & SAFETY CODE § 125115 (West 2004).

<sup>61.</sup> ALA. CODE § 34-24-501 (a) (1975). The same definition is used by Mississippi, MISS. CODE ANN. § 73-25-34 (1998); Missouri, MO. REV. STAT. § 334.010 (2001); New Mexico, N.M. STAT. ANN. § 61-6-6 (Michie 2004); and Oregon, OR. REV. STAT. § 677.135 (2004).

<sup>62.</sup> ARIZ. REV. STAT. § 36-3601(2) (2003).

<sup>63.</sup> CAL. BUS. & PROF. CODE § 2290.5(a)(1) (West 2003).

<sup>64.</sup> MONT. CODE ANN. § 37-3-342 (2003).

telemedicine" is limited to diagnosis or treatment by out-of-state physicians.<sup>65</sup>

The assumption that cross-border telemedical consultations are exempt from regulation by an additional state board is also being challenged. For example, while the Alabama statute purports to still exclude consultations from regulation, this exemption is limited to uncompensated, informal consultations where the remote physician has not given a formal or written opinion.<sup>66</sup> The same state exempts physicians from the requirement of a telemedicine practice certificate ("special purpose license") in emergency situations<sup>67</sup> or "on an irregular or infrequent basis."<sup>68</sup>

The types of interactions the emerging telemedicine definitions seek to regulate differ among states. While the Arizona law applies broadly to all forms of technologically-mediated healthcare,<sup>69</sup> the California statute is limited to "real time (synchronous) or near real time (asynchronous) twoway transfer of medical data and information."<sup>70</sup> The statute explicitly excludes telephone or email.<sup>71</sup> It is not immediately clear why regulators make distinctions based on the technologies employed or would disfavor likely secure) systems such as teleradiology or closed (and videoconferencing over open or public systems such as telephony. There is reason to suspect technophobia; in practice, stringent regulation of synchronous interactions disproportionately targets physicians employing sophisticated and secure technologies that are professionally appropriate.

Not content with tightening up their existing controls and reducing exemptions for telemedicine, states are targeting telemedicine and other

ALA. CODE § 34-24-501(a)(3) (1975).

67. Id. § 34-24-505(a).

68. The statute defines the latter as one that "occurs less than 10 times in a calendar year or involves fewer than 10 patients in a calendar year or comprises less than one percent of the physician's diagnostic or therapeutic practice." *Id.* § 34-24-505(b).

<sup>65.</sup> W. VA. CODE § 30-3-13 (Michie 2003).

<sup>66.</sup> According to Alabama law,

this definition is not intended to include an informal consultation between a licensed physician located in this state and a physician located outside this state provided that the consultation is conducted without compensation to or the expectation of compensation to either physician and does not result in the formal rendering of a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient by the physician located outside the state.

<sup>69.</sup> ARIZ. REV. STAT. § 36-3601(2) (West 2003).

<sup>70.</sup> CAL. BUS. & PROF. CODE § 2290.5(a) (2) (West 2003).

<sup>71.</sup> Id. § 2290.5(a)(1).

models of technologically mediated care for additional regulation. For example, several states, including Alabama,<sup>72</sup> Minnesota,<sup>78</sup> Montana,<sup>74</sup> New Mexico,<sup>75</sup> and Ohio<sup>76</sup> require an out-of-state physician to apply for a specialty-specific telemedicine practice certificate. Another trend, exemplified by regulatory changes in Arizona,<sup>77</sup> California,<sup>78</sup> Kentucky,<sup>79</sup> Nebraska,<sup>80</sup> Oklahoma<sup>81</sup> Puerto Rico,<sup>82</sup> and Texas,<sup>83</sup> is to require telemedicine-specific consent and correlated record-keeping.<sup>84</sup> For example, California requires "verbal and written informed consent [including a] description of the potential risks, consequences, and benefits of telemedicine."<sup>85</sup> Kentucky, among other states, emphasizes compliance with state and federal confidentiality and privacy laws.<sup>86</sup>

- 72. Ala. Code § 34-24-502 (1975).
- 73. MINN. STAT. § 147.032 (West 2003).
- 74. Mont. CODE ANN. § 37-3-343 (2003).
- 75. N.M. STAT. ANN. § 61-6-11-1 (Michie 2004).
- 76. OHIO REV. CODE ANN. § 4731.296 (Anderson 2003).
- 77. ARIZ. REV. STAT. § 36-3602 (West 2003).
- 78. CAL. BUS. & PROF. CODE § 2290.5 (West 2003).

79. Ky. REV. STAT. ANN. § 311.5975(1)(a) (Michie 2001) ("A treating physician who provides or facilitates the use of telehealth shall ensure: . . . [t] hat the informed consent of the patient, or another appropriate person with authority to make the health care treatment decision for the patient, is obtained before services are provided through telehealth...").

- 80. NEB. REV. STAT. § 71-8505 (2002).
- 81. OKLA. STAT. ANN. TIT. 36, § 6804 (West 1999).
- 82. 20 P.R. LAWS ANN. § 6006 (2003).
- 83. Texas State Board of Medical Examiners, Rule 174.10,

http://www.tsbme.state.tx.us/rules/rules/174.htm.

84. See, e.g., ALA. CODE § 34-24-504 (1975) ("Any licensee licensed under the provision of this article shall comply with all laws, rules, and regulations governing the maintenance of patient medical records, including patient confidentially requirements, regardless of the state where the medical records of any patient within this state are maintained."). Not all states, however, apply these requirements to intrastate relationships. See also 36 OKLA. STAT. ANN. tit. 36, § 6804 (F) (G) (West 1999).

85. CAL. BUS. & PROF. CODE § 2290.5(c) (West 2003); see also CAL HEALTH & SAFETY CODE § 123149.5 (West 2004).

86. Ky. REV. STAT. ANN. § 311.5975(1)(b) (Michie 2001) ("A treating physician who provides or facilitates the use of telehealth shall ensure . . . [t] hat the confidentiality of the patient's medical information is maintained as required by this chapter and other applicable law. At a minimum, confidentiality shall be maintained through appropriate processes, practices, and technology as designated by the board and that conform to applicable federal law.").

#### C. Emerging Regulation of Internet Prescribing

State legislatures or medical boards seem to favor three approaches to controlling Internet prescribing. First, some states rely on the regulatory changes that they have already made to accommodate telemedicine. Second, other states concentrate on the specifics of the physician-patient relationship, either by requiring a so-called "traditional" or "proper" relationship, or more transparently, by requiring face-to-face contact or prohibiting questionnaire-based prescribing. Third, some states have shifted their focus from physician to pharmacy regulation by concentrating on the product of an often out-of-state technologically-mediated relationship (i.e., the prescription) and seeking to control its in-state dispensing. Many states have adopted two or more of these approaches, creating overlapping and frequently confusing regulatory regimes.

Some states impose explicit new controls on prescribing by requiring an existing physician-patient relationship and a physical face-to-face examination prior to prescribing.<sup>87</sup> This requirement aims to eliminate "one-shot" transactions between Internet prescribers and patients where the interaction is the fulfillment of a single drug order (the previously noted opportunistic physician-patient relationship); it is also supposed to outlaw so-called questionnaire prescribing.<sup>88</sup>

Questionnaires are widely used by both illegal and marginally legal websites.<sup>89</sup> Typically, the questionnaire is a web-based form that purports to

<sup>87.</sup> The California statute provides that "[p]rescribing, dispensing, or furnishing dangerous drugs... without a good faith prior examination and medical indication therefor, constitutes unprofessional conduct." CAL. BUS. & PROF. CODE § 2242(a) (West 2003). Arizona extends its definition of "[u]nprofessional conduct," other than in emergencies, to "[p]rescribing, dispensing or furnishing a prescription medication or a prescription-only device to a person if the licensee has not conducted a physical examination of that person or has not previously established a physician-patient relationship." ARIZ. STAT. §32-1854(51) (West 2003).

<sup>88.</sup> See Sana Siwolop, Buying Your Pills Online May Save You Money, but Who's Selling Them?, N.Y. TIMES, Sept. 29, 2002, at 3-10 ("According to the Federation of State Medical Boards, a professional group, only one state, Kentucky, has passed legislation that specifically prohibits prescriptions based only on online questionnaires, while 22 states, including New York, have rules that essentially require a physical exam before an online prescription can be filled.")

<sup>89.</sup> According to the National Center on Addiction and Substance Abuse (CASA), of the sites selling controlled prescription drugs on the Internet forty-five percent required no prescription or made no mention of it, forty-nine percent provided an online consultation in lieu of a prescription, but only six percent required a preexisting prescription. NAT'L

collect a health history and asks questions specific to the drug requested. The drug-related questions are usually based on information taken from the *Physicians' Desk Reference.*<sup>90</sup> The completed questionnaire is then transmitted for approval. This approval may well be placed in the hands of a physician licensed to practice medicine in the patient's home state, and the process that follows purports to be the functional equivalent of in-office or telephone prescribing. The suspicion, however, is that in most cases any "approval" is performed by contract ghost-writers of indeterminate licensure who rubber-stamp hundreds of such prescriptions per week.<sup>91</sup> In some cases, the "approval" seems to be omitted or automated, and the order is merely forwarded for fulfillment.

States are increasingly tightening their scrutiny of these practices. Some have chosen a statutory route that adds a gloss to its requirement of a "proper physician-patient relationship," taking the position that "an electronic, on-line, or telephonic evaluation by questionnaire is inadequate for the initial evaluation of the patient or for any follow-up evaluation."<sup>92</sup> At least one state seems to be relying on its medical board to issue rules<sup>93</sup> or guidance<sup>94</sup> that have a similar effect.

Regulatory amendments to control the prescribing practices of out-ofstate physicians or automated pill-mills are ineffective without strong cross-

91. See, e.g., United States v. Nelson, 72 Fed. Appx. 837 (10th Cir. 2003). One doctor contacted by congressional investigators has admitted to writing 100,000 prescriptions for several Internet pharmacies over a two-year period. Typically he received \$2.50 to \$5 per prescription. He approved ninety-five percent of the drug applications sent to him, although the online pharmacy pre-screened out some applications. *N.J. Doctor's Rx on the Web Draws Scrutiny*, THE RECORD (Bergen County, NJ), Jan. 21, 2004, at A01; see also Gilbert M. Gaul, *Crossing Lines To Prescribe Online, Internet Pathologist Outmaneuvers State Medical Boards*, WASH. POST, Dec. 18, 2003, at A1 (discussing prescribing practices of Dr. Miles J. Jones and noting "Jones said he has written online prescriptions for more than 35,000 patients for netdr.com and its affiliatemaleclinic.com. Nearly eight of every 10 customers have requested Viagra, the popular drug for treating erectile dysfunction. All but about 100 of the requests have been approved.").

92. Ky. REV. STAT. STAT. §311.597(1)(e) (Michie 2003).

93. Ala. Admin. Code §540-X-9-.11 (1975).

94. See, e.g., Texas State Board of Medical Examiners, Internet Prescribing Policy (Dec. 8-11, 1999), http://www.tsbme.state.tx.us/guidelines/ipp.htm (last visited Apr. 16, 2004).

CTR. ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA, YOU'VE GOT DRUGS! PRESCRIPTION DRUG PUSHERS ON THE INTERNET 5 (2004),

http://209.208.151.183:8080/pdshopprov/files/you\_ve\_got\_drugs.pdf.

<sup>90.</sup> *Physicians' Desk Reference*, now in its fifty-eighth edition, is the standard prescription drug reference manual.

border enforcement mechanisms. Recognizing the practical difficulties of curtailing the activities of those outside their borders, several states have introduced a more indirect form of regulation that requires in-state pharmacists to verify that the prescriptions presented to them are written after physical (and hence for all practical purposes in-state) examinations.<sup>95</sup> Thus, some state rules now prohibit a pharmacist from dispensing a prescription drug if he "knows or should have known that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid patient-practitioner relationship."<sup>96</sup>

Regulation is sure to escalate as illegal pill-mills learn to hide in cyberspace and, like pornographers and online casinos, move their physical businesses offshore. Regulators will be forced to "follow the money" as they have in pornography and gambling cases and hope for the cooperation of credit card companies,<sup>97</sup> other financial intermediaries,<sup>98</sup> and shipping companies<sup>99</sup> while legitimate businesses bring pressure on infomediaries such as search engines to de-list illegal operations.<sup>100</sup>

95. See, e.g., CAL. BUS. & PROF. CODE § 4067; see also id. § 2242.1(b); VA. CODE ANN. § 54.1-3303(A)(B) (Michie 2004).

96. TEX. ADMIN. CODE §§ 291.34, 291.36 (West 2004). California imposes a similar rule and backs it with fines up to \$25,000 per occurrence. CAL. BUS. & PROF. CODE § 4067; see also id. § 2242.1 (b); VA. CODE ANN. § 54.1-3303(A) (B) (Michie 2004).

97. See, e.g., Associated Press, MasterCard Sets Rules for Online Gambling To Settle Lawsuit (July 14, 1999), http://standup.quiknet.com/news/1999/ap\_1999\_july\_14.html; Press Release, MasterCard Voices Support for Measures To Stop the Use of Payment Cards for Illegal Internet Gambling (Mar. 17, 2003), http://www.mastercardintl.com/cgi-bin/newsroom.cgi?id=708.

98. See, e.g., CNET News.com, PayPal Turns Off the Red Light (Apr. 30, 2003), at http://news.com.com/2100-1017-999002.html (discussing decision by PayPal's revised policy on processing payment for adult material). PayPal already places limits on payments for prescription drugs, PayPal, at PayPal Prescription Drugs and Devices Policy, http://www.paypal.com/cgibin/webscr?cmd=p/gen/ua/use/index\_frameoutside&ed=prescript\_drugs (last visited July 29, 2004).

99. See, e.g., Gilbert M. Gaul & Mary Pat Flaherty, Google To Limit Some Drug Ads, Web Giants Asked To Help Discourage Illicit Online Pharmacies, WASH. POST, Dec. 1, 2003, at A1 [hereinafter Gaul & Flaherty, Google To Limit]; Gilbert M. Gaul & Mary Pat Flaherty, Firms Pressed on Internet Drugs; Senate Panel Writes to Credit Card Companies, Shippers, WASH. POST, Dec. 10, 2003, at A04 [hereinafter Gaul & Flaherty, Firms Pressed]; Rick Brooks, FedEx and UPS Say They Shun Parcels Containing Illicit Drugs, WALL ST. J., Jan. 9, 2004, at A8.

100. See, e.g., CNET News.com, Search Engines Face Drug Test (Nov. 10, 2003), at http://rss.com.com/2100-1024\_3-5105044.html?tag=prntfr. Google, Yahoo, and MSN have announced plans to refuse advertising from unlicensed pharmacies. Google also will prevent the names of certain controlled drugs from appearing in the results of keyword

### D. Regulating Online Dispensing

Illegal online dispensing is an extension of the previously discussed Internet prescribing. Since few Internet prescribers have their own distribution business, they pass the prescriptions they write onto a subset of legally suspect fulfillment pharmacies usually based in the United States. Much of domestic Internet prescribing is driven by patients seeking drugs, including controlled substances, which their physicians will not prescribe or that are "lifestyle" drugs that patients do not want to publicly request. In most cases, patients are prepared to pay at least as much for the drugs as they would at a local or legal Internet pharmacy. Simultaneously, a new model of international fulfillment is flourishing that promises to deliver considerable savings over U.S.-sourced drugs by importing "legend drugs"<sup>101</sup> from non-U.S. sources such as Canada.

#### 1. Domestic Drug Distribution

The Food and Drug Administration's (FDA) process for new drug approval (NDA) and the Drug Enforcement Agency's (DEA) controlled substances policies underpin domestic drug availability. Thereafter, the core operational rules on domestic distribution are found in state pharmacy statutes and regulations. The relationship between state and federal regulators has generally been harmonious,<sup>102</sup> with the states usually happy to rely on their better funded federal counterparts to provide enforcement.

State regulation of drug distribution has both negative and positive aspects. State law generally prohibits anyone in the chain of distribution from purchasing or receiving prescription drugs from anyone other than a licensed person.<sup>103</sup> Having reinforced the retail prescription drug monopoly of pharmacies, state law then regulates the practice of pharmacy through the traditional tools of licensure and discipline. Assuming compliance with the FDA, DEA, and state licensing board regulations, the

searching. Gaul & Flaherty, Google To Limit, supra note 99.

<sup>101. &</sup>quot;Legend drugs" are those that, under Section 503(b) of the Federal Food, Drug, and Cosmetic Act, cannot be dispensed without a prescription.

<sup>102.</sup> There are some exceptions to the general harmony, such as occasional differences over issues such as medical marijuana. *Cf.* Conant v. Walters, 309 F.3d 629 (9th Cir. 2002).

<sup>103.</sup> See, e.g., N.D. CENT. CODE § 43-15.1-02 (2001) ("No person may knowingly purchase or receive any prescription drug from any source other than a wholesale drug distributor, manufacturer, pharmacy distributor, pharmacy, or other person licensed pursuant to the laws of this state except where otherwise provided.").

growth of technology in prescription fulfillment affects a local pharmacy in two situations. First, and beyond the reach of this Article, technology facilitates the disintermediation of pharmacists through a combination of technology and lower-paid pharmacy technicians and so sharpens an emerging scope of practice issue. Second, local pharmacists increasingly face regulation on their fulfillment of out-of-state prescriptions written by Internet-based physicians.<sup>104</sup> However, it is worth mentioning that states have successfully regulated pharmacy distribution located outside their borders for several decades.

State pharmacy law addressed issues concerning out-of-state pharmacies long before the growth of Internet prescribing. Mail-order dispensing is at least a century old and involves hundreds of thousands of deliveries per year.<sup>105</sup> Mail-order pharmacies are frequently subject to regulations in importing states,<sup>106</sup> and even though regulators track down the occasional miscreants, mail-order fulfillment is relatively uncontroversial. Mail-order pharmacies and national pharmacy chains are large-volume businesses and so likely possess the resources to absorb multiple licensing costs. While the primary concern of state pharmacy regulation is distribution to consumers, some states regulate other participants in the distribution chain, including out-of-state wholesalers and distributors.<sup>107</sup>

The states have sought to extend their mail-order model of required licensure to interstate Internet prescribing. As with mail-order models, large e-pharmacies or click-and-brick operations can absorb the costs of multiple licensure. States frequently prosecute or enjoin out-of-state pillmills, but they are often hindered by insufficient enforcement resources and, frequently, by the inadequacy of their own regulations. Increasingly,

Any pharmacy operating outside the state which ships, mails, or delivers in any manner a dispensed prescription drug or legend drug into North Dakota shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state law and rules of the board.

N.D. CENT. CODE § 43-15-34.1 (2001).

107. See, e.g., N.D. CENT. CODE, § 43-15.1-05 (2001).

<sup>104.</sup> Some border states allow the "importation" of a prescription, allowing their pharmacists to fill prescriptions written by, for example, Canadian or Mexican doctors. *See, e.g.*, ARIZ. REV. STAT. § 32-1969 (2003).

<sup>105.</sup> See Nat'l Pharms. v. De Melecio, 221 F.3d 235, 237 (1st Cir. 2000).

<sup>106.</sup> *Nat'l Pharms.*, 221 F.3d at 242; *see also* Pharm. Mfrs. Ass'n v. New Mexico Bd. of Pharmacy, 525 P.2d 931 (N.M. Ct. App. 1974) (upholding state pharmacy board regulation of out-of-state manufacturers and distributors). For example, the North Dakota statute provides:

states are re-vamping their pharmacy rules to deal specifically with the latest generation of Internet businesses.<sup>108</sup> For example, the Arkansas Internet Prescription Consumer Protection Act 2001,<sup>109</sup> which updates the traditional prohibitions on unlicensed dispensing to specifically include Internet operations,<sup>110</sup> requires the disclosure of the identity of and contact information for the business,<sup>111</sup> and outlaws the disclaimers and waivers commonly found on Internet prescribing and dispensing sites.<sup>112</sup> The Texas statute, perhaps conscious of VIPPS efforts to validate licensure,<sup>113</sup> requires that e-pharmacies link to the Texas Pharmacy Board website.<sup>114</sup>

#### 2. Cross Border Drug Distribution

While some illegal prescribing operations are moving offshore, the scenario of Internet prescribing remains a primarily domestic, interstate paradigm. In contrast, Internet dispensing is increasingly an international phenomenon involving many regulatory actors and a complex legal landscape.<sup>115</sup> Over the last few years, direct personal importation of pharmaceuticals into the United States has shown explosive growth; approximately ten million U.S. citizens per year transport drugs over land borders,<sup>116</sup> and approximately two million shipments of foreign-sourced prescription drugs entered the United States in 2002, double the number in 2001.<sup>117</sup>

The importation of drugs into the United States is regulated by a combination of federal laws and policies enforced by the DEA and FDA in conjunction with state pharmacy and controlled substance laws. Federal authorities have traditionally taken the enforcement lead, in part because

117. A New Source for Discount Prescriptions, N.Y. TIMES, Dec. 26, 2002, at A36.

<sup>108.</sup> See, e.g., ILL. COMP. STAT. 85/16a (1998); IND. CODE ANN. § 25-26-18-1 (Supp. 2003); NEV. REV. STAT. ANN. §§ 453.3618, 453.3625, 453.3638, 453.3643, 453.3648, 639.00865, 639.012; 639.2328 (2000).

<sup>109.</sup> Ark. Code Ann. §17-92-1001 to -1007 (2002).

<sup>110.</sup> Id. § 17-92-1004.

<sup>111.</sup> Id. § 17-92-1005.

<sup>112.</sup> Id. § 17-92-1006.

<sup>113.</sup> See infra note 374 and accompanying text.

<sup>114.</sup> TEX. OCC. CODE ANN. § 562.1045 (Vernon 2004).

<sup>115.</sup> See, e.g., Customs Confiscates Viagra Ordered over the Internet: Hundreds of Finns Order Prescription Drugs Unaware That It Is Illegal, HELSINGIN SANOMAT, Oct. 23, 2002, http://www.helsinki-hs.net/news.asp?id=20021023IE4.

<sup>116.</sup> Mary Pat Flaherty & Gilbert M. Gaul, Millions of Americans Look Outside U.S. for Drugs, WASH. POST, Oct. 23, 2003, at A1.

of their greater resources but also because suspect drugs are usually discovered by the United States Customs Service, the agency charged with enforcing the drug laws and policies of the DEA and FDA.

According to the Federal Food, Drug, and Cosmetic Act (FDCA), "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application... is effective with respect to such drug."<sup>118</sup> Thus, the central plank of the FDA's prohibition of non-U.S. sourced prescription drugs is that they lack approval under the NDA process. The FDA's position is that this prohibition extends beyond foreign versions to also include a grey market version of an approved drug, because the latter is unlikely to comply with all the technical information required for domestic approval, such as source of ingredients, place of manufacture, labeling and packaging of containers.<sup>119</sup>

More controversially, regulators view reimported drugs as unapproved on the basis that they will comply with their destination market's labeling and packaging requirements rather than those necessary in the United States.<sup>120</sup> In addition, the FDA takes the speculative position that grey market or reimported drugs are likely to be mislabeled<sup>121</sup> or dispensed without a prescription.<sup>122</sup> The agency may be on firmer ground in relying on legislation that grants the sole right of reimportation to U.S. manufacturers.<sup>123</sup>

Federal law prohibits breach of these FDCA provisions.<sup>124</sup> The

123. Id. § 381(d)(1) ("[N]o drug subject to section 353(b) of this title . . . which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug."); see also Warning Letter from David J. Horowitz, Director, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration to Harry Lee Jones, Store Manager, Rx Depot, Inc. (Mar. 21, 2003) [hereinafter Warning Letter from David J. Horowitz],

http://www.fda.gov/foi/warning\_letters/g3888d.htm; Letter from William K. Hubbard, Associate Commissioner for Policy and Planning FDA to Robert P. Lombardi, The Kullman Firm (Feb. 12, 2003) [hereinafter Letter from William K. Hubbard], http://www.fda.gov/ora/import/kullman.htm.

124. 21 U.S.C. § 331(a), (d), (t) (2000).

<sup>118. 21</sup> U.S.C. § 355(a) (2000).

<sup>119.</sup> See 21 C.F.R. § 314.50 (2003) (listing drug application requirements).

<sup>120.</sup> See, e.g., id. § 314.50(c)(2)(i).

<sup>121. 21</sup> U.S.C. § 353(b)(2) (2000).

<sup>122.</sup> See id. § 353(b)(1). Also note that the exception to § 352 is inapplicable to mail order drugs. Id. § 353(b)(2).

prohibition is applicable to both interstate and intrastate traffic.<sup>125</sup> If the drug is a controlled substance it is further subject to regulation by the DEA under the Controlled Substances Act of 1970 (CSA).<sup>126</sup> Operationally, state pharmacy and other drug laws enter the regulatory mix because they frequently prohibit possession or trafficking of drugs without a U.S. prescription, or of drugs that do not comply with the federal act.<sup>127</sup>

There are sound policy reasons for allowing some level of personal importation of pharmaceuticals into the United States. First, as a practical matter, residents and visitors will enter the United States carrying drugs prescribed outside the United States or even within the United States prior to outbound travel. In addition to the dangers it would pose to a traveler's health, policing a rigid non-possession rule would be as nonsensical as it would be unenforceable. Second, there is a small but significant traffic in persons leaving the United States for treatment not otherwise available in the United States. It would be punitive to deny, upon the patient's return to the United States, pharmaceuticals related to the treatment. Third, the high expense of travel and the small amounts of prescription drugs that people can physically bring with them imposes high transaction costs on patients, thus minimizing risks of diversion. Fourth, many if not most of the drugs personally presented at United States borders are approved for sale in the United States in some form or another, thus minimizing safetyrelated risks.

These policies are effectuated by federal rules and policies that allow a limited level of cross-border pharmaceutical traffic. The CSA, for example, has a limited personal importation exception that allows individuals to bring a controlled substance with them if: 1) the substance is found in one of the approved "schedules," 2) the substance is in its original container, 3) a declaration is made to the United States Customs Service, and 4) use of such substance is permitted by federal and state laws.<sup>128</sup>

Concerns about the introduction of large amounts of controlled substances, particularly over the border with Mexico, led to the tightening of this exception by the Controlled Substances Trafficking Prohibition Act of 1998 (CSTPA). The act states that a U.S. resident may not enter the U.S. through an international land border with more than fifty dosage units of a controlled substance unless the individual possesses a valid prescription

<sup>125.</sup> See, e.g., White v. United States, 399 F.2d 813 (8th Cir. 1968).

<sup>126.</sup> Controlled Substances Act (CSA), 21 U.S.C. §§ 801-971 (2000).

<sup>127.</sup> See, e.g., ARIZ. REV. STAT. § 32-1962(A) (2002).

<sup>128. 21</sup> U.S.C. § 956(a) (2000).

issued by a practitioner in accordance with federal and state law.<sup>129</sup>

The CSA exemption clearly assumes that the drugs are in the possession of a traveler.<sup>130</sup> The FDCA Guidance implies personal possession by excluding commercial and promotional shipments.<sup>181</sup> To determine if a shipment is commercial or promotional, the Guidance suggests looking at . "the type of product, accompanying literature, size, value, and/or destination of the shipment."<sup>132</sup> The Guidance also states that non-commercial shipments generally include products that are: "personally carried, shipped by a personal non-commercial representative of a co-

129. Id. § 956(a) (2). The CSTPA has been the source of much confusion, some of which derives from the misrepresentation seeded by parallel importers. On its face, the legislation does not exempt amounts below fifty dosage units but uses that quantity as a ceiling. Id. Nonetheless, the statutory phrase "50 dosage units," is cited frequently by importers as exempting all pharmaceutical imports up to that amount. See, e.g., Nancy A. Melville, U.S. Health Experts Say Caveat Emptor on South-of-Border Prescription Drugs, at

http://www.roadandtravel.com/health/prescriptiondrugs.htm (last visited July 10, 2004). The DEA, however, has frequently disputed this interpretation. See, e.g., Hearing Before the House Comm. on Energy and Commerce Subcomm. on Oversight and Investigations, 107th Cong. (2001) (statement of Laura M. Nagel, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration),

http://www.usdoj.gov/dea/pubs/cngrtest/ct060701.htm ("This does not mean that any U.S. resident may enter the United States with up to 50 dosage units of a particular controlled substance 'no questions asked.' Rather, the resident must satisfy all the requirements set forth in 21 C.F.R. 1301.26. States may impose additional requirements as well."). There is no personal importation exception in the FDCA. The FDA, however, has issued enforcement guidelines that create a de facto exemption and answers the issue (or at least the federal issue) left hanging by the Controlled Substances regulations. See 21 C.F.R. § 1301.26 (2003) ("Any individual who has in his/her possession a controlled substance ... may enter or depart the United States with such substance ... providing ... [t]he importation of the controlled substance for personal medical use is authorized or permitted under other Federal laws and state law."). Described as "guidance" to its own personnel, the FDA applies this "exemption" when "the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user." FDA/ORA, Regulatory Procedures Manual, http://www.fda.gov/ora/compliance\_ref/rpm\_new2/ch9pers.html (discussing personal importations). The agency emphasizes that "[a]lthough FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments." Id.

130. 21 C.F.R. § 1301.26 (2003) ("Any individual who has in his/her possession a controlled substance . . . may enter or depart the United States . . . . ").

131. Marvin A. Blumberg, Information on Importation of Drugs, Prepared by the Division of Import Operations and Policy, FDA, U.S. Food & Drug Administration,

http://www.fda.gov/ora/import/pipinfo.htm (Apr. 3, 1998).

132. Id.

signee, or shipped from a foreign medical center where person has undergone treatment."<sup>133</sup>

Because the guidance stresses that there is no particular magic in a U.S. prescription or a foreign prescription, the apparent keys to FDA approval (i.e., non-enforcement) are personal use of a drug otherwise not available and evidence of medical supervision.<sup>134</sup>

Crucially, the FDA denies that its de facto exemption applies to grey market or reimported drugs whether personally or commercially imported. According to the FDA,

foreign-made chemical versions of drugs available in the U.S. are not intended to be covered by the policy.... FDA cannot assure that such products have been properly manufactured and are effective; therefore... their use would present an unreasonable risk... unless the person seeking importation could establish that the drugs were needed to refill a prescription while traveling....<sup>135</sup>

Despite this relatively clear regulatory position, importation drug sites routinely and inaccurately cite this Guidance (albeit usually without specific identification) as permitting the commercial importation of a ninety-day supply of drugs.<sup>136</sup>

#### 3. The Canada-United States Connection

The movement of grey market and reimported drugs over the Canadian-U.S. border predates Internet dispensing. For example, there are old press reports of U.S. retirees taking buses across the border and stocking up on prescription drugs.<sup>137</sup> Current economic conditions encourage the traffic: The Canadian government closely controls drug prices, and the weakness of the Canadian dollar favors U.S. purchasers. Dr. Alan Sager of Boston University has estimated that paying Canadian prices

http://csmweb2.emcweb.com/durable/2000/04/18/p3s1.htm; Randi Hunter Epstein, Some Retirees Look Abroad for Prescription Drugs, N.Y. TIMES, Sept. 24, 2002, at F5.

<sup>133.</sup> Id.

<sup>134.</sup> See id.

<sup>135.</sup> Id.

<sup>136.</sup> GetMeds Direct, at http://www.getmedsdirect.com (last visited May 29, 2003) ("Did you know U.S. law permits you to order a 60-90 day personal supply of Medications from International Pharmacies?").

<sup>137.</sup> See, e.g., Sarah Lueck, Senators Push Drug-Reimportation Bill, WALL ST. J., June 3, 2002, at A4; see also Alexander Calhoun, Get on the Bus: Extreme Answers to Prescription Drug Costs, CHRISTIAN SCIENCE MONITOR, Apr. 18, 2000, at

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for U.S. prescription drugs would result in savings of \$38.4 billion per annum, a figure which underpins much of the debate over the Canadian connection.<sup>138</sup> A congressional estimate is even more optimistic: "Allowing open pharmaceutical markets could save American consumers at least \$635 billion of their own money each year."<sup>139</sup>

By early 2003, there were approximately one hundred and fifty Canadian e-pharmacies exporting price controlled drugs to the United States.<sup>140</sup> Unlike the practices of the domestic Internet prescribing and dispensing sites frequently pursued by regulators, potential customers of Canadian e-pharmacies typically are required to furnish copies of a prescription written by their U.S. physician. Some of these businesses claim that licensed Canadian physicians will perform the prescribing, and the prescriptions will be fulfilled by licensed Canadian pharmacies.<sup>141</sup> In fact, that is generally the case, although not without some legal gymnastics north of the border. For example, Manitoba, home to about one-third of the e-pharmacies, requires that a Canadian licensed physician co-sign the prescription but the pharmacies have to use out-of-province physicians because Manitoba physicians have been threatened with disciplinary action if they become involved.<sup>142</sup>

True to the ideals of web-commerce, there has been a growth of infomediaries that provide licensure information and price comparisons for U.S. and Canadian sources of prescription drugs.<sup>143</sup> A relatively new twist in the U.S.-Canada traffic has been the proliferation of U.S.-based intermediaries. These small bricks-and-mortar stores, frequently established in locations with a large elderly population, assist patients who

143. See, e.g., Pharmacy Checker.com, at http://www.pharmacychecker.com (last visited Apr. 13, 2004). United Health Alliance, a Vermont-based non-profit, is among the most visible. It lobbies for lower prescription drug costs and through its "Medicine Assist" program provides pricing and ordering information from Canadian e-pharmacies. See United Health Alliance, at http://www.unitedhealthalliance.com (last visited Apr. 13, 2004).

<sup>138.</sup> See, e.g., Markian Hawryluk, Drugs Without Borders: When Prescription Drugs Go over the Line, AMNEWS, Oct. 22/29, 2001, at http://www.ama-assn.org/sci-

pubs/amnews/pick\_01/gvsa1022.htm (last visited Apr. 17, 2004).

<sup>139.</sup> Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. § 2(5).

<sup>140.</sup> See Joel Baglole, Canada's Southern Drug, WALL ST. J., Mar. 31, 2003, at B3.

<sup>141.</sup> See Joel Baglole, Manitoba Fills Niche for Affordable Drugs, WALL ST. J., Oct. 10, 2002, at B3.

<sup>142.</sup> Plug May Be Pulled on On-line Pharmacies, GLOBE & MAIL, Dec. 15, 2003, available at http://www.globeandmail.com/servlet/ArticleNews/front/RTGAM/20021215/wpharm12 15a/Front/homeBN/breakingnews (last visited Apr. 13, 2004).

are less likely to be Internet savvy and may have difficulty filing out the forms.<sup>144</sup> The intermediaries take prescription requests from U.S. patients and transmit them to Canadian drugstores for direct fulfillment. The drugs are then supplied via mail to the patients in the United States, with the intermediary collecting a referral fee or commission on the sale.<sup>145</sup> A number of web-based businesses offer similar services.<sup>146</sup>

Although the amounts involved are modest, approximately \$700 million in annual Canadian e-pharmacy sales to the United States<sup>147</sup> compared to the overall \$150 billion U.S. pharmaceuticals market, U.S.based pharmaceutical companies have become increasingly wary of this developing distribution channel.<sup>148</sup> Their attention seems to have become particularly focused after the United Health Group Inc., which insures nearly 100,000 AARP members, agreed to reimburse clients for prescriptions filled abroad. Pharmaceutical interests in the United States have also lobbied against legislation permitting drug reimportation on the basis that it would increase the likelihood of counterfeit, contaminated, or illegal drugs coming into the United States.<sup>149</sup>

This "quality" theme has underpinned the FDA's reaction to the Canadian connection. The alleged fear of the FDA is that the drugs are coming from some other country and simply passing through Canada.<sup>150</sup>

147. Tedeschi, *supra* note 24. Some estimates project the number at \$800 million to \$1 billion for 2003. See Once Just a Trickle, Canada's Rx Drugs Pouring into USA, USA TODAY, Oct. 7, 2003, at A1 [hereinafter Once Just a Trickle]; U.S. Targets Internet Pharmacies, Health Canada Co-operating with U.S. Authorities, NAT'L POST, Nov. 11, 2003, at http://medical.marijuana.com/article.php?sid=7843.

148. See Joel Baglole, Getting the Gray Out: Canadian and U.S. Regulators Are Looking To Impose Order on the Sale of Cheap Online Drugs, WALL ST. J., Feb. 11, 2003, at R6.

149. See, e.g., National Association of Chain Drug Stores News Release, National Association of Chain Drug Stores Joins Pharmacists in Endorsing the Cross-Border Communiqué Opposing Illegal Importation of Prescription Drugs (May 13, 2003), http://www.nacds.org/wmspage.cfm?parm1=3028; see also Lueck, supra note 137.

150. Michelle Meadows, Imported Drugs Raise Safety Concerns, FDA CONSUMER MAG., Sept.-Oct. 2002, http://www.fda.gov/fdac/features/2002/502\_import.html. The FDA currently has a task force working on counterfeit drugs and their impact on the U.S. distribution system. See FOOD & DRUG ADMIN., COUNTERFEIT DRUG TASK FORCE INTERIM REPORT (2003), http://www.fda.gov/oc/initiatives/counterfeit/report/interim\_report.html.

<sup>144.</sup> Buying Drugs via Canada Gets Tougher, SEATTLE TIMES, May 29, 2003, at A1.

<sup>145.</sup> A New Source for Discount Prescriptions, N.Y. TIMES, Dec. 26, 2002, at A36.

<sup>146.</sup> See, e.g., Canadian Meds USA, at http://www.canadianmedsusa.com (last visited Apr. 13, 2004); Denver-based Web Site Helps Consumers Buy Cheaper Medications, SiliconValley.com, at http://www.siliconvalley.com/mld/siliconvalleynews/editorial/3541606.htm?template= (June 25, 2002).

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The sensitive question is whether U.S. (FDA) drug regulation is significantly superior to that found north of the border.<sup>151</sup> Health Canada's Therapeutic Products Directorate (TPD)<sup>152</sup> performs drug approvals under the Food and Drug Regulations made under the Canadian Food and Drugs Act.<sup>153</sup> The fact that Canada has a drug approval regulatory system that places a value on quality similar to that of the FDA continues to add its share of embarrassment to the dispute. In May 2003, a published report suggested that the quality argument would be preempted because the TPD would take responsibility for the safety of drugs reimported into the United States.<sup>154</sup> Further discussions between the governments led to a clarification to the effect that the Canadian government made no such guarantee;<sup>155</sup> subsequently, Health Canada offered to assist with enforcement.<sup>156</sup>

There are other reasons why dealing with the Canadian connection is considerably more difficult than typical regulatory policies and enforcement actions aimed at unlawful or marginally lawful domestic distributors. First, the traffic does not generally include controlled substances, depriving regulators of their traditional moral imperative. Second, the pharmaceuticals involved tend not to be lifestyle drugs, but rather life-sustaining or long-term maintenance drugs favored by seniors. Third, the practical difficulties of closing down the Canadian channel are immense. Huge numbers of suspect packages are crossing the border daily, rendering enforcement impractical. And, even if U.S.-based intermediary storefronts were closed, the bus trips by seniors across borders would

153. Food and Drugs Act, R.S.C., ch. F-27, §1 (1985) (Can.).

154. Marc Kaufman, *Canada To Guarantee Imported Medicine*, WASH. POST, May 8, 2003, at A6.

155. Marc Kaufman, Canadian Drug Position Misinterpreted, WASH. POST, May 26, 2003, at A11.

156. FDA Seeks Help To Enforce Drug Laws; Health Canada Pledges Co-operation, CANADIAN PRESS, Oct. 21, 2003; U.S. Targets Internet Pharmacies, Health Canada Co-operating with U.S. Authorities, NAT'L POST, Nov. 11, 2003, at A1.

<sup>151.</sup> According to William Hubbard, FDA associate commissioner, "My own 90-year-old mother cannot afford her drugs. . . . I know that. But nobody made FDA the drug-price-and-safety administration. They just made us the drug-safety guys. Our mission is not to establish prices of drugs, only to make sure they are safe." U.S. Moves To Shut Companies Selling Imported Drugs, HEALTH DAY, Sept. 11, 2003, at

http://www.healthcentral.com/news/NewsFullText.cfm?id=515064.

<sup>152.</sup> Health Canada, Therapeutic Products Directorate, *at* http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/aboutus\_e.html (last visited Apr. 19, 2004).

continue<sup>157</sup> and the storefronts likely would be replaced by less formal channels, such as "Tupperware"-style parties.<sup>158</sup>

It is the politicization of the issue that creates particular challenges. Decreasing the cost of prescription drugs is a broadly-held political goal. The elderly population that tends to face the most difficulty in affording their drugs is electorally-significant and well-represented by lobbyists. While the media is happy to display its mock indignation at web-supplied Viagra, coverage of the enforcement of the reimportation prohibition against a U.S. senior and AARP member struggling to pay her escalating drug bill for life-sustaining medications is far more negative.<sup>159</sup>

In January 2003, the pharmaceutical multinational GlaxoSmithKline (GSK) increased monitoring of Canadian sales and threatened to cut off supplies to Canadian pharmacies that shipped to U.S. patients.<sup>160</sup> Canadian pharmacies and U.S. patient groups responded by urging a boycott of GSK products.<sup>161</sup> The Canadian Competition Bureau launched a brief investigation, but found no evidence that GSK was breaching the country's antitrust laws.<sup>162</sup> In August 2003, Pfizer joined the other major drug manufacturers in requiring exporting Canadian pharmacies to buy supplies dictated by Canadian demand direct from Pfizer rather than from wholesalers.<sup>163</sup> Pfizer also requires its wholesale distributors to report orders

159. The poster "children" of the drug reimportation fight are Ray and Gaylee Andrews of Elk Grove Village, Illinois. The two seventy-four year-olds spend \$800 to \$1,000 a month to buy prescriptions and have filed suit against HHS and the FDA mounting an equal protection challenge on the FDCA. Robert Pear, U.S. To Study Importing Canada Drugs, N.Y. TIMES, Feb. 26, 2004, at A16.

160. Press Release, GlaxoSmithKline Acts To Prevent Illegal, Potentially Unsafe Imports of Prescription Drugs (Jan. 21, 2003), available at

http://www.gsk.com/press\_archive/press\_01212003.htm; Sarah Lueck & Joel Baglole, Glaxo Warns Canadian Clients Against Drug Sales to the U.S., WALL ST. J., Jan. 13, 2003, at B4.

161. See Julie Appleby, Canadian Druggists Mobilize Against Glaxo, USA TODAY, Feb. 5, 2003, at 1B.

162. Press Release, Competition Bureau, Competition Bureau Responds to Complaints Regarding Supply of Canadian-Based Internet Pharmacies (Mar. 21, 2003),

http://strategis.ic.gc.ca/epic/internet/incb-bc.nsf/en/ct02528e.html.

163. Scott Hensley & Anna Wilde Mathews, *Pfizer Warning May Curb Drugs from Canada*, WALL ST. J., Aug. 7, 2003, at A2. A company spokesman stated "The objective of us having more customers as direct clients is for us to better enforce our terms of sale which are that our products are only to be sold in Canada for Canadian patients and that they are not for export." Jane Taber, *Pfizer Takes Aim at Resale of Drugs*, GLOBE & MAIL, Aug. 7, 2003, *at* 

<sup>157.</sup> See Once Just a Trickle, supra note 147.

<sup>158.</sup> Gardiner Harris, Canada Fills U.S. Prescriptions Under the Counter, N.Y. TIMES, June 4, 2003, at A1.

from individual drugstores and requires them to seek approval before selling large amounts to any pharmacy or any amounts to new customers.<sup>164</sup> With the drug companies strangling the supply chain, Canadian pharmacies are being forced to buy the surplus supplies of other Canadian pharmacies or through intermediaries<sup>165</sup> and pass the increased costs onto U.S. consumers. At the same time, both individual pharmaceutical companies and their trade group increased their spending on lobbying against reimportation and other congressional threats to their price structures.<sup>166</sup>

The FDA signaled its intention to crack down on U.S.-Canada prescription drug traffic in February 2003.<sup>167</sup> In March 2003, the FDA's Office of Compliance sent out its first warning notice to a U.S.-based storefront, apparently an Arkansas affiliate or agent of a Manitoba pharmacy.<sup>168</sup> The FDA took the position that "almost every time an individual or business ships a prescription drug from Canada to a U.S. consumer, the individual or business shipping the drug violates the [FDCA]. Moreover, individuals and businesses, such as Rx Depot ... and its responsible personnel, that cause those shipments also violate the Act."169 The **FDA** reiterated its position in а letter to CanadianDiscountDrugs, an Alabama-based intermediary.<sup>170</sup> Subsequently,

164. Bernard Simon, *Pfizer Moves To Try To Stop Drugs from Canada*, N.Y. TIMES, Jan. 14, 2004, at W1.

165. See Mark Heinzl & Tomsin Carlisle, *Canadian Pharmacies vs. Big Drug Makers*, WALL ST. J., Aug. 12, 2003, at D4; see also Cohen, supra note 163.

166. Drug Group Spent \$8.5 Million Lobbying Against Importation, PHILA. INQUIRER, Oct. 13, 2003.

167. See Thomas A. Burton, The FDA Begins Cracking Down on Cheaper Drugs from Canada, WALL ST. J., Mar. 12, 2003, at A1; Letter from William K. Horowitz, supra note 123.

168. See Warning Letter from David J. Horowitz, supra note 123; see also Jeff Gottlieb, Stores Selling Drugs from Canada Thrive, L.A. TIMES, Mar. 24, 2003, at 2-1.

169. Warning Letter from David J. Horowitz, *supra* note 123; *see also* Press Release, Food & Drug Admin., FDA Collaborates with Arkansas State Board of Pharmacy in Enforcement Action Against Storefront Obtaining Unapproved Drugs from Canada (Mar. 21, 2003), http://www.fda.gov/bbs/topics/NEWS/2003/NEW00882.html.

170. Letter from David J. Horowitz, Director, Office of Compliance, Food & Drug Administration to Principals in CanadianDiscountDrugs (June 30, 2003), http://www.nacds.org/user-

assets/PDF\_files/FDA\_Letter\_Canadian\_Discount\_Drugs\_AL.pdf.

http://globeandmail.com/servlet/story/RTGAM.20030807.wxudrugn0807/BNstory/Busin ess/; see also Tom Cohen, Canada's Internet Pharmacies Hurting from Industry Steps To Halt U.S. Sales, MERCURY NEWS, Aug. 29, 2003, http://www.detnews/2003/health/0308/31/health-258099.htm.

both federal<sup>171</sup> and state authorities<sup>172</sup> have moved against pharmacies and leading intermediaries involved in reimportation of drugs from Canada and, with rare exception,<sup>173</sup> have been successful in obtaining preliminary injunctions.<sup>174</sup>

The most extraordinary development in the reimportation scenario has been the interest of some state and municipal governments in reducing their drug costs by obtaining drugs from Canada. The issue was presaged by an exchange between the FDA and the State of California; concerned about the growing cost to its own pension fund, the State of California inquired about buying reimported drugs, but was rebuffed by the FDA.<sup>175</sup> Nonetheless, Montgomery, Alabama and Springfield,

172. Al. State Bd. of Pharm. v. Canadian Discount Drugs, No. CV03287M (Ala. Dale County Crt. June 30, 2003) (granting temporary restraining order),

http://www.nacds.org/user-assets/PDF\_files/AL\_TRO\_Canadian\_Discount\_Drugs.pdf; Plaintiff's Complaint, Okla. State. Bd. of Pharmacy v. Rx Depot, 290 F. Supp. 2d 1238 (N.D. Okla. 2003) (No. 2003-2643), http://www.nacds.org/user-

http://newsobserver.com/business/story/2953672p-2709936c.html; *see also* Letter from Charles S. Campbell, Executive Director, Arkansas State Board of Pharmacy to Henry Jones, Rx Depot, http://www.nacds.org/user-assets/PDF\_files/AR\_BOP\_Letter\_March\_03.pdf (Mar. 21, 2003); Letter from Rebecca H. Deschamps, Executive Director, Montana Board of Pharmacy to Gary Moffitt, Club Medzrx, http://www.nacds.org/userassets/PDF\_files/Club\_Medz\_Cease\_Desist\_MT.pdf (Mar. 10, 2003).

173. The exception was a West Virginia circuit court that ruled against a state pharmacy board in favor of an intermediary on the basis that there was no evidence to show that anyone had been misled into confusing the intermediary with a pharmacy. Susan Bush, *W. Va. Court Decision Approves Importing of Drugs from Canada*, BERKSHIRE EAGLE, Jan. 2, 2004, http://www.canadianpharmacytrust.com/media/news4.html.

174. United States v. Rx Depot, Inc., 290 F. Supp.2d 1238 (N.D. Okla. 2003); see also Julie Appleby, Firms Told To Cease Canadian Drug Orders, USA TODAY, Sept. 9, 2003, at 3B; Canadian Press, U.S. Judge Agrees to Government Request To Shut Down Canadian Drug Importer (Nov. 7, 2003),

http://mediresource.sympatico.ca/health\_news\_detail.asp?channel\_id=10&menu\_item\_id =&news\_id=2651. *But see* United States v. Rx Depot, Inc., 297 F. Supp. 2d 1306 (N.D. Okla. 2003) (motion for emergency stay denied).

175. Letter from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Gregory Gonot, Deputy Attorney General, State of California, http://www.fda.gov/opacom/gonot.pdf (Aug. 24, 2003) (discussing Opinion No. 03-601).

<sup>171.</sup> See, e.g., Press Release, Food & Drug Admin., FDA Takes Action Against Companies That Are Importing Unapproved, Potentially Unsafe Drugs (Sept. 9, 2003), http://www.fda.gov/bbs/topics/NEWS/2003/NEW00939.html.

assets/PDF\_files/Oklahoma\_BOP\_Complaint.pdf; Jean P. Fisher, Board Sues Canadian Medicine Connections, NEWS & OBSERVER, Oct. 17, 2003,

Massachusetts have announced plans to supply their employees with drugs from Canada.<sup>176</sup> In response, the FDA targeted Springfield with a sting operation.<sup>177</sup> Iowa, Illinois, Vermont, and Minnesota have all requested a variance from federal law to set up importation programs.<sup>178</sup> New Hampshire has created a website that links to Canadian pharmacies from which prescription drugs can be ordered; the site requires original packaging and a prescription from a physician licensed in New Hampshire.<sup>179</sup> Minnesota has adopted a somewhat more cautious approach, setting up websites linking to Canadian pharmacies that meet its safety criteria.<sup>180</sup> Meanwhile, the Governor of Illinois<sup>181</sup> and the Massachusetts Attorney General<sup>182</sup> have publicly called for a liberalization of the FDA position. Throughout, the FDA has been resolute in its

177. Christopher Rowland, FDA Drug Scrutiny Rapped as Uneven, BOSTON GLOBE, Nov. 16, 2003, at A1.

178. Tony Leys, Vilsack Offers Plan on Canadian Drugs, Iowa Would Be Testing Ground for Purchase of Prescriptions, DES MOINES REG., Jan. 22, 2004, at

http://desmoinesregister.com/news/stories/c4780934/23326025.html (last visited May 1, 2004).

179. Prescription Drugs for New Hampshire, New Hampshire, at http://www.nh.gov/governor/prescription/prescription.html (last visited July 29, 2004); see also Anna Wilde Mathews, States To Help Citizens Import Canadian Drugs, WALL ST. J., Dec. 18, 2003, at B1.

180. Welcome to Minnesota RxConnect Online, Minnesota RxConnect Online, at http://www.minnesotarxconnect.com (last visited July 29, 2004); see Bruce Murphy, State Plans Web Link to Canada Pharmacies, MILWAUKEE J. SENTINEL, Dec. 23, 2003, at http://www.jsonline.com/news/state/dec03/194984.asp. Wisconsin planned a similar site but recanted; a message on the state website from Governor Doyle stated: "I would like to provide you with the names of those Web sites, but I can't. The Bush administration refuses to permit states to help people save money by purchasing medicine from Canada." Wisconsin Prescription Drug Resource Center, at http://drugsavings.wi.gov (last visited Feb. 8, 2004).

181. Press Release, Rod R. Blagojevich, Blagojevich Calls on FDA To Reverse Policy on Importing Drugs from Canada (Sept. 19, 2003),

http://www100.state.il.us/PressReleases/ShowPressRelease.cfm?SubjectID=1&RecNum=22 83; see also Monice Davey, Illinois To Seek Exemption To Buy Drugs from Canada, N.Y. TIMES, Dec. 22, 2003, at A27.

182. Christopher Rowland, AG Pushes for Medicine from Canada, BOSTON GLOBE, Oct. 14, 2003, at A1.

<sup>176.</sup> See Julie Appleby, More Cities, States Opt for Canadian Drugs, USA TODAY, Dec. 23, 2003, at 3B; Mathew Mosk, Montgomery Explores Medicines from Canada, WASH. POST, Nov. 2, 2003, at C7.

opposition,<sup>183</sup> has ramped up inspections on imported packages,<sup>184</sup> and has issued statements highly critical of some state actions.<sup>185</sup>

Congress has reacted somewhat negatively to the efforts to block drugs from Canada, viewing safety issues as exaggerated<sup>186</sup> and the FDA as siding with the pharmaceutical industry.<sup>187</sup> Ironically, legislation to permit reimportation already existed. The Medicine Equity and Drug Safety Act of 2000 (MEDS Act) was signed into law by President Clinton on October 28, 2000. The MEDS Act granted U.S. patients broad access to reimported drugs. Its implementation, however, was conditioned on the Department of Health and Human Services (HHS) completing a study and implementing regulations. Secretary Shalala<sup>188</sup> and Secretary Thompson, after the 2000 election, refused to implement the MEDS Act.<sup>189</sup> Secretary Shalala presciently identified practical flaws in the legislation that would have allowed pharmaceutical interests to nullify its intended effects.<sup>190</sup> Secretary Thompson, however, voiced concern about moving the United States from a "closed" distribution system, arguing that "opening our borders as required under this program would increase the likelihood that the shelves of pharmacies in towns and communities across the nation would include counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under

185. Minnesota's Canadian Drug Site Draws FDA Warning, USA TODAY, Feb. 24, 2004, at http://usatoday.com/tech/webguide/internetlife/2004-02-24-fda-minn-warning\_x.htm (reporting a letter sent by the FDA to Governor Pawlenty of Minnesota that noted "you . . . shine a bright light on a path used not only by profiteers masquerading as pharmacists, but by outright criminals").

186. See, e.g., U.S. House Members Slam FDA for Blocking Imports from Canada, REUTERS HEALTH, Apr. 3, 2003.

187. International Prescription Drug Parity, Hearing Before the House Gov't Reform Subcomm. on Human Rights and Wellness, 108th Cong. 1-5 (2003); see also Rowland, supra note 177.

188. Robert Pear, In a Turnaround, White House Kills Drug-Import Plan, N.Y. TIMES, Dec. 27, 2000, at A1.

189. Tommy G. Thompson, Secretary, Department of Health and Human Services, Response to Senator James Jeffords (July 9, 2001),

http://www.fda.gov/oc/po/thompson/medsact.html.

190. Pear, supra note 188.

<sup>183.</sup> William M. Welch, FDA on Canada Drugs: 'No way', USA TODAY, Dec. 23, 2003, at 1A (quoting FDA Associate Commissioner Peter Pitts as saying "It's very clear it's absolutely illegal.... There's no way importing drugs not FDA-approved can be legal in any way or form").

<sup>184.</sup> Gardiner Harris & Monica Davey, U.S. Steps Up Effort Against Drug Imports, N.Y. TIMES, Jan. 24, 2004, at C1.

inappropriate and unsafe conditions."<sup>191</sup>

Reimportation became a cause célèbre in the 108<sup>th</sup> Congress.<sup>192</sup> Several bills were introduced that prohibited discrimination against parallel importers by pharmaceutical companies,<sup>193</sup> essentially legalizing the Canadian connection.<sup>194</sup> Bi-partisan support in the House finally coalesced behind the Pharmaceutical Market Access Act of 2003.<sup>195</sup> This would have required the FDA to design and implement a system to grant individuals, pharmacists, and wholesalers in the United States access to FDA-approved drugs from FDA-approved facilities in industrialized nations including the European Union, Australia, and Canada, but not Mexico.<sup>196</sup> Senate and White House opposition, however, was strong,<sup>197</sup> and House action was more a warning shot to the administration regarding ongoing negotiations on prescription drug benefits and drug prices than a genuine commitment to legalizing reimportation. As the Medicare bill negotiations dragged on into the fall of 2003, there were signs that a robust reimportation provision was unlikely.<sup>198</sup> Nevertheless, as the AARP noted when it endorsed the bill,

191. Thompson, supra note 189.

192. See, e.g., Preserving Prescription Drugs Discounts Act, S. 477, 108th Cong. (2003); North American Prescription Price Equity Act of 2003, H.R. 354, 108th Cong. (2003); Prescription Drug Affordability Act, H.R. 616, 108th Cong. (2003); Senior Bill of Rights Act of 2003, H.R. 1733 108th Cong. (2003); Preserving Access to Safe, Affordable Canadian Medicines Act of 2003, H.R. 847, 108th Cong. (2003); Medical Independence, Privacy, and Innovation Act of 2003, H.R. 2196, 108th Cong. (2003); Prescription Drug Benefit and Cost Containment Act of 2003, S. 7, 108th Cong. (2003); see also Prescription Drug Price Reduction Act, H.R. 5534, 107th Cong. (2002); Drug Importation Act of 2002, H.R. 5186, 107th Cong. (2002); Personal Prescription Drug Import Fairness Act, H.R. 1229, 107th Cong. (2002); Affordable Drugs Access Act , H.R. 5217, 107th Cong. (2002); H.R. 4614, 107th Cong. (2002); Prescription Drug Price Parity for Americans Act, H.R. 2244, 107th Cong. (2002); Prescription Drug Affordability Act, H.R. 2801, 107th Cong. (2002); Prescription Reimportation, Improvement, Correction, and Enhancement Act, H.R. 698, 107th Cong. (2002).

194. E.g., Prescription Drug Parity for Americans Act, H.R. 2497, 108th Cong. (2003).

195. H.R. 2427, 108th Cong. (2002); see also Robert Novak, Drug Company Backlash Hits Fever Pitch in Congress, CHI. SUN-TIMES, July 17, 2003, at 33.

196. See Jim VandeHei & Juliet Eilperin, House Approves Drug Reimports, WASH. POST, July 26, 2003, at A1.

197. Nick Anderson, In Senate, Stiff Resistance to a Drug-Import Bill, LA TIMES, July 26, 2003, at 1-10.

198. See Amy Goldstein & Helen Dewar, *Hill Negotiators Rethink Reimported Drugs*, WASH. POST, Nov. 6, 2003, at A2.

<sup>193.</sup> E.g., Preserving Access to Safe, Affordable Canadian Medicines Act, H.R. 847, 108th Cong. (2003).
"It is a national embarrassment that in a country with the most advanced medical system in the world, so many of our citizens can obtain affordable prescription drugs only by seeking them in foreign countries."<sup>199</sup> Legalized reimportation was dropped from the final Medicare legislation, replaced by what is in essence an update of the MEDS Act.<sup>200</sup> However, Congress continues to consider legislation seeking to liberalize reimportation of prescription

# **IV. UNDERSTANDING THE STAKEHOLDERS**

In 1999, President Clinton initiated the current war on Internet drug sales, signaling "zero tolerance for prescription drug Internet sites that ignore federal and state laws and harm patient safety and health."<sup>202</sup> In fact, there is even more at stake. Simmering behind the layers of regulation, parochial regulators, and patchy enforcement are crucial questions about the future of U.S. healthcare delivery. Most aspects of e-health, Internet prescribing and dispensing in particular, are disruptive technologies that challenge the status quo.<sup>203</sup> The stakeholders have frequently divergent views on the specific issues and the role of technologically mediated care.

### A. Federal and State Regulators

It should be clear from the discussion above that U.S. drug marketing, prescribing, and fulfillment exists in an immensely complex regulatory matrix involving state, federal, and professional bodies. The matrix affects more than local professional regulations and national quality regulation,

<sup>199.</sup> Dan Balz, *Edwards Seeks a Lift with TV Ads*, WASH. POST, Aug. 7, 2003, at A3 (discussing a letter from AARP to sponsoring House members Reps. Emanuel and Gutknecht).

<sup>200.</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2469 (replacing 21 U.S.C. § 384). The 2003 legislation calls for a study of reimportation similar to that called for by the MEDS Act. FDA Commissioner (and CMS Secretary designate) Mark McClellan has been appointed to head the study. *McClellan To Study Drug Imports*, WALL ST. J., Feb. 26, 2004, at D4.

<sup>201.</sup> See, e.g., Pharmaceutical Market Access and Drug Safety Act of 2004, S. 2328, 108th Cong. (2004).

<sup>202.</sup> PBS, Clinton Proposes Regulation of Internet Drug Sales, Public Broadcasting Service, at http://www.pbs.org/newshour/updates/december99/internet\_drugs\_12-28.html (Dec. 28, 1999).

<sup>203.</sup> See generally Philip Evans & Thomas S. Wurster, Blown to Bits: How the New Economics of Information Transforms Strategy 180-89 (2000).

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but also strong criminal enforcement (e.g., DEA) necessitated by the distribution of illegal controlled substances and the diversion of legally prescribed drugs.<sup>204</sup> The international connection adds more complexity as stakeholders confront not only illegal and offshore<sup>205</sup> sources but also the more benign, yet politically charged, Canadian connection.

The shifts in healthcare delivery implicate even broader interests for regulators in the United States. Some of these interests are consistent with a more positive approach to technologically-mediated care, while others are the product of conservatism, parochialism, protectionism, and even technophobia.

The federal government is committed to leveraging health technology to decrease costs and improve medical quality.<sup>206</sup> The Bush Administration has tried to assuage industry concerns about the HIPAA privacy regulations but has remained committed to the introduction of the foundational health Electronic Data Interchange (EDI) system.<sup>207</sup> The federal government remains committed to inter-operability and technology-led efficiency in interstate medical and insurance markets.<sup>208</sup> Federal regulators recognize that the cost-savings of technologically-mediated care will be

205. See Melissa K. Cantrell, The Taming Of E-Health: Asserting U.S. Jurisdiction over Foreign and Domestic Websites, 103 W. VA. L. REV. 573 (2001); Ivette P. Gomez, Note, Beyond the Neighborhood Drugstore: U.S. Regulation of Online Prescription Drug Sales by Foreign Businesses, 28 RUTGERS COMPUTER & TECH. L.J. 431 (2000).

206. See, e.g., Press Release, United States Department of Health & Human Services, Secretary Thompson Announces Steps To Reduce Medication Errors (Mar. 13, 2003), http://www.hhs.gov/news/press/2003pres/20030313.html; Ceci Connolly, Bar Codes on Drugs Proposed, Errors Could Be Cut by Matching Hospital Patient, Prescription, WASH. POST, Mar. 8, 2003, at A7.

207. HIPAA's "Administrative Simplification" Subtitle F, sets out the framework and provided CMS with the regulatory authority "to improve . . . the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." Health Insurance Portability and Accountability Act of 1996, Pub. L No. 104-191, § 261, 110 Stat. 2021 (1996). The pivotal "Administrative Simplification" subtitle introduced by the HIPAA regulations was the establishment of an Electronic Data Interchange (EDI) for the healthcare system. When fully implemented, this EDI architecture will provide for a fully interoperable, standardized system for processing all data exchanges between healthcare entities.

208. This commitment is evidenced by the introduction of the administrative simplification system. *See infra* note 207.

<sup>204.</sup> One example is the abuse of OxyContin. See OxyContin Diversion and Abuse, U.S. D.O.J. INFORMATION BULLETIN, Jan. 2001, at 1, available at

http://www.usdoj.gov/ndic/pubs/651/651p.pdf.

realized more rapidly if consumers have confidence in the new systems, which requires that providers internalize many of the privacy and security costs in the healthcare information domain.

The White House has subordinated concerns about medical error to the more populist rhetoric of the "malpractice crisis,"<sup>209</sup> although in the 2004 State of the Union address the expected populist oversimplification of "we must eliminate wasteful and frivolous medical lawsuits" was followed by a more technical and forward-thinking directive— "[b]y computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care."<sup>210</sup> Federal agencies continue to push initiatives, such as e-prescribing,<sup>211</sup> that directly reduce error<sup>212</sup> or indirectly decrease patient information costs in choosing safe providers through increased reporting, analysis and disclosure.<sup>213</sup>

Other federal goals are less clearly stated. Federal regulators appear desperate to cut health costs by encouraging states to use technology to increase the efficiency of federally-funded intrastate services and are thus re-thinking reimbursement and subsidy programs. Although there are articulated federal goals to prevent distortions in market conditions between states,<sup>214</sup> these have not been applied in the e-health domain. Finally, the principle of comity<sup>215</sup> suggests a conservative approach to dealing with international traffic in drugs; the United States needs to

210. George W. Bush, State of the Union Address, http://www.whitehouse.gov/news/releases/2004/01/20040120-7.html (Jan. 20, 2004).

212. One example is the work of the Agency for Healthcare Research and Quality (AHRQ).

213. See infra notes 475-477.

214. Cf. infra text accompanying note 311 (discussing FTC report on the interstate wine market).

215. "Comity, in the legal sense, is neither a matter of absolute obligation, on the one hand, nor of mere courtesy and good will, upon the other. But it is the recognition which one nation allows within its territory to the legislative, executive, or judicial acts of another nation, having due regard both to international duty and convenience, and to the rights of its own citizens, or of other persons who are under the protection of its laws." Hilton v. Guyot, 159 U.S. 113, 163-64 (1895).

<sup>209. &</sup>quot;Because of excessive litigation, everybody pays more for healthcare, and many parts of America are losing fine doctors. No one has ever been healed by a frivolous lawsuit; I urge the Congress to pass medical liability reform." George W. Bush, State of the Union Address, http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html (Jan. 28, 2003); see also Jeanne Cummings, Doctors' Activism Revives Malpractice Bill; Inspired By Bush, Physicians Are Pressuring Congress To Cap Damage Awards, WALL ST. J., Jan. 13, 2003, at A4.

<sup>211.</sup> See supra note 17.

respect borders in order to gain international cooperation in curtailing illegal traffic in a wide array of Internet enabled goods and services, whether child pornography, gambling, or pharmaceuticals.

Today, improvements in health quality and safety primarily flow from federal initiatives (e.g., the FDA and the Agency for Healthcare Research and Quality), Medicare/Medicaid standards, and other national initiatives such as those emanating from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Leapfrog Group,<sup>216</sup> and the Markle Foundation's "Connecting for Health Collaborative."<sup>217</sup> The blunter instruments of state-law discipline and malpractice litigation have been overshadowed by these initiatives.

State health departments have specific positive experiences with technologically mediated care, such as telemedical outreach to underserved populations,<sup>218</sup> and increasingly leverage technology to provide a greater range of intrastate services.<sup>219</sup> State regulators, however, have failed to articulate any discrete local quality standards and safety interests in an increasingly national healthcare delivery system. State medical boards continue to give credence to the fallacy that quality and safety can be addressed by rooting out the few "bad apples" in the professions, while appearing to be less than conversant with national process or system-wide problems of medication errors, wrong-site surgery, iatrogenic injury, physician fatigue, and the nursing shortage.<sup>220</sup> Furthermore, rather than taking a holistic approach to quality of care, state boards tend to concentrate on discrete, often interpersonal violations of their codes (e.g., sexual relations with patients, substance abuse and, of course, Internet prescribing).

In the areas of licensure and discipline, the states continue to take their police powers very seriously. Yet, they reference only the broadest notions of quality and the protection of the public health. Despite the flurry of enforcement activity surrounding Internet prescribing and dispensing, state medical boards are principally interested in interactions

<sup>216.</sup> The Leapfrog Group, at http://www.leapfroggroup.org (last visited Apr. 17, 2004).

<sup>217.</sup> Connecting for Health, *at* http://www.connectingforhealth.org (last visited Apr. 17, 2004).

<sup>218.</sup> See, e.g., Telemedicine Reaches over 200 Alaska Locations, ALASKA J. COMM., Jan. 27, 2003.

<sup>219.</sup> See, e.g., Virginia Board of Medicine's Practitioner Information Website, at http://www.vahealthprovider.com/ (last visited Apr. 17, 2004).

<sup>220.</sup> See generally Lucian L. Leape, Preventing Medical Accidents: Is "Systems Analysis" the Answer?, 27 AM. J.L. & MED. 145, 147 (2001) (arguing human errors can be "prevented by redesigning systems . . . to make it difficult to impossible for the errors to occur"); James Reason, Human Error: Models and Management, 320 BRIT. MED. J. 768 (2000).

within their own borders. In some interstate interactions, they do, however, rightfully assert their right to make policy. For example, medical boards have to counter negative externalities suffered by their citizens when neighbor states fail to enforce their licensure rules regarding "exported" prescribing and dispensing services.<sup>221</sup>

Both state and federal regulators view Internet prescribing and dispensing negatively and have derived moral imperatives from its more dangerous and obviously illegal practices. Regulators have targeted telemedicine in order to better police cybermedicine and Internet prescribing. Similarly, they target prescribing and dispensing because of tangential goals, such as consumer protection and public health. As a result, regulatory activity tied to Internet prescribing and dispensing is frequently prophylactic—leveraging the "hard" law of licensure to curtail conduct that offends other policies or laws—yet it is more difficult to regulate using "softer" consumer protection laws or offences requiring a showing of *mens rea*.

Legally suspect cyber-physicians and e-pharmacies indulge in the same array of dubious practices as their gambling and pornography fellow travelers: auction fraud, credit card fraud, and non-delivery of merchandise.<sup>222</sup> Grey and black-market sites are not interested in "stickiness" or persistence,<sup>223</sup> or otherwise creating a marketing and service atmosphere that promotes repeat business. These operators subscribe to a more practical and immediate imperative: to keep moving and morphing to stay ahead of pursuing regulators. Bad service, poor quality products, and even outright fraud are therefore par for the course.<sup>224</sup>

The Federal Trade Commission (FTC) and state consumer protection agencies are active in the prescribing and fulfillment domains,<sup>225</sup> but their

223. For an explanation of this concept, see Martin Nemzow, Array Development Ecommerce "Stickiness" for Customer Retention, *at* 

http://www.arraydev.com/commerce/jibc/9908-03.htm (last visited Apr. 16, 2004). 224. See Internet Prescribing, Medical Board of California, at

http://www.medbd.ca.gov/buyerbeaware.htm (last visited Apr. 16, 2004) (explaining the risks associated with ordering prescriptions through the internet).

225. See, e.g., The Internet Sale of Prescription Drugs from Domestic Websites: Hearings Before the House Comm. on Gov't Reform, 108th Cong. (2003) (prepared statement of J. Howard Beales,

<sup>221.</sup> This is what Goldsmith and Sykes would call a "nonpecuniary externality that affects citizens outside of the regulating state." Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 YALE L.J. 785, 798 (2001).

<sup>222.</sup> NAT'L WHITE COLLAR CRIME CTR. & FED. BUREAU OF INVESTIGATION, IFCC 2002 INTERNET FRAUD REPORT, JANUARY 1, 2002—DECEMBER 31, 2002, at 5 (2003), *available at* http://wwwl.ifccfbi.gov/strategy/2002\_IFCCReport.pdf (last visited Apr. 16, 2004).

regulatory powers are somewhat limited, often generalized, and frequently limited to cases where misrepresentation or fraud can be proved.<sup>226</sup> The FTC has argued that "the Commission has authority to bring an enforcement action where an online pharmacy makes false or misleading claims about the products or services it provides. However, the online prescribing and dispensing of prescription drugs that does not involve a deceptive or unfair practice generally does not fall within the agency's scope of authority."<sup>227</sup>

Regulatory interests are also sparked by concerns over pricing. The Canadian connection that opens a channel to less expensive drugs is the exception that proves the rule. Unlike the majority of goods and services offered over the Web, Internet prescribing and dispensing do not attract consumers primarily because of lower prices. In fact, many are seeking drugs that their own physicians refuse to prescribe and are prepared to pay a premium for back-channel services. Paul Starr recounts how in the late 1890s a patent medicine company pandered to Victorian modesty, attracting women customers away from male physicians with advertisements such as "Do you want a strange man to hear all about your particular diseases?" and "Men NEVER See Your Letters."<sup>228</sup> For many lifestyle drugs, stealth and anonymity may still be the predominant factors promoting online purchases.<sup>229</sup>

The Internet's oft-touted transactional transparency (based on reduced transaction costs and generally low information costs)<sup>250</sup> does not seem to apply to the current traffic in interstate prescription drugs. A survey by the California State Board of Pharmacy even concluded that some drugs cost five times as much on the Internet as they did in local

http://www.ftc.gov/opa/2003/07/ephedra.htm.

III, Director, Bureau of Consumer Protection of the Federal Trade Commission),

<sup>[</sup>hereinafter *Hearings*], http://www.ftc.gov/os/2003/03/030327internetprescriptions.pdf (last visited Apr. 16, 2004).

<sup>226.</sup> See, e.g., Press Release, Fed. Trade Comm'n, Online Pharmacies Settle FTC Charges (July 12, 2000), http://www.ftc.gov/opa/2000/07/iog.htm; see also Press Release, Fed. Trade Comm'n, FTC Charges Direct Marketers of Ephedra Weight Loss Products with Making Deceptive Efficacy and Safety Claims (July 1, 2003),

<sup>227.</sup> Hearings, supra note 225, at 11 (footnotes omitted).

<sup>228.</sup> PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 128 (1982).

<sup>229.</sup> For the views on patient motives from a doctor who has written more than 10,000 Internet prescriptions for Viagra, see Miles J. Jones & William Alvis Thomasson, *Establishing Guidelines for Internet-based Prescribing*, 96 S. MED. J. 1, 2-3 (2003).

<sup>230.</sup> For a thoughtful analysis, see Robert P. Merges, The End of Friction? Property Rights and Contract in the "Newtonian" World of On-Line Commerce, 12 BERKELEY TECH. L.J. 115 (1997).

pharmacies.<sup>231</sup>

This counter-intuitive phenomenon was at the root of the prosecutors' failed attempt in *State ex rel. Stovall v. Confimed.com, L.L.C.*<sup>232</sup> to persuade the Supreme Court of Kansas that a charge of seventy-five dollars for an online consultation and dispensing fee was unconscionable.<sup>233</sup> However, infomediaries such as price "bots" (websites that offer price comparisons across multiple suppliers) are moving into the prescription drug domain, providing comparison pricing information across online and bricks-and-mortar suppliers.<sup>234</sup>

Federal authorities have been extensively involved in attempts to crack down on abuses such as fraud and diversion. For example, "Operation Web Slinger," a joint U.S.-Canadian investigation coordinated by the DEA, has targeted the illegal Internet trafficking of "date rape" drugs such as GHB.<sup>235</sup> Similarly, the FTC and FDA are jointly leading "Operation Cure.All,"<sup>236</sup> directing considerable federal law enforcement energies against companies marketing fraudulent health products over the Internet. Targeted companies include those that market nutritional supplements, herbal products, and medical devices that claim to treat ailments as diverse as cancer, HIV/AIDS, arthritis, hepatitis, Alzheimer's disease, and diabetes.<sup>237</sup> A particularly disturbing set of cases arose after September 11, 2001 with online entrepreneurs offering "civil defense" products such as

234. For an example of such a company, see DestinationRx, *at* http://www.destinationrx.com (last visited Apr. 16, 2004).

237. See, e.g., Herb Remedy Web Sites Break Law, Study Finds, AKRON BEACON J., Oct. 28, 2003.

<sup>231.</sup> Siwolop, *supra* note 88. A PharmacyChecker.com analysis reported that U.S. sites not requiring prescriptions charged, on average, fifty-four percent more than sites that do require prescriptions. Pharmacychecker.Com, *Fifty Percent of Internet Pharmacies Not Licensed According to Pharmacychecker.Com; Canadian Prices Half That of U.S.*, Pharmacy Checker, *at* http://www.pharmacychecker.com/news/news\_040703.asp (Apr. 7, 2003).

<sup>232. 38</sup> P.3d 707 (Kan. 2002). For a full discussion of *Stovall*, see *infra* note 411 and accompanying text.

<sup>233. 38</sup> P.3d at 714 ("[The investigators] at best made a bad bargain, but, lacking any indication of deceptive bargaining conduct or unequal bargaining power, the \$75 charge for the consultation was not unconscionable.").

<sup>235.</sup> Press Release, Drug Enforcement Admin., "Date Rape" Drug Sold over the Internet (Sept. 19, 2002), http://www.usdoj.gov/dea/pubs/pressrel/pr091902.html.

<sup>236.</sup> Greg Winter, U.S. Vows More Scrutiny of Health Ads on Net, N.Y. TIMES, June 15, 2001, at C4; see Press Release, Fed. Trade Comm'n, "Operation Cure.All" Wages New Battle in Ongoing War Against Internet Health Fraud (June 14, 2001), at

http://www.ftc.gov/opa/2001/06/cureall.htm.

anti-radiation pills<sup>238</sup> or Ciprofloxacin, designed to treat Anthrax.<sup>239</sup> Such cases replicated themselves after other public health scares such as the SARS outbreak.<sup>240</sup> State and federal authorities will likely continue to target the Internet sale of other dangerous products such as nicotine-laced lollipops,<sup>241</sup> or those likely to be used for illegal purposes such as "cleaning" urine.<sup>242</sup> Regulators in the United States face a growing problem of counterfeit<sup>243</sup> and contaminated drugs,<sup>244</sup> and are particularly keen to slow the development of new or suspect distribution channels.<sup>245</sup>

# B. The Pharmaceutical Industry

It is relatively easy to paint the U.S. pharmaceutical industry as the real villain in the Internet dispensing controversy. After all, the industry is stimulating demand for pharmaceuticals by marketing to physicians<sup>246</sup> and through DTC advertising,<sup>247</sup> and the industry also must appreciate that the drugs for which they create this demand are frequently out-of-formulary<sup>248</sup>

238. New York Says Pill Seller Invoked Terror Case, N.Y. TIMES, Dec. 4, 2002, at A19.

239. See Press Release, Fed. Trade Comm'n, FTC Cracks Down on Marketers of Bogus Bioterrorism Defense Products (Nov. 19, 2001),

http://www.ftc.gov/opa/2001/11/webwarn.htm.

240. Internet Is Awash in Ads for Products Promising Cures or Protection, N.Y. TIMES, Apr. 14, 2003, at A12.

241. See, e.g., Press Release, Fed. Trade Comm'n, FDA Warns Sellers of Nicotine Lollipops & Lip Balm That Their Products Are Illegal (Apr. 10, 2002),

http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01144.html.

242. See, e.g., Curtis v. State, 549 S.E.2d 591 (S.C. 2001).

243. See, e.g., Lauren Neergaard, FDA Says Web Site Is Selling Counterfeit Contraceptives, WASH. POST, Feb. 4, 2004; see also FOOD & DRUG ADMIN., COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION (2004),

http://www.fda.gov/oc/initiatives/counterfeit/report02\_04.html.

244. See, e.g., Lax System Allows Criminals To Invade the Supply Chain, WASH. POST, Oct. 22, 2003, at A01; U.S. Prescription Drug System Under Attack, WASH. POST, Oct. 19, 2003, at A01.

245. See FOOD & DRUG ADMIN., supra note 150.

246. Robert Pear, U.S. Warns Drug Makers on Illegal Sales Practices, N.Y. TIMES, Apr. 28, 2003, at A16; cf. Press Release, PhRMA, PhRMA Adopts New Marketing Code (Apr. 19, 2002), http://www.phrma.org/mediaroom/press/releases/19.04.2002.390.cfm.

247. See, e.g., Lars Noah, Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues, 32 GA. L. REV. 141 (1997); David W. Opderbeck, How Should FDA Regulate Prescription Drug Promotion on the Internet?, 53 FOOD DRUG L.J. 47 (1998); Peter S. Reichertz, Understanding Government Regulation of the Marketing and Advertising of Medical Devices, Drugs, and Biologics: The Challenges of the Internet, 52 FOOD DRUG L.J. 303 (1997).

248. In 2002, out-of-pocket spending on prescription drugs increased from \$6.1 billion

and potentially off-label, and so are less likely to be satisfied through traditional prescribing or dispensing channels.<sup>249</sup>

It also seems beyond cavil that U.S. pharmaceutical companies regularly practice price and distribution discrimination, with the U.S. market bearing disproportionate and escalating drugs costs. The primary reason for the lower costs abroad, however, is that non-U.S. healthcare delivery services are larger, monopsonic, or have otherwise put themselves into better bargaining positions with pharmaceutical companies. In particular, non-U.S. national health services are willing to use their monopoly purchasing power to extract low prices for pharmaceuticals. Arguably, the real objection to the high costs of pharmaceuticals in the United States is that the pharmaceutical companies, forced to internalize costs in foreign markets, disproportionately externalize their research and development costs to U.S. consumers. The federal government has done little to reverse this trend and the states have only recently begun to explore their market power by forming procurement collectives.<sup>250</sup> Illustrative of the U.S. drug pricing dynamic has been the pharmaceutical industry's opposition to a Medicare prescription drug benefit, which is driven by the fear that centralized government purchasing would drive

to \$48.6 billion, or twenty-three percent of out-of-pocket spending. Robert Pear, Health Spending Rises to Record 15% of Economy, N.Y. TIMES, Jan. 9, 2004. According to the GAO,

Pharmaceutical companies have increased spending on DTC advertising more rapidly than they have increased spending on research and development. Between 1997 and 2001, DTC advertising spending increased 145 percent, while research and development spending increased 59 percent. Promotion to physicians accounted for more than 80 percent of all promotional spending by pharmaceutical companies in 2001. Total promotional spending was equivalent to 12 percent of drug sales in the United States in 2001.

GEN. ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 3 (GAO-03-17, 2002) [hereinafter PRESCRIPTION DRUGS].

249. "Ninety percent of the people who buy medications at PlanetRx pay for the prescriptions themselves, not through their insurance plans, whereas only 20 percent of the customers at brick-and-mortar pharmacies pay out of their own pocket." Jennifer Couzin, *The Internet's Drug Lords*, THE INDUSTRY STANDARD, Apr. 10, 2000. The GAO has also noted:

To date, the few studies that have examined the effects of DTC spending on prescription drug spending and utilization have found that DTC advertising increases both. In addition, there is clear evidence from consumer surveys that DTC advertising encourages consumers to request prescriptions for specific brand-name drugs from their physicians and that some physicians provide the requested prescription.

#### PRESCRIPTION DRUGS, supra note 248, at 11.

250. Milt Freudenheim, *Nine States Form Group To Lower Drug Costs*, S.D. UNION-TRIB., Jan. 14, 2003, at A1.

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down prices<sup>251</sup> or that cost-effectiveness analysis would counter pharmaceutical marketing and create limited formularies.<sup>252</sup>

#### C. Physicians and Pharmacists

Although patients are apparently keen to increase the level of technological intermediation with their healthcare providers,<sup>253</sup> it can be difficult to find reciprocal interest among physicians<sup>254</sup> or institutional providers.<sup>255</sup> Despite evidence that use of rich and self-documenting email,<sup>256</sup> as well as other robust electronic communications with patients,<sup>257</sup> make treatment more effective, many physicians and their representatives on state boards view email and web contact with patients or potential patients as further signs (along with managed care, Internet web advice, and the general "HIPAA-ization" of medical practice)<sup>258</sup> that they are losing control of the physician-patient relationship.<sup>259</sup>

251. Jim Drinkard, Drug Bill a Well-Financed Victory for Industry; Companies Avert Version Feared Most, USA TODAY, July 7, 2003, at 4A.

252. Robert Pear, Congress Weighs Drug Comparisons, N.Y. TIMES, Aug. 24, 2003, at 18.

253. See infra notes 275-279.

254. According to one study, seventy-four percent of parents of children wish to communicate with their children's doctors online, but seventy-nine percent of pediatricians are unwilling to communicate directly with patients via email. Katie D. Kleiner et al., *Parent and Physician Attitudes Regarding Electronic Communication in Pediatric Practices*, 109 PEDIATRICS 740 (2002).

255. Beth Healy, *Health Plans Fall Short in Web Service, Study Finds, BOSTON GLOBE, Apr. 9, 2003, at D1 ("The more consumers access information about their health in general online, and the more premiums and copays that are pushed onto their shoulders, the more they want to be treated like customers." ) (quoting Forrester Research study)).* 

256. Leonard Holmes, Writing Email About Problems Can Improve Health, About.com., at http://mentalhealth.about.com/library/sci/0402/blemail402.htm (last visited Apr. 16, 2004); see also Florian Strasser et al., E-motions: Email for Written Emotional Expression, 20 J. CLINICAL ONCOLOGY 3352 (2002).

257. See, e.g., 'Virtual Visits' Helping Parents of Preemies, N.Y. TIMES, Dec. 5, 2000, at 14 (reporting that premature infants whose families had web access to updates on the babies' health, information about medical conditions, explanations of medical equipment and terminology, and a videoconferencing system with which to interact with medical staff had shorter stays in neonatal intensive care units).

258. See supra note 56 and accompanying text.

259. See Edd Fleming & Jens Riese, On-line Healthcare: Why Are Physicians Still Dragging Their Feet?, HEALTHLEADERS, at

http://www.healthleaders.com/news/feature1.php?contentid=11288&CE\_Session=47b8086 16122e9a96290e0574f68fb83 (Feb. 5, 2001).

Less frequently articulated are genuine concerns about the legal and operational uncertainties surrounding patient email.<sup>260</sup> Although some guidance for professionals has been published,<sup>261</sup> genuine questions remain about legal exposure for responding to unsolicited email,<sup>262</sup> and the related question of exactly what creates a physician-patient relationship on the Internet.<sup>263</sup> Such uncertainties include: difficulties in positively identifying online participants; questions about responsibility for "operator error" or mistakenly forwarded e-mail; the chilling effect of HIPAA's security and privacy rules; and the scope of document retention,<sup>264</sup> particularly the way that the self-documenting nature of email may increase malpractice exposure.

Physicians also have understandable "business" concerns. They view email communications with patients as creating an expectation of aroundthe-clock services and something to be delegated to their staff.<sup>265</sup> This antipathy is, no doubt, fuelled by the relative lack of reimbursement for any such contact with patients.<sup>266</sup> In contrast, physicians involved in subscription-based email services show considerably more enthusiasm.<sup>267</sup>

262. See, e.g., MV Seeman & B Seeman, *E-psychiatry: The Patient-Psychiatrist Relationship in the Electronic Age*, 161 CANADIAN MED. ASS'N J. 1147 (1999) ("Clearly, the most judicious course of action is not to respond to email queries.").

263. This is analogous to the telephone cases where "it must be shown that it was foreseeable that the prospective patient would rely on the advice and that the prospective patient did in fact rely on the advice." Miller v. Sullivan, 625 N.Y.S.2d 102, 104 (App. Div. 1995). Chat functions, and in some instances email, are more likely to trigger this formal relationship due to the contemporaneous nature of relationship creation and provision of services.

264. NASD has a three-year rule for retention of email and IM communications. *Notice to Members, at* http://www.nasdr.com/pdf-text/0333ntm.pdf (last visited Apr. 17, 2004).

265. See Hafner, supra note 260. See generally CA. HEALTHCARE FOUND., ONLINE PATIENT-PROVIDER COMMUNICATION TOOLS: AN OVERVIEW 19-25 (2003),

http://www.chcf.org/documents/ihealth/PatientProviderCommunicationTools.pdf.

<sup>260.</sup> See Katie Hafner, Dear Doctor Meets Return to Sender, N.Y. TIMES, June 6, 2002, at G1; Francesca Lunzer Kritz, Some Doctors Use Patient E-mail in Their Practices, but Most Aren't Ready To Log on, WASH. POST, Apr. 1, 2003, at HE1.

<sup>261.</sup> See, e.g., Beverly Kane & Daniel Z. Sands, Guidelines for the Clinical Use of Electronic Mail with Patients, 5 J. AM. MED. INFORMATICS ASS'N 104 (1998),

http://www.amia.org/pubs/other/email\_guidelines.html.

<sup>266.</sup> See Laura Landro, The Informed Patient: Please Get the Doctor Online Now, WALL ST. J., May 22, 2003.

<sup>267.</sup> See, e.g., GreenField Health System, at http://www.greenfieldhealth.com/. See generally

E-Mail Could Transform Medical Care, Northwest News Channel 8, at

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As for pharmacists, David Brushwood has argued convincingly that the changing nature of medical practice and health policy leads to pharmacists "being asked to do more for each patient, and there are more patients whose needs pharmacists are being asked to meet."<sup>268</sup> This trend will continue as medical practice continues to favor pharmaceutical treatment models while at the same time relying on the pharmacist as the second line of defense to reduce medication errors.

Just as it is naïve to paint pharmaceutical companies as the villains of ths story, it would stretch credulity to classify most Internet physicians and pharmacists as victims. They may characterize themselves as guiltless pioneers protecting the access rights of their customers, but most of their businesses and business practices too closely resemble those employed by less reputable Internet sites. Internet physicians and pharmacies market through spam<sup>269</sup> and impede the continuity of care by disappearing and reappearing under different names and web addresses.<sup>270</sup> The shadowwriter or ghost-writer physicians they often employ must either possess superhuman powers or ignore quality of care given the hundreds of prescriptions they sign per week.<sup>271</sup>

By the same token, Internet physicians and pharmacists cannot be viewed as innocent victims of an overly complex regulatory system. Internet prescribers and dispensers are generally quite sophisticated and structure their businesses to exploit "soft" states or regulatory gaps. If they were willing, they could avoid controlled substances, develop track records of quality practices, decouple their prescribing and dispensing businesses,

http://www.clearswift.com/news/pressreleases/232.aspx.

http://www.kgw.com/health/stephanie\_stricklen/stories/kgw\_0423\_health\_stricklen\_emai l\_doctors.lca31ac9.html (Apr. 23, 2002).

<sup>268.</sup> David B. Brushwood, *Responsive Regulation of Internet Pharmacy Practice*, 10 ANN. HEALTH L. 75, 76 (2001).

<sup>269.</sup> The spam subject line "Check out our new lower prices. Many 'drug' types available." made SurfControl's list of "Top 10 Most Annoying Spam in 2002." Press Release, SurfControl, Anti-Spam Leader SurfControl Cites Top 10 Most Annoying Spam in 2002, *at* http://www.surfcontrol.com/news/newsitem.aspx?id=543 (last visited Apr. 17, 2004). According to Clearswift, healthcare spam accounted for almost fifty percent of spam in November 2003. Press Release, Clearswift, Spammers Peddling Viagra and Diet Pills in Run Up to Party Season (Dec. 16, 2003),

<sup>270. &</sup>quot;It's like rabbits," said Wayne A. Michaels, a senior investigator for the Drug Enforcement Administration. "Every day, there are more of them. They're up, they're down, they're foreign, they're domestic." Gilbert M. Gaul & Mary Pat Flaherty, *Internet Trafficking in Narcotics Has Surged*, WASH. POST, Oct. 20, 2003, at A01.

<sup>271.</sup> See Gaul & Flaherty, supra note 18.

and restrict their operations to one or a small number of states where their physicians are licensed—either by refusing to prescribe to patients in states where their doctors are not licensed or by using what Jack Goldsmith has called "information discrimination technology."<sup>272</sup>

### D. Patients

Patient interest in Internet prescribing and dispensing is not difficult to explain; it is part of a broader pattern of consumer use of health-related email and web resources.<sup>273</sup> Searching for health information and advice is one of the primary uses of the Internet in the United States, behind only email and product research.<sup>274</sup> Eighty percent of, or 110 million, online adults use the Internet to access health information.<sup>275</sup> Forty-five percent of U.S. adults use the Internet for healthcare-related purposes, including health research, prescribing, and comparison-shopping on health services.<sup>276</sup> Thirty-four percent of Internet users have searched for pharmaceutical-related information.<sup>277</sup> In contrast, only sixteen percent refer to their physicians for health-related information.<sup>278</sup>

Ninety percent of adults online would like to communicate online with

278. Id. Baker and his colleagues report a less robust picture:

Laurence Baker et al., Use of the Internet and E-mail for Health Care Information: Results from a National Survey, 289 JAMA 2400 (2003).

<sup>272.</sup> Jack L. Goldsmith, Against Cyberanarchy, 65 U. CHI. L. REV. 1199, 1225 (1998).

<sup>273.</sup> See FOX & FALLOWS, supra note 54.

<sup>274.</sup> Id. at i.

<sup>275.</sup> Humphrey Taylor, Cyberchondriacs Update, Harris Interactive, at

http://www.harrisinteractive.com/harris\_poll/index.asp?PID=299 (May 1, 2002). This is compared to fifty-four million in 1998, sixty-nine million in 1999, and ninety-seven million in 2001. *Id.* 

<sup>276.</sup> Press Release, Solucient, Nearly Half of U.S. Adults Turn to Web for Health Care Needs (July 15, 2003), http://www.solucient.com/news\_press/news20030715.shtml (last visited Apr. 17, 2004).

<sup>277.</sup> See FOX & FALLOWS, supra note 54, at 8.

Approximately 40% of respondents with Internet access reported using the Internet to look for advice or information about health or healthcare in 2001. Six percent reported using e-mail to contact a physician or other health care professional. About one third of those using the Internet for health reported that using the Internet affected a decision about health or their health care, but very few reported impacts on measurable health care utilization; 94% said that Internet use had no effect on the number of physician visits they had and 93% said it had no effect on the number of telephone contacts. Five percent or less reported use of the Internet to obtain prescriptions or purchase pharmaceutical products.

their physicians to ask questions, fix appointments, refill prescriptions, and receive test results.<sup>279</sup> A significant number aspire for a more robust experience, wanting more information on drug interactions, access to their electronic patient records, and increased availability of home or mobile diagnostic tools.<sup>280</sup> A 2003 survey found that thirty-seven percent of connected and relatively affluent patients were prepared to pay modest subscription or per-email fees in order to have online interaction with their physicians.<sup>281</sup>

Six million U.S. adults have purchased prescription drugs online.<sup>282</sup> The drugs most often bought online were Lipitor<sup>283</sup> for lowering cholesterol, Viagra<sup>284</sup> for erectile dysfunction, and Celebrex,<sup>285</sup> a pain reliever.<sup>286</sup> Seventy per cent of online purchases were for drugs previously prescribed in the course of a conventional physician-patient relationship.<sup>287</sup> The overwhelming majority of purchasers reported being equally satisfied (56%) or more satisfied (34%) than they were with purchases from a traditional pharmacy,<sup>288</sup> although a majority believed that buying drugs online is much more dangerous (39%) or somewhat more dangerous (22%) than buying them from a pharmacy.<sup>289</sup>

Online prescribing and dispensing no doubt attract customers for many of the same reasons that make other business-to-consumer storefronts so popular: convenience, round-the-clock availability,

281. Harris Interactive, Patient/Physician Online Communication: Many Patients Want It, Would Pay for It, and It Would Influence Their Choice of Doctors and Health Plans, HEALTH CARE NEWS, Apr. 10, 2002,

http://www.harrisinteractive.com/news/newsletters/healthnews/HI\_HealthCareNews2002 Vol2\_Iss08.pdf.

282. Harris Interactive, Six Million People Have Bought Prescription Drugs Online; Most Are Satisfied, HEALTH CARE POLL, Mar. 23, 2004,

<sup>279.</sup> Fast Facts, RelayHealth, at

http://www.relayhealth.com/rh/general/news/fastFacts.aspx (last visited July 29, 2004) (citing Harris Interactive poll from April 2002).

<sup>280.</sup> See FOX & FALLOWS, supra note 54, at 29.

http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline\_HI\_Health -CarePoll2004vol3\_iss06.pdf.

<sup>283.</sup> Lipitor, at http://www.lipitor.com/ (last visited Apr. 17, 2004).

<sup>284.</sup> Viagra, at http://www.viagra.com/ (last visited Apr. 17, 2004).

<sup>285.</sup> Celebrex, at http://www.celebrex.com/ (last visited Apr. 17, 2004).

<sup>286.</sup> Harris Interactive, supra note 282, at 3 tbl.5.

<sup>287.</sup> Id. at 2 tbl.2.

<sup>288.</sup> Id. tbl.3.

<sup>289.</sup> Id. tbl.4.

comparison-shopping, and variety. It is more difficult to assess what factors specifically motivate Internet prescribing. As discussed earlier, anecdotal evidence suggests that lower prices may not be as strong a factor as it is in other forms of online retailing, although it may still be a consumer aspiration. Rather, the specific "convenience" sought by those who purchase prescriptions online is the circumvention of the conventional physician-patient relationship. Some patients will go online following a refusal by their usual physician to prescribe a particular drug because of, for example, off-label use or the potential for abuse. Those seeking lifestyle drugs no doubt seek a level of anonymity or confidentiality that they assume to be missing from the traditional office visit. Similar factors probably explain patient interest in online fulfillment, although the cost factor is more complex. Customers of lifestyle drugs already face considerable "sticker shock" because such drugs are infrequently included in health plan formularies.<sup>290</sup> Patients who purchase from online pharmacies without a previously-issued orthodox prescription will seldom see significant savings over the local bricks-and-mortar pharmacy price and, counter-intuitively, may even find premium pricing.<sup>291</sup> In contrast, we know that seniors equipped with bricks-and-mortar prescriptions using the Canadian connection are doing so almost exclusively because of significant cost savings.<sup>292</sup>

There may be a more deep-seated, long-term, and disruptive basis for patient interest in online medicine and other controversial pharmaceutical channels. There are detectable signs of a fundamental shift in patient perspectives on prescribing and dispensing. Concomitant with their growing appetite for alternative medicine,<sup>293</sup> patients may be losing confidence in, and respect for, the traditional prescribing process, and hence its moral imperative. They view the transfer of drugs from legend to over the counter status as a function of expiring patents and perceive restrictive managed care formularies to be in stark contrast to the direct-toconsumer pharmaceutical advertising with which they are deluged and the free samples with which they are plied. Although a majority of patients still trust their personal physicians "to do the right thing for them personally

<sup>290.</sup> See Harrow v. Prudential Ins. Co. of Am., 279 F.3d 244 (3d Cir. 2002) (unsuccessful action by consumer against health plan that refused to cover Viagra).

<sup>291.</sup> See supra note 231 and accompanying text.

<sup>292.</sup> See supra note 138 and accompanying text.

<sup>293.</sup> See Sheryl Gay Stolberg, Alternative Care Gains a Foothold, N.Y. TIMES, Jan. 31, 2000, at A1; see also Kathleen M. Boozang, Western Medicine Opens the Door to Alternative Medicine, 24 AM. J. L. & MED. 185 (1998); Nat'l Insts. of Health, What Is Complementary and Alternative Medicine (CAM)?, at http://nccam.nih.gov/health/whatiscam/ (May 2002).

and for their health care,"<sup>294</sup> they are more skeptical about interactions involving pharmaceuticals.<sup>295</sup> Increasingly, patients view their physicians' prescribing decisions as being driven by formulary rules rather than their needs; the traditional prescribing process and dispensing process is no longer viewed as providing access, but rather of erecting barriers.<sup>296</sup>

# V. RECURRING REGULATORY THEMES

In law and practice the "interlocking trellis"<sup>297</sup> of regulation that applies to interstate prescribing and dispensing often appears inconsistent and uncoordinated. More significantly, the way that our regulatory matrix deals unhappily with the supply of pharmaceuticals is suggestive of a difficult regulatory future for the broader e-health domain.

### A. Uneasy Federalism

First generation legal scholarship about the Internet was quick to point out the inherent difficulties of applying extant geographically "zoned" regulation to geographically incoherent cyberspace.<sup>298</sup> The

http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline\_HI\_Health -CarePoll2004vol3\_iss02.pdf (reporting sixty-three percent of patients so trusted their physicians).

295. Id. Forty-nine percent trust their pharmacies; forty-four percent trust their drugs; and fourteen percent trust pharmaceutical companies. Id. at 2.

296. One study reported, "The more money people spend out of pocket on drugs, the more likely they are to shop abroad. Fully 16 percent of those with out-of-pocket costs for drugs of over \$1,000 a year have shopped abroad." Harris Interactive, *Drug Companies May Be Headed for a Bruising Battle as Drug Importation Grows* (Oct. 9, 2003),

http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline\_HI\_Health -CarePoll2003vol2\_iss8.pdf.

297. State v. Rasmussen, 213 N.W.2d 661, 665 (Iowa 1973).

298. See, e.g., David R. Johnson & David Post, Law and Borders—The Rise of Law in Cyberspace, 48 STAN. L. REV. 1367, 1375 (1996); David G. Post, Governing Cyberspace, 43 WAYNE L. REV. 155 (1996); Joanna Zakalik, Law Without Borders in Cyberspace, 43 WAYNE L. REV. 101 (1996). See generally LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE 24-29 (1999). For contemporary analysis, see Goldsmith, supra note 272, at 1250 ("There is no general normative argument that supports the immunization of cyberspace activities from territorial regulation. And there is every reason to believe that nations can exercise territorial authority to achieve significant regulatory control over cyberspace transactions."); Dan Hunter, Cyberspace as Place and the Tragedy of the Digital Anticommons, 91 CAL. L. REV. 439

<sup>294.</sup> Harris Interactive, Health-Care Professionals, Pharmacies, Hospitals Gain the Public's Top Trust (Jan. 28, 2004),

avoidance of concrete examples by local social policies, such as those restricting gambling and pornography, has highlighted the tensions between state and federal systems.<sup>299</sup> The issues surrounding interstate Internet traffic have not been lost on those commenting on the growth of telemedicine and other forms of technologically-mediated care.<sup>300</sup>

The uneasy, or perhaps fragile, federalism that regulates the online health domain is largely a function of the historical divide between federal and state regulation of healthcare. After *Dent v. West Virginia*<sup>301</sup> established the legitimacy and primacy of state regulation of health professionals and the passage of the FDCA by Congress,<sup>302</sup> the stage was set for dichotomized regulation of approval and distribution. The escalating regulatory landscape at both federal<sup>303</sup> and state<sup>304</sup> levels has managed to simultaneously blur and confirm this dichotomy. Such a patchwork of regulation of the largest industry in the United States<sup>305</sup> is both inefficient and strained in the face of a developing market for interstate, technologically mediated care.

# 1. Inconsistencies and Inefficiencies

Federal and state health policies and regulations frequently seem disharmonized and inconsistent. Health privacy is just one example. The existing patchwork of state common law privacy and confidentiality rules

301. See supra note 33 and accompanying text.

<sup>(2003);</sup> and Mark A. Lemley, Place and Cyberspace, 91 CAL. L. REV. 521 (2003).

<sup>299.</sup> See, e.g., Charles R. Topping, The Surf Is Up, but Who Owns the Beach?—Who Should Regulate Commerce on the Internet?, 13 NOTRE DAME J.L. ETHICS & PUB. POL'Y 179 (1999); Stevie A. Kish, Note, Betting on the Net: An Analysis of the Government's Role in Addressing Internet Gambling, 51 FED. COMM. L.J. 449 (1999).

<sup>300.</sup> See, e.g., Ross D. Silverman, Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards, 26 AM. J.L. & MED. 255 (2000); P. Greg Gulick, E-Health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs, 12 ALB. L.J. SCI. & TECH. 351 (2002).

<sup>302. 21</sup> U.S.C. § 355(a) (2000).

<sup>303.</sup> The federal regulatory framework includes the FDA, DEA, FTC, Centers for Medicare and Medicaid Services (CMS), and an array of federal reporting, fraud, and abuse laws.

<sup>304.</sup> Malpractice doctrine, privacy laws, state controlled substances law, as well as state fraud and abuse laws make up the state regulatory framework.

<sup>305.</sup> In 2001, the U.S. bill for healthcare was \$1.4 trillion (14.1 percent of GDP). See American Health Care: Why So Costly?: Hearing Before the Subcomm. on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Comm., 108th Cong. 6 (2003) (testimony of Karen Davis & Barbara S. Cooper, The Commonwealth Fund).

were insufficient to promote consumer confidence in the growing national health infrastructure. Yet, deficiencies in the resulting federal law cheated the Centers for Medicare and Medicaid Services (CMS) out of the power to create a truly comprehensive federal privacy system that superceded and improved upon state privacy protections. As a result, the federal Privacy of Individually Identifiable Health Information (PIHI) regulations made under HIPAA featured what is sometimes called cooperative preemption, which sets a federal floor that states may exceed.<sup>806</sup> As flaws in the PIHI regulations became more obvious and the Bush Administration reduced federal requirements,<sup>807</sup> the gap between the federal floor and the more stringent state law became evident, and privacy advocates looked to the states to carry the federal flag of reducing patient privacy costs externalized by providers.

Such differences between state and federal law, coupled with interstate inconsistencies, jeopardize efficient workings of national markets for technologically-mediated healthcare. The FTC has expressed particular interest in "state and local regulations, such as occupational licensing and physical office requirements, that may have pro-consumer and procompetition goals, but that nevertheless may restrict the entry of new Internet competitors or hamper their operations."<sup>308</sup> One of the businesses explicitly on the FTC radar is "Healthcare, Pharmaceuticals, and Telemedicine."<sup>300</sup> The agency has already weighed in on Connecticut's attempts to regulate cross-border sales of replacement prescription contact lenses. It found that requiring sellers of replacement contact lenses to obtain Connecticut optician and optical licenses would harm the public health by increasing costs. Those increased costs would in turn result in people replacing their contacts less frequently than recommended.<sup>310</sup> Similarly, in its report on online interstate sales of wine, the FTC

309. Id.

310. In Re: Declaratory Ruling Proceeding on the Interpretation and Applicability of Various Statutes and Regulations Concerning the Sale of Contact Lenses, Comments of the Staff of the Federal Trade Commission, Intervenor (Mar. 27, 2002), http://www.ftc.gov/be/v020007.htm.

<sup>306. 45</sup> C.F.R. §§ 160.201-.205 (2003).

<sup>307.</sup> An example is removing any requirements of consent for data used for TPO purposes. *Id.* § 164.506.

<sup>308.</sup> Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the House Comm. on Energy and Commerce, 107th Cong. (2002) (prepared statement of Ted Cruz, Director of the Office of Policy Planning, Federal Trade Commission); see Virginia Postnel, A Look at Wine Sales over the Internet Shows the Price of Some Regulations in the Name of Consumer Protection, N.Y. TIMES, July 17, 2003, at C2.

concluded that "consumers could reap significant benefits if they had the option of purchasing wine online from out-of-state sources and having it shipped directly to them. Consumers could save money, choose from a much greater variety of wines, and enjoy the convenience of home delivery."<sup>311</sup> The agency also noted that where such bans have been successfully challenged "states appear to have found means of satisfying their tax and other regulatory goals that are less restrictive than an outright ban."<sup>312</sup>

From questions posed by the agency to prescribing and dispensing stakeholders, it seems clear that the FTC is attempting to assess the degree to which medical licensure laws have chilled interstate drug traffic.<sup>313</sup> What remains to be seen is whether the Commission can be persuaded of the benefits of online healthcare and the importance of a national e-health market, or if states can achieve their public health policies associated with pharmaceutical distribution with regulation that is less restrictive than framed local licensure.

# 2. The Specter of the Dormant Commerce Clause

This picture of uneasy federalism in the United States exists beyond political and economic domains. State regulation that discriminates between intrastate and interstate e-health scenarios may face constitutional challenge.<sup>314</sup> The Commerce Clause that gives Congress the power to regulate commerce "among the several States"<sup>315</sup> not only grants interstate powers to Congress but also has a "dormant" or "reverse" aspect that limits the power of the states to regulate interstate commerce.<sup>316</sup> No court has

312. Id.

<sup>311.</sup> FED. TRADE COMM'N, POSSIBLE ANTICOMPETITIVE BARRIERS TO E-COMMERCE: WINE 4 (2003), http://www.ftc.gov/os/2003/07/winereport2.pdf.

<sup>313.</sup> FED. TRADE COMM'N, PUBLIC WORKSHOP: POSSIBLE ANTICOMPETITIVE EFFECTS TO RESTRICT COMPETITION ON THE INTERNET, FOURTH SESSION—TELEMEDICINE AND ONLINE PHARMACEUTICAL SALES 593-664 (2002) [hereinafter PUBLIC WORKSHOP],

http://www.ftc.gov/opp/ecommerce/anticompetitive/021009antitrans.pdf.

<sup>314.</sup> In addition to the Commerce Clause arguments discussed in this Section a clumsilyworded state law could infringe the Privileges and Immunities Clause if it insisted on, for example, the residence of a physician in the state as a condition of licensure. *See supra* note 40.

<sup>315.</sup> U.S. CONST. art. I, § 8, cl. 3.

<sup>316.</sup> See, e.g., Oregon Waste Sys. v. Dep't of Envtl. Quality, 511 U.S. 93 (1994); Dennis v. Higgins, 498 U.S. 439, 447 (1991); Passenger Cases, 48 U.S. (7 How.) 283 (1849); Willson v. Black Bird Creek Marsh Co., 27 U.S. (2 Pet.) 245 (1829). The court in *Kassel v. Consolidated* 

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considered the constitutionality of state statutes that seek to regulate Internet prescribing or dispensing.<sup>317</sup> Notwithstanding recent judicial approval of state spam regulation,<sup>318</sup> decisions striking down state laws regulating interstate e-commerce in wine<sup>319</sup> and protected speech<sup>320</sup> suggest that overreaching legislative activity affecting cross-border prescribing or dispensing could face serious constitutional challenge.

While the possibility of a dormant commerce clause challenge is easy to state, the resolution of such a challenge is far more difficult to predict. First, modern scholarship has identified judicial overreaching in the early e-commerce cases, particularly in cases that rely on "chilling" or "inconsistent regulation" analysis.<sup>321</sup> Second, dormant commerce clause jurisprudence is replete with deferential references to "state legislation in the field of safety where the propriety of local regulation has long been recognized."<sup>322</sup> Third, there is a threshold question, related to the second

*Frieghtways Corp.* stated that "[t]he Clause requires that some aspects of trade generally must remain free from interference by the States. When a State ventures excessively into the regulation of these aspects of commerce, it 'trespasses upon national interests'... and the courts will hold the state regulation invalid under the Clause alone." 450 U.S. 662, 669 (1981) (internal citations omitted).

317. Cf. Nat'l Pharms. v. Feliciano-de-Melecio, 221 F.3d 235 (1st Cir. 2000) (interpreting a Puerto Rican pharmacy statute as not applying to mail-order pharmacies based outside of Puerto Rico and therefore not reaching the constitutional issues). Pre-Internet cases are discussed below. See infra text accompanying note 331-336.

318. See, e.g., Ferguson v. Friendfinders, Inc., 115 Cal. Rptr. 2d 258 (Ct. App. 2002) (holding that a statute governing unsolicited commercial e-mail does not unconstitutionally burden interstate commerce).

319. See, e.g., Dickerson v. Bailey, 212 F. Supp. 2d 673 (S.D. Tex. 2002) (holding that Texas Alcoholic Beverage Code that allowed consumers to purchase wines from Texas wineries and to have the wines shipped to their homes, but expressly prohibited such activity as to out-of-state wineries, violated the dormant Commerce Clause); see also Heald v. Engler, 342 F.3d 517 (6th Cir. 2003); Bolick v. Danielson, 330 F.3d 274 (4th Cir. 2003); Beskind v. Easley, 325 F.3d 506 (4th Cir. 2003); Swedenburg v. Kelly, 232 F. Supp. 2d 135 (S.D.N.Y. 2002).

320. See, e.g., Am. Booksellers Found. for Free Expression v. Dean, 202 F. Supp. 2d 300 (D. Vt. 2002).

321. Goldsmith & Sykes, Dormant Commerce Clause, supra note 221; see also James E. Gaylord, Note, State Regulatory Jurisdiction and the Internet: Letting the Dormant Commerce Clause Lie, 52 VAND. L. REV. 1095 (1999).

322. Pike v. Bruce Church, Inc., 397 U.S. 137, 143 (1970) (citing S. Pac. Co. v. Arizona, 325 U.S. 761, 796 (Douglas, J., dissenting)). *But see* Kassel v. Consolidated Freightways Corp., 450 U.S. 662, 670 (1981) ("[T]he incantation of a purpose to promote the public health or safety does not insulate a state law from Commerce Clause attack. Regulations

reservation, as to whether commerce clause analysis appropriately applies to dangerous or impure goods or services that clearly will be the targets of some state Internet prescribing and dispensing regulation.<sup>323</sup> Fourth, in challenges to state prescribing and dispensing regulation, the courts will likely attempt to avoid the constitutional question by first attempting to interpret the suspect state law as having only intrastate effects.<sup>324</sup>

Traditionally explained, dormant commerce clause analysis distinguishes between state regulation that impinges on cross-border commerce and regulation that facially discriminates between interstate and intrastate commerce. The former is assessed under a balancing test,<sup>325</sup> while the latter is assessed under strict scrutiny.<sup>326</sup> Therefore, the first challenge is to identify the correct test for the various types of Internet prescribing and dispensing regulation that may be confronted. The majority of state ehealth law is not facially discriminatory. This seems to be the case with state laws that require physicians who are engaged in the "practice of medicine" within the state to be licensed or to have telemedicine practice certificates. In such cases, the out-of-state physician resisting such "foreign" regulation presumably would have to argue that the state requirement of licensure impinges on cross-border commerce. If the state law contains granular consent requirements, the argument could be extended to allege inconsistent regulation premised on multiple state laws requiring, for

323. Pike, 397 U.S. at 143; see also Sligh v. Kirkwood, 237 U.S. 52, 59-60 (1915).

324. See, e.g., Nat'l Pharms. v. De Melecio, 221 F.3d 235 (1st Cir. 2000). A direct-indirect burdens test may also be used. "Occasionally the Court has candidly undertaken a balancing approach in resolving these issues, but more frequently it has spoken in terms of "direct" and "indirect" effects and burdens." *Pike*, 397 U.S. at 142 (internal citations omitted).

325. In Pike, the court noted:

Id. at 142 (internal citation omitted).

326. Kassel v. Consol. Freightways Corp., 450 U.S. 662 (1981).

designed for that salutary purpose nevertheless may further the purpose so marginally, and interfere with commerce so substantially, as to be invalid under the Commerce Clause.").

Although the criteria for determining the validity of state statutes affecting interstate commerce have been variously stated, the general rule that emerges can be phrased as follows: Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

example, different consent specifics. Applying a balancing analysis, including deference to state public health interests, and assuming that the state would argue that the physician or pharmacist was capable of identifying the residence of the patient, it would be a brave court that would strike down such local regulation on Commerce Clause grounds.<sup>327</sup>

In contrast, strict scrutiny could well apply to state regulations that differentiate between intrastate and interstate activities. For example, Montana applies its telemedicine-specific regulation only to interstate exchanges between physician and patient,<sup>378</sup> and West Virginia defines the "practice of telemedicine" as diagnosis or treatment by out-of-state physicians,<sup>329</sup> while several states now require their local pharmacists to reject or further investigate (and hence chill the market in) Internet (and typically interstate) prescriptions.<sup>330</sup>

Pre-Internet bricks-and-mortar and mail order decisions contribute little to the analysis. However, in *State v. Rasmussen*,<sup>331</sup> an Iowa pharmacy challenged a state law that made it unlawful for the pharmacy to dispense prescriptions written by out-of-state physicians who were not licensed in Iowa. The court rejected strict scrutiny because the "Iowa statute does not discriminate in its language between foreign practitioners and those registered in Iowa—all are required to register under the provisions of the Iowa Act in order to dispense drugs in Iowa."<sup>332</sup> Due to its indirect protectionist effects, the court still viewed the regulation as constitutionally infirm under a balancing test.<sup>533</sup> Given that the state-federal regulatory mix was more sophisticated and structured than anything seen to date in the Internet prescribing or dispensing domains (the Iowa statute was passed pursuant to the Uniform Controlled Substances Act<sup>334</sup> and synchronized with the federal Comprehensive Drug Abuse Prevention and Control Act of 1970<sup>335</sup> implicitly

331. 213 N.W.2d 661 (Iowa 1973).

332. Id. at 667.

333. *Id.* at 667-68; *cf.* Nichols v. Bd. of Pharm., 657 P.2d 216 (Or. Ct. App. 1983) (holding that an Oregon statute which permitted pharmacies to fill only prescriptions written by practitioners licensed only in Oregon was not in "positive conflict" with federal law).

334. UNIFORM CONTROLLED SUBSTANCES ACT (1994).

335. 21 U.S.C. § 801(a) (2000).

<sup>327.</sup> See Tenn. Op. Atty. Gen. No. 98-202, 1998 WL 851333 (Oct. 28, 1998). An alternative set of arguments could apply in the case of a First Amendment argument. See generally Gaylord, supra note 321.

<sup>328.</sup> MONT. CODE ANN. § 37-3-342 (2003).

<sup>329.</sup> W. VA. CODE ANN. § 30-3-13 (Michie 2002).

<sup>330.</sup> CAL. BUS. & PROF. CODE § 2242.1(b) (West 2003); TEX. ADMIN. CODE §§ 291.34, 291.36 (West 2004).

reducing the role of state-based regulation of interstate activities), some might argue that a limited reading of *Rasmussen* is appropriate. Nonetheless, *Rasmussen* is familiar to state attorneys general and clearly informs some conservative opinions warning state legislatures to stay clear of protectionist policies or interstate regulation.<sup>336</sup>

# B. The Failure of Self-Regulation

Various types of self or private regulation have been promoted as a solution to emerging issues in technologically-mediated care. This is consistent with the broader world of Internet interaction and e-commerce. There, the call for self-regulation has been a product of: 1) utopian views of how cyberspace regulation *should* be disconnected from traditional regulation;<sup>337</sup> 2) a desire not to impede e-commerce with extensive governmental regulation; and 3) a reflection of the general lack of preparedness of traditional regulatory standards and agencies to deal with Internet phenomena. In the health arena, self-regulation is of particular significance because of the historical impact of American Medical Association (AMA) ethical standards and, more narrowly, because of the frequently praised VIPPS accreditation system.<sup>338</sup>

Four types of self-regulatory systems have demonstrated traction in the e-health domain. The first system is purely aspirational: a code of conduct promulgated by some group, often a not-for-profit organization, with a hope of voluntary compliance.<sup>339</sup> Obviously, codes that are promulgated by important stakeholders or that reach a critical mass of adopters tend to be more effective in catching the attention of consumers and attracting further adopters. Typically, compliance is voluntary and not policed. The second system is one that signifies participation in the self-regulatory process by making available a "kitemark" or "trustmark."<sup>340</sup> Such a scheme

340. See, e.g., The Health on the Net Foundation (HonCode), at http://www.hon.ch (last

<sup>336.</sup> See, e.g., Tex. Atty. Gen. Op. JM-555, 1986 WL 219401.

<sup>337.</sup> As Dan Hunter puts it, "[T]he received wisdom has confused the descriptive question of whether we think of cyberspace as a place with the normative question of whether we should regulate cyberspace as a regime independent of national laws." Hunter, *supra* note 298, at 443.

<sup>338.</sup> For more information on the accreditation system, see VIPPS, *at* http://www.nabp.net/vipps/ (last visited Apr. 17, 2004).

<sup>339.</sup> See, e.g., eHealth Code of Ethics, Internet Healthcare Coalition, at http://www.ihealthcoalition.org/ethics/ehcode.html (last visited Apr. 17, 2004); Hi-Ethics Ethical Principles For Offering Internet Health Services to Consumers, Hi-Ethics, at http://www.hiethics.org/Principles/index.asp (Apr. 17, 2004).

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assumes the existence of a rudimentary code authority that owns the intellectual property in the trustmark and, at least in theory, will act to stop fraudulent use of the trustmark or its continued use by those out of code compliance. Along with the simpler code model, it is primarily dependent upon self-rating and, as the number of adopters grows, the likelihood of non-compliance will increase.<sup>341</sup>

The third type of system is a variant of the second, except that it is not wholly dependent upon self-rating. The scheme uses either a centralized or peer (de-centralized) system that applies (or checks the application of) the code's quality criteria.<sup>342</sup> It is not necessarily self-regulatory or voluntary in that the rating authority may apply quality criteria regardless of the content owner's wishes, a characteristic that is itself the source of potential legal problems.<sup>343</sup> The fourth type of system is a code that operates conterminously with an existing membership or ethically-constraining system, such as when a medical society issues guidelines for how its membership might navigate particular web or email issues.<sup>344</sup>

Some codes of conduct that associate membership or compliance with a data object (such as a trustmark or an Internet domain such as dot.health) attempt to increase their robustness and penetration by leveraging web technologies. Again, there are several models. For example, a trustmark system whose data object complies with the Platform for

342. See, e.g., About MedCIRCLE, MedCIRCLE, at

visited Apr. 17, 2004); Truste, eHealth Privacy Seal Program, at

http://www.truste.org/programs/pub\_ehealth.html (last visited Apr. 17, 2004).

<sup>341.</sup> There are two reasons for this decline in compliance: First, the larger the number of adopters the higher are the costs of discovering non-compliance; second, as the number of adopters grows so more marginal players will be attracted to the model because the trustmark will have increasing market-access or marketing value.

http://www.medcircle.org/about.php?lanxid=641562d82ald56a797812c7f0dfabb2d (last visited Apr. 17, 2004).

<sup>343.</sup> See generally Nicolas P. Terry, Rating the "Raters": Legal Exposure of Trustmark Authorities in the Context of Consumer Health Informatics, at 2 J. MED. INTERNET RES. e18 (2000), available at http://www.jmir.org/2000/3/e18/.

<sup>344.</sup> See, e.g., AM. MED. ASS'N, ETHICAL GUIDELINES FOR THE USE OF ELECTRONIC MAIL BETWEEN PATIENTS AND PHYSICIANS (CEJA Report 3-I-02, 2002) [hereinafter AM. MED. ASS'N, ETHICAL GUIDELINES], http://www.ama-

assn.org/ama1/pub/upload/mm/369/ceja\_report\_3i02.pdf; Press Release, Am. Med. Ass'n, AMA Adopts New Guidelines To Help Physicians Ensure Safe and Secure Internet Prescribing (June 19, 2003) [hereinafter AMA Adopts], http://www.amaassn.org/ama/pub/article/1616-7802.html.

Internet Content (PICS) specifications<sup>345</sup> could leverage "downstream filtering,"<sup>346</sup> allowing a patient to use browser or third party software to rate or exclude content by reference to the data object.<sup>347</sup> A second type is "upstream filtering," which is more likely to leverage a distinct "top-level domain" (TLD),<sup>348</sup> a system favored by the World Health Organization.<sup>349</sup> Assume, for example, that only certain health content providers (e.g., professional bodies or peer-reviewed sites) would be granted a dot.health TLD name. Then web directories could list them separately or search engines could prioritize them in search results. A third type of technology layer added to self-regulatory systems may be described as closed-loop verification. Most trustmark systems allow or compel the trustmark user to "link" the trustmark: Rudimentary systems link back to the trustmark authority's principles or code of conduct. More sophisticated systems, however, close the loop by linking to a specific page on the trustmark authority's site that verifies the good standing of the trustmark user.<sup>350</sup> Such an interlinking model decreases fraudulent use of the trustmark and encourages code compliance by facilitating consumer feedback to the trustmark authority.

#### 1. Content Regulation

The integrity and reliability of Internet health information has been of acute concern to the medical profession,<sup>351</sup> although patients seem to be

http://www.hon.ch/HONcode/Conduct.html?HONConduct386169).

351. See Site Reading Physicians Grapple with Recommending Web Sites, AMNews, at http://www.ama-assn.org/sci-pubs/amnews/pick\_00/tesa1023.htm (Oct. 23/30, 2000); see also Berland et al., Health Information on the Internet: Accessibility, Quality, and Readability in English and Spanish, 285 JAMA 2612 (2001); KM Griffiths & H. Helen Christensen, Quality of Web Based Information on Treatment of Depression: Cross Sectional Survey, 321 BRIT. MED. J. 1511

<sup>345.</sup> PICS is a specification frequently used in filtering applications and allows labels to be associated with specific internet content.

<sup>346.</sup> Filtering generally will likely become more common on the web following the Supreme Court's opinion in United States. v. Am. Library Ass'n, Inc., 123 S. Ct. 2297 (2003) (upholding Children's Internet Protection Act that conditioned federal assistance of public libraries on the installation of filtering software to block obscene or pornographic images).

<sup>347.</sup> See, e.g., MedCIRCLE, at http://www.medcircle.org/ (last visited Apr. 17, 2004).

<sup>348.</sup> See ICANN, at http://www.icann.org/tlds/ (last visited Apr. 17, 2004).

<sup>349.</sup> *TLD Application for .health*, ICANN, *at* http://www.icann.org/tlds/health1/ (last visited Apr. 17, 2004). The WHO's initial application was denied, but is being renewed. *See Domain Firms Get Second Shot at ICANN Approval*, COMPUTERWIRE, June 25, 2003.

<sup>350.</sup> See, e.g., healthAtoZ, at http://www.healthatoz.com/ (last visited Apr. 17, 2004) (linking to its HONCode verification page at

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more accepting of the medium's flaws.<sup>352</sup> The pursuit of Internet content quality assurance exists in something of a legal vacuum. Public law intervention tends to be limited to obviously dangerous health content where government agencies<sup>353</sup> can apply their traditional consumer protection, drug regulation, and fraud powers.<sup>354</sup> More robust public law regulation or private litigation is likely to conflict with guarantees of free speech.<sup>355</sup> Several well-known codes of conduct have sought to fill this vacuum.<sup>356</sup> Specifically, the European Commission has endorsed this approach by publishing its own "Quality Criteria for Health Related Websites."<sup>357</sup>

In the area of medical web content, the focus of self-regulatory systems has been to strengthen the role of the market by reducing the patient's information costs regarding the integrity and reliability of health information on the web. Such improvements could positively influence the growth of, and regulatory attitudes towards, Internet prescribing and dispensing because prescribing sites tend to contain medical and health information and content sites frequently link to prescribing or fulfillment sites.

Unfortunately, the self-regulatory content system is dangerously flawed. Trustmarks are easily copied and pasted into non-compliant sites with the link back to the trustmark authority conveniently omitted. Content and prescribing sites also use counterfeit trustmarks that resemble well-known trustmarks. There are also no constraints on who can create a

353. See, e.g., Press Release, Fed. Trade Comm'n, Eli Lilly Settles FTC Charges Concerning Security Breach (Jan. 18, 2002), http://www.ftc.gov/opa/2002/01/elililly.htm.

354. See supra notes 235-242 and accompanying text.

355. See Nicolas P. Terry, Cyber-Malpractice: Legal Exposure for Cybermedicine, 25 AM. J.L. & MED. 327 (1999).

356. See supra notes 339-340.

357. Quality Criteria for Health Related Websites, Information Society, at http://europa.eu.int/information\_society/eeurope/ehealth/quality/draft\_guidelines/ind ex\_en.htm (last visited Apr. 17, 2004).

<sup>(2000),</sup> http://www.bmj.com/cgi/content/full/321/7275/1511.

<sup>352.</sup> Cyberchondriacs Continue To Grow in America, HEALTH CARE NEWS, May 8, 2002, http://www.harrisinteractive.com/news/newsletters/healthnews/HI\_HealthCareNews2002 Vol2\_Iss09.pdf. According to a Harris Interactive survey in 2000, fifty-six percent of respondents were of the opinion that the Internet helped them gain an understanding of their health problems; this compares to seventy-three percent in the 1999 survey. There were also declines in how patients viewed the Internet as helping them manage their personal healthcare overall (sixty percent down to forty-one percent) and communicate with their doctor (fifty-one percent down to twenty-nine percent).

self-regulatory or trustmark system. For example, the Council for Responsible Telemedicine (CRT)<sup>358</sup> was formed by three Internet prescribing companies that have been involved in several regulatory skirmishes with state boards. The AMA was less than impressed by the CRT's position on supplying lifestyle drugs.<sup>359</sup> Even assuming that a trustmark is valid and that users accurately self-rate themselves, the sheer shallowness of most self-regulatory standards creates concern.<sup>360</sup> Overall, it is arguable that all benefits to patients from self-regulatory codes are outweighed by the risks of overconfidence generated by valid trustmarks or outright fraud from the counterfeit ones.

One system that has the potential to counter this negative conclusion is the Health Web Site Accreditation Program instituted by the Utilization Review Accredidation Commission (URAC).<sup>361</sup> There are several reasons for this optimism: the URAC standards are robust;<sup>362</sup> an accreditation model is substituted for suspect self-rating or unfunded and impractical external review; trustmark posting is subject to closed-loop verification; and URAC offers sophisticated downstream filtering via an external search engine.<sup>363</sup>

#### 2. The Physician-Patient Relationship

As already noted, there has been considerable professional angst about the legal and ethical issues surrounding electronic communications between physicians and patients.<sup>364</sup> The most authoritative discussion of this issue has been the guidelines issued by the American Medical

<sup>358.</sup> Council for Responsible Telemedicine, at

http://www.councilforresponsibletelemedicine.org/ (last visited Apr. 17, 2004).

<sup>359.</sup> Questions Linger over Group's "Responsible" Prescribing, AMNews, at http://www.ama-assn.org/sci-pubs/amnews/pick\_02/bisc1014.htm (Oct. 14, 2002).

<sup>360.</sup> See, e.g., HON Code of Conduct (HONcode) for Medical and Health Web Sites, Health on the Net Foundation, at http://www.hon.ch/HONcode/Conduct.html (last visited Apr. 17, 2004).

<sup>361.</sup> URAC, *at* http://webapps.urac.org/websiteaccreditation/default.htm (last visited Apr. 17, 2004). URAC is also known as the American Accreditation HealthCare Commission.

<sup>362.</sup> Health Web Site Standards, URAC, at

http://webapps.urac.org/websiteaccreditation/Portal/Business/Docs/web%20site%20stds %20v1-0.doc (last visited Apr. 17, 2004).

<sup>363.</sup> VitalSeek, at http://www.vitalseek.com/ (last visited Apr. 17, 2004).

<sup>364.</sup> See supra notes 254-267 and accompanying text.

Informatics Association.<sup>365</sup> As with the more recent amendments to the AMA Ethics Policy,<sup>366</sup> these guidelines assume an existing physician-patient relationship.<sup>367</sup> The AMA policy seems even more restrictive, asserting that "[e]-mail correspondence should not be used to establish a patient-physician relationship. Rather, e-mail should supplement other, more personal, encounters."<sup>368</sup>

That idea of enhancing an existing relationship, coupled with a firm belief that interpersonal interaction is at the core of the patient-physician relationship, has dominated the way the AMA has addressed online medicine. In the process, it has taken a position that has been consistently hostile to Internet prescribing and dispensing. For example, an AMA policy pledges that the organization will "work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications."<sup>369</sup> That same policy pledges to "work with federal and state regulatory bodies to close down Internet web sites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States."<sup>370</sup>

This approach was reiterated and expanded upon by AMA guidelines issued in 2003 that deal specifically with Internet prescribing. The Guidance for Physicians on Internet Prescribing endorses requiring licensure in the patient's state of residence.<sup>371</sup> Further, it reiterates the AMA's position that an existing physician-patient relationship and a physical examination are prerequisites for online prescribing.<sup>372</sup> In

115.997.HTM&nxt\_pol=policyfiles/HOD/H-120.950.HTM&.

<sup>365.</sup> See supra note 261.

<sup>366.</sup> AM. MED. ASS'N, ETHICAL GUIDELINES, supra note 344.

<sup>367.</sup> However, the American Medical Informatics Association's (AMIA) guidelines use the more ambiguous term "contractual relationship." *See supra* note 261.

<sup>368.</sup> CEJA REPORT, supra note 344, at para. 1.

<sup>369.</sup> AM. MED. ASS'N, H-120.956(3) INTERNET PRESCRIBING (BOT Rep. 35, A-99), http://www.ama-

assn.org/apps/pf\_online/pf\_online?f\_n=browse&doc=policyfiles/HOD/H-

<sup>120.956.</sup>HTM&&s\_t=&st\_p=&nth=1&prev\_pol=policyfiles/HOD/H-

<sup>370.</sup> Id. at H-120.956(6).

<sup>371.</sup> AM. MED. ASS'N, GUIDANCE FOR PHYSICIANS ON INTERNET PRESCRIBING (Resolution 518, A-02, 2003), http://www.ama-assn.org/ama1/upload/mm/annual03/bot7a03.doc; *see also* AMA Adopts, *supra* note 344.

<sup>372.</sup> AMA Adopts, supra note 344. The release states:

commentary, the guidelines state that "[w]eb sites that offer a prescription solely on the basis of an online questionnaire (or online consultation) with no other interaction between the physician and patient are insufficient."<sup>373</sup> This type of regulation is typical of a code model that operates conterminously with a closed professional system. It is noticeably conservative and uncompromising in the hard position it takes towards online prescribing.

## 3. Pharmacy Regulation and VIPPS

The National Association of Boards of Pharmacy (NABP) has been no less hostile to Internet dispensing, but it has shown more interest in leveraging web technology to decrease patient information costs. Its wellknown response to Internet dispensing and fulfillment is the Verified Internet Pharmacy Practice Sites, or "VIPPS," program.<sup>374</sup> VIPPS is a code model that operates conterminously with the closed system of multi-state pharmacy licensure. Indeed, one state allows its Internet pharmacies to choose whether to display its state permit number or VIPPS trustmark.<sup>375</sup> VIPPS resembles an accreditation model, charging participants a fee and performing on-site physical inspection, complaint investigation, and periodic re-inspections.<sup>376</sup> Its trustmark uses closed-loop verification to reduce fraud.

David Brushwood has argued that "[p]romotion of the VIPPS program is the best assurance regulators can provide to the public that individual

Id.

373. Id.

375. ARK. CODE ANN. § 17-92-1005(4) (Michie 2002) (requiring Internet pharmacies to clearly display their state permit number or VIPPS seal on their internet site).

376. VIPPS® Certification Process, *at* http://www.nabp.net/vipps/pharmacy/intro.asp (last visited Apr. 17, 2004).

Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall: obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided; have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s); as appropriate, follow up with the patient to assess the therapeutic outcome; maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and include the electronic prescription information as part of the patient medical record.

<sup>374.</sup> VIPPS, at http://www.nabp.net/vipps/intro.asp (last visited Apr. 17, 2004).

Internet pharmacy users are being protected by the professionalism that state-licensed pharmacists offer through their oversight of the medication use process.<sup>377</sup> While it is correct that VIPPS certification tells us something positive about the few accredited pharmacies, its absence tells us little about the level of risk that the consumer might expect when the pharmacy is not accredited.<sup>378</sup> Thus, VIPPS tends to confirm the status quo without substantially aiding patients who choose to operate outside of the traditional dispensing paradigm.

VIPPS has accredited relatively few sites.<sup>379</sup> VIPPS's apparent requirement of licensure in the patient's state of residence means that, as presently constituted, it is not a solution to the Internet dispensing conundrum, as evidenced by the chilly reception given by Canadian Internet pharmacies towards proposals to extend the program north of the border.<sup>380</sup>

#### C. Under-regulation: Patient Incurred Costs

The goal of medical and pharmacy licensure systems is to promote provider quality and patient safety. In practice, however, the state board processes tend to concentrate on the more inter-personal aspects of the physician-patient relationship,<sup>381</sup> and when quality is addressed, it is done retrospectively.<sup>382</sup> The healthcare system continues to externalize most of its quality and safety risks to patients. This is exacerbated in the areas of Internet prescribing and dispensing, in which regulators concentrate on the method of providing services: technology, questionnaire prescribing, and importation. In practice, patients seeking online care face considerable privacy and quality risks. In Internet prescribing and

382. See Leape, supra note 220.

<sup>377.</sup> Brushwood, supra note 268, at 102-03.

<sup>378.</sup> An absolutist would argue that absent accreditation, the risk is too high. A relativist interested in the market determining the better or safer online unaccredited pharmacists would need more than a null response.

<sup>379.</sup> See VIPPS Database Search Results, at http://www.nabp.net/vipps/consumer/listall.asp (last visited Apr. 17, 2004).

<sup>380.</sup> See, e.g., Carl Bialik, U.S., Canada Pharmacy Groups Seek To Deter Exporting of Drugs, WALL ST. J., Nov. 13, 2002, at D3.

<sup>381. 1</sup> AVEDIS DONABEDIAN, THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT 4 (1980) ("Technical care is the application of the science and technology of medicine, and of the other health sciences, to the management of a personal health problem. Its accompaniment is the management of the social and psychological interaction between client and practitioner.").

dispensing, these risks are undervalued and under-regulated.

### 1. The Privacy Externality

As with other information domains, technology has dramatically changed the way patient health data is acquired, stored, aggregated, processed, accessed, and distributed. Additionally, there are inherent tensions in the health information domain between the key stakeholders and their needs: government access and security for public health;<sup>383</sup> healthcare institutions' access for quality assurance and marketing; and patient interests in confidentiality, privacy, and anonymity.<sup>384</sup>

Few pieces of legislation or regulation in contemporary healthcare law have been as controversial as the privacy<sup>385</sup> and security<sup>386</sup> regulations promulgated under HIPAA.<sup>387</sup> Designed to force providers to internalize privacy and security risks associated with technologically-mediated care, record-keeping, and billing, the HIPAA regulations are primarily applicable to bricks-and-mortar care providers.<sup>388</sup> Technical limitations in the HIPAA statute were primarily responsible for this limitation,<sup>389</sup> though it is also the case that, principally, the regulations were drafted prior to the explosive growth of Internet prescribing and dispensing. Conceptually, the PIHI standards, as they exist today, are similar to, but not co-extensive with, the statutory controls that exist in a small minority of U.S. states,<sup>390</sup> and the

385. Privacy Standards (Privacy of Individually Identifiable Health Information or PIHI), Final Rule, 67 Fed. Reg. 53182 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160, 164).

386. Security Standards Final Rule, 68 Fed. Reg. 8334 (Feb. 20, 2003) (to be codified at 45 C.F.R. pts. 160, 162, 164).

387. See supra note 207.

http://www.healthprivacy.org/usr\_doc/PIP\_HPP\_HealthPriv\_report.pdf; Press Release, Pew Internet & American Life Project, Federal Health Privacy Regulation Does Not Cover Most Internet Medical Searches, Services, or Purchases (Nov. 19, 2001), http://www.pewinternet.org/releases/release.asp?id=33.

389. The limited definition of "covered entity" in the federal regulations is one example. 45C.F.R. § 160.103 (1982).

390. See, e.g., CAL. CIV. CODE § 56.10 (1982); see also UNIFORM HEALTH CARE INFORMATION

<sup>383.</sup> See, e.g., Senate Blocks Privacy Project, N.Y. TIMES, Jan. 24, 2003, at A3 (reporting U.S. Senate vote against Pentagon project to search for terrorists by scanning information in Internet mail and, inter alia, databases of health companies).

<sup>384.</sup> See generally Nicolas P. Terry, Privacy and the Health Information Domain: Properties, Models and Unintended Results, 10 EUR. J. HEALTH L. 223, 223-27 (2003).

<sup>388.</sup> See generally Angela Choy et al., Health Privacy Project, Exposed Online: Why the New Federal Health Privacy Regulation Doesn't Offer Much Protection to Internet Users (2001),

federal rules do not preempt more rigorous state patient privacy protections.

Patients who go online for medical care or prescriptions are poorly served by PIHI or PIHI-like<sup>391</sup> regulations. Such regulations are usually described as protecting patient *privacy*. In fact, it is more accurate to describe them as disclosure-centric rules that protect patient *confidentiality*. Confidentiality places limits on disclosure, while privacy, much like anonymity,<sup>392</sup> is functionally an antecedent to confidentiality, limiting data collection. Federal and state "privacy" rules generally fail to protect against the collection of patient data or frustrate its collection with anonymity rights.<sup>393</sup> True health privacy protection is, in most U.S. jurisdictions, limited to older common law rules that are limited and lack generalized robustness. They tend to be nominate and discrete rules rather than applications of any general privacy principle.<sup>394</sup>

Amongst those who provide online care, traditional telemedicine practitioners are likely to be PIHI-covered entities.<sup>395</sup> As a result they will be over-regulated when they also fall under revised telemedicine statutes that require specific disclosures or protections relating to privacy and security.<sup>396</sup> In contrast, non-traditional providers, such as those engaged in Internet prescribing and dispensing (larger e-pharmacies and PBMs aside), generally are not covered by disclosure-centric regulation. Thus, they tend to be under-regulated. Privacy regulation affecting this latter group generally will be limited to scenarios where the business has published a privacy policy that it then breaches.<sup>397</sup>

392. Anonymity enhances privacy by frustrating the collection of personal identifiers. 393. *See* Terry, *supra* note 384, at 223-37.

394. RESTATEMENT (SECOND) OF TORTS § 652A(2); see, e.g., Knight v. Penobscot Bay Med. Ctr., 420 A.2d 915 (Me. 1980) (involving doctor taking photographs of dying cancer patient); Berthiaume v. Pratt, 365 A.2d 792 (Me. 1976) (finding that where nurse's husband watched plaintiff's wife's delivery the claim failed on the facts because there was no proof of intentional intrusion).

395. See supra note 389 and accompanying text.

397. See, e.g., Press Release, Fed. Trade Comm'n, supra note 353.

ACT, PROPOSED REVISIONS (2000), http://www.law.upenn.edu/bll/ulc/uhcia/hci0600.pdf.

<sup>391.</sup> Even in states with relatively strong privacy protection. *See, e.g.*, CAL. CIV. CODE § 56-56.37 (1982); MONT. CODE ANN. §§ 50-16-501 to 50-6-504 (2003); R.I. GEN. LAWS § 5-37-22 (2004); WASH. REV. CODE §§ 70.02.005 to 70.02.904 (2002); WIS. STAT. §§ 146.83, 610.70(3) (1997).

<sup>396.</sup> See supra notes 85-86 and accompanying text.

#### 2. The Error/Risk Externality

Patient utilization and enthusiasm for all aspects of online care continue to increase,<sup>598</sup> despite considerable skepticism from the medical profession as to its quality.<sup>399</sup> Indeed, there are signs that patients who search for advice are cognizant of declining quality,<sup>400</sup> although not particularly troubled by that phenomenon.<sup>401</sup> Clearly, however, patients using online care (e.g., advice sites, email contact with physicians, telemedicine, telehealth, or Internet prescribing and fulfillment) are internalizing certain costs (risks) that are either not present or not as high in traditional healthcare delivery.

In the Internet prescribing and fulfillment domains, these enhanced risks include: 1) the identity and qualifications of the prescriber; 2) the choice of drug; 3) the quality of the drug; 4) follow-up treatment or advice; and 5) indeterminacy of recourse.<sup>402</sup> Internet users likely have some awareness of the first of these risks, while those who opt for Internet prescribing or dispensing services are likely to have already made the drug choice. Non-traditional channels clearly do not offer the persistence of a physician-patient or pharmacist-patient relationship that tends to guarantee quality care. In the event of a problem with the drug, whether because of fraud or error, recourse against an online provider will be problematic.

It is extremely difficult to map out a constitutionally acceptable legal strategy to control web content or advice<sup>403</sup> in the absence of obviously dangerous activities, products, or services.<sup>404</sup> Not surprisingly, therefore, considerable faith is placed in technological or self-regulatory solutions in an attempt to reduce patient-incurred risks.

Many of the novel risks introduced by online care involve information

402. See generally C. Anderson, A Call for Internet Pharmacies To Comply with Quality Standards, 12 QUALITY SAFETY HEALTH CARE 86 (2003) (discussing poor quality of consumer information on Internet prescribing and dispensing sites (particularly drug interaction information), out-of-date stock, and substitution).

403. See generally Nicolas P. Terry, Cyber-Malpractice: Legal Exposure for Cybermedicine, 25 AM. J.L. & MED. 327 (1999); Nicolas P. Terry, A Transatlantic Perspective on Regulating Health Information, 324 BRIT. MED. J. 602 (2002).

404. See supra notes 235-236 and accompanying text.

<sup>398.</sup> See supra note 352.

<sup>399.</sup> See supra note 351 and accompanying text.

<sup>400.</sup> See supra note 352.

<sup>401.</sup> Online Medical Advice Expands: Some Data Shaky, but Public Unfazed, MIAMI HERALD, Jan. 05, 2003.

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costs incurred by patients. These include the quality-related risks such as the identity and qualifications of the prescriber as discussed above. Specifically, the cost-quality-access formula has different values in the online context. The conventional health law tool for dealing with information asymmetry or choice is informed consent. Case law has not yet developed in this area, but as already noted,<sup>405</sup> some state legislatures have introduced enhanced consent provisions for some aspects of online care that may affect prescribing or dispensing. These provisions, however, tend to focus on warning of risks associated with Internet prescribing and dispensing, or on the mechanics of telemedical services, such as security, privacy, or other unarticulated "technology" risks that seem less conducive to improving patient choice.

### D. Over-regulation

There is no doubt that states, encouraged by federal regulators and professional organizations, are attacking Internet prescribing and dispensing with reformulated regulatory standards and renewed enforcement vigor. Across the country, medical boards, assisted by compliant attorneys general, are seeking injunctive relief against physicians and pharmacists who stray into their states' web space. Some of this regulation and enforcement is prophylactic. States are finding it easier to use licensure regulation than prove the more difficult burdens associated with, say, the *mens rea* component for illegal drug distribution or the elements of consumer fraud.

The state boards and the AMA have articulated two primary objections to Internet prescribing. First, it operates independent of a physicianpatient relationship, and second, drugs are prescribed in the absence of a physical examination. These two features are deeply offensive to the medical establishment's view of how healthcare is or should be delivered. That paradigm is centered on an in-person office consultation between an informed professional and compliant patient who are in a long-term relationship. The physician performs a fact-finding inquiry, including a physical examination, that informs the diagnosis and, where appropriate, the writing of a prescription. The patient takes the prescription to a bricksand-mortar pharmacy or a VIPPS certified e-pharmacy, where an additional layer of error-checking occurs and additional effects and interaction information may be provided.

For some regulators, the absence of a physician-patient relationship or

<sup>405.</sup> See supra notes 77-83 and accompanying text.

physical examination is little more than code for technophobia or a conflation of normative objections to Internet prescribing with regulatory language that best identifies its practitioners. Both of these traditional indicators, however, have deeper constructs and cannot be lightly dismissed.

The "physician-patient relationship" concept exists in three overlapping domains: ethical, legal, and operational. As an ethical construct, it is the foundation of competence, respect, and confidence.<sup>406</sup> In the legal domain, the existence of a "physician-patient relationship" establishes the contractual responsibilities of the parties (such as service and payment) and is the touchstone for legal duty, signifying that the physician must internalize some of the patient's treatment risks.<sup>407</sup>

In the Internet prescribing debate, the "physician-patient relationship" is primarily used in its third operational sense where it is coterminous with "continuity of care." Continuity of care has several components; the most important of which are access to the patient's existing record (and the correlate responsibility of adding to that record to minimize fragmentation of patient data) and availability of follow-up care. Continuity also lowers transaction costs, such as positively identifying the patient and matching her to any ongoing treatment plan (replete with information about possible drug interactions), while its sense of longevity may translate into a more holistic therapeutic plan, rather than purely pharmaceutical treatment. In contrast to this "continuity" model, Internet prescribing is centered on an opportunistic physician-patient relationship, defined by a single pharmaceutical transaction.

The concept of "physical examination" is also multi-layered. It too reduces transactions costs by facilitating the positive identification of the patient and makes it more likely that the white-coated person in the office is actually a licensed physician. Therapeutically, a physical examination may add to the quality of the diagnosis, and a face-to-face interaction may

<sup>406.</sup> See, e.g., Am. Med. Ass'n, Principles of Medical Ethics, June 2001, at http://www.ama-assn.org/ama/pub/category/2512.html (last visited Apr. 17, 2004).

<sup>407.</sup> See, e.g., Sterling v. Johns Hopkins Hosp., 802 A.2d 440 (Md. 2002) (holding that a hospital that accepted the transfer of a patient without having any direct contact with that patient and whose doctor engaged in discussion with patient's doctor over transport options was entitled to summary judgment because its doctor did not have a physician-patient relationship with the patient, who was still under the care of her doctor); Kruger *ex rel.* Estate of Kruger v. Jennings, 2002 WL 344268 (Mich. Ct. App. 2002) (holding that an on-call surgeon who offered advice to the physicians working with a patient could be held to have been in physician-patient relationship because he actively participated in the course of treatment), *superseded by* Kruger v. Jennings, 2002 WL 652098 (Mich. Ct. App. 2002).

provide the physician visual clues as to the patient's health and, perhaps, truthfulness in answering questions. Again, there is a legal and regulatory subtext. An examination places the patient-physician interaction in physical space, facilitating regulatory scrutiny while making it more likely that the provider is a bricks-and-mortar provider covered by modern privacy laws.

Whether or not medical boards articulate or fully explain these objections to Internet prescribing, they know them when they see them; the primary identifier for regulators is substitution of an online questionnaire for aspects of the traditional paradigm.

#### 1. Questionnaire Prescribing

There are no easy answers to the inquiry into exactly what is occurring in the online prescribing interaction between patients and Internet prescribers. It is self-evident that there are websites supplying U.S. patients with prescription drugs without even the most rudimentary safeguards. In such cases, the only requirement for consumer access to controlled substances or prescription drugs is a credit card. The drugs may or may not be fakes; they may or may not be delivered or delivered in good condition; and obtaining the consumer's credit card information may well be the first step in an identity theft fraud. For some regulators, the existence of this unquantified criminal activity may itself be justification for closing down *all* Internet prescribing and dispensing.

From the perspective of regulators, the Internet prescribing case is well-represented by *United States v. Nelson*, in which the United States Court of Appeals for the Tenth Circuit upheld a physician's conviction for conspiracy to prescribe controlled substances and money laundering.<sup>408</sup> Nelson and his co-conspirators created NationPharmacy.com, which distributed controlled substances, particularly the Schedule II painkiller Hydrocodone.<sup>409</sup> Nelson periodically visited the pharmacy and signed thousands of "questionnaire" prescriptions at a time.<sup>410</sup>

We know little about the slightly less seamy side of Internet prescribing and dispensing. This is because state medical boards tend to work off an absolutist model and the physicians and pharmacies they prosecute have little to gain from fighting the charges. It makes more sense for culprits to

<sup>408. 72</sup> Fed. Appx. 837 (10th Cir. 2003).

<sup>409.</sup> See U.S. Drug Enforcement Admin., Hydrocodone, at

http://www.usdoj.gov/dea/concern/hydrocodone.html (last visited Apr. 17, 2004).

<sup>410. 72</sup> Fed. Appx. at 839.
agree to a consent decree, and then register or spoof a new domain name or move on to states with less committed or effective enforcement. An exception is the Kansas case, *State ex rel. Stovall v. Confimed.com, L.L.C.*<sup>411</sup> The first Internet prescribing case to reach a state high court, *Stovall* involved a successful "sting" operation that caught out-of-state prescribers and dispensers delivering prescription drugs. *Stovall* suggests, however, that there are grey areas of Internet prescribing and dispensing and, further, that the courts may not always share the black-and-white antipathy of state boards and prosecutors.

An investigator and the supervised minor son of another investigator purchased Viagra<sup>412</sup> from a website operated by an out-of-state physician; neither the physician nor the pharmacy were licensed to practice in Kansas. The site appeared to be quite robust. It had the usual e-commerce functions, a liability waiver, warnings about the drug, recommended dosage, links to information on the drug manufacturer's site, and required the patient to represent that he had received a recent physical. The female investigator and the minor filled out the diagnostic questionnaire. The minor did not fill out all the diagnosis questions on the form, though he did give symptoms suggesting erectile dysfunction. The minor's order was filled but the female investigator's request for Viagra was initially denied. An employee of the physician-pharmacy contacted the agent and informed her that Viagra could not be supplied to a female. The drug was supplied when the agent resubmitted the order and questionnaire under a false, male name.

Predictably, the trial court granted the state's application to enjoin the defendants from dispensing medication or practicing medicine in Kansas.<sup>413</sup> The issue was whether such conduct breached the state's consumer protection act<sup>414</sup> and enabled the prosecutors to recover attorney fees, investigative fees, and penalties. The trial court held that the consumer protection act was not breached, noting:

[T]here was no actual harm done to anyone. Nothing was misrepresented. All drugs furnished were authentic. The pharmacy expert testified that if the waivers in the orders signed by the investigators were true, more would have been understood by them than 'regular'

<sup>411. 38</sup> P.3d 707 (Kan. 2002).

<sup>412.</sup> A companion case, *State ex rel. Stovall v. DVM Enters.*, 62 P.3d 653 (Kan. 2003), dealt with a similar sting involving controlled substances, but the court came to the same basic conclusion.

<sup>413. 38</sup> P.3d at 709.

<sup>414.</sup> Kan. Stat. Ann. §§ 50-636, 59-623, 59-627 (2004).

doctors and druggists typically advise their patients or customers.  $\dots^{415}$ 

The Supreme Court of Kansas affirmed, refusing to hold that a seventy-five dollar consultation fee, prescribing without a physical examination, or supplying the drug to a minor constituted consumer fraud.<sup>416</sup> Neither the trial court nor the Supreme Court approved of the conduct of the defendant,<sup>417</sup> but the courts were also clearly not pleased by the agents' false representations in conducting the sting. Notably, the Supreme Court made a point of referring to the state's pharmacy expert's statement that "had the purchasers in fact read the manufacturer information about Viagra, they would know more information than [the expert] provides his own customers. *He also admitted that the questions asked on the computerized consultation form were more in depth than those he poses to individuals who have been prescribed Viagra.*"<sup>418</sup>

Of course, not all questionnaires are created equal. For example, some are rudimentary and merely tacked onto the end of order forms, showing contempt for the medical process of prescribing. Some electronic forms have their defaults set in a more dangerous fashion. For example, if medical history questions are pre-answered as "none," the patient has to affirmatively overrule the default.<sup>419</sup> The snapshot of Internet prescribing and dispensing supplied by *Stovall* is not necessarily representative. However, what we learn is that licensed professionals do staff at least some of these sites and that not all prescription requests are automatically filled.

# 2. A Suspect Paradigm: The Realities of Modern Bricks-and-Mortar Medicine

A major component of the "bad medicine" premise behind the targeting of Internet prescribing is that it compares so unfavorably with the bricks-and-mortar paradigm. As succinctly addressed by the physician's attorney in the Kansas Viagra case, "Doctors who prescribe in the office don't examine your equipment, so what is the real medical issue that is not being addressed?"<sup>420</sup> In fact, the prescribing paradigm relied on by state

<sup>415. 38</sup> P.3d at 710 (describing lower court findings).

<sup>416.</sup> *Cf.* ARK. CODE ANN. § 17-92-1007 (Michie 2002) (deeming breach of the Arkansas Internet Prescription Consumer Protection Act to constitute unconscionable conduct under the state consumer protection statute); *see also id.* § 4-88-107.

<sup>417.</sup> The court quoted the trial judge's statement that "these people ought to be defrocked as medical practitioners, as pharmaceutical practitioners." 38 P.3d at 715.

<sup>418. 38</sup> P.3d at 714 (emphasis added).

<sup>419.</sup> Siwolop, supra note 88.

<sup>420.</sup> Web Prescriptions Thrive Despite Sting, WASH. TIMES, Mar. 5, 2002, at A1 (quoting James

regulators bears only passing resemblance to the realities of modern healthcare delivery.

The cradle-to-grave physician-patient relationship has long since disappeared. Continuity of care may be a valid goal, but not one that seems able to co-exist with managed care; it is now employers and HMOs that decide whether the patient has the same physician from one year to the next. Continuity of care is also hard to detect in treatment provided by fee per visit walk-in centers,<sup>421</sup> the pejoratively labeled "doc-in-a-box" or "mall medicine." Here, the AMA has been consistent, approaching these new forms of transient relationships with the same type of concern displayed toward online care, primarily objecting to any misleading use of the term "emergency" in the branding or marketing of these walk-in centers.<sup>422</sup>

The "physician" component of the paradigm is also overstated; collaborative, protocol, or formulary prescribing by nurse practitioners is now widespread,<sup>423</sup> and New Mexico has become the first jurisdiction to permit prescribing by psychologists, independently within a formulary and collaboratively in other cases.<sup>424</sup> The paradigm's reference to a single "physician" is also inaccurate; we now recognize the growth and importance of "shared care,"<sup>425</sup> referring either to more than one physician taking care of a patient or to the growing role and responsibilities of the patient herself in sharing her care with her physician.<sup>426</sup> Research suggests that this is the context for the use of Internet-sourced medical information by patients, not as a substitute for traditional physician-patient relationships, but as a way of increasing their knowledge and asserting

Generation\_Health\_Plan\_\_Not\_If,\_but\_When\_and\_How.htm.

426. David Brushwood puts a normative and questioning spin on this sharing of care between patient and medical professional. Brushwood, *supra* note 268, at 96-97.

R. Jarrow).

<sup>421.</sup> See Milt Freudenheim, Shopping Mall Medicine, N.Y. TIMES (MAGAZINE), Dec. 5, 1982, at 6-146.

<sup>422.</sup> See AM. MED. ASS'N, FREESTANDING EMERGENCY MEDICAL CARE POLICY (1993), http://www.ama-assn.org/apps/pf\_new/pf\_online?f\_n=browse&doc=policyfiles/HnE/H-130.990.HTM (last visited May 1, 2004).

<sup>423.</sup> See, e.g., ALA. CODE § 34-21-81 to -87 (1975).

<sup>424.</sup> N.M. STAT. ANN. § 61-9-17.2 (Michie 2004). This statute has been repealed, effective July 1, 2010.

<sup>425.</sup> See Steve O'Dell & Jim Hansen, The Next-Generation Health Plan: Not If, but When and How, HEALTHPLAN, Mar./Apr. 2003, at

http://www.aahp.org/Content/NavigationMenu/Inside\_AAHP/Healthplan\_Magazine/March\_April\_2003\_E-ssentials\_The\_Next-

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their autonomy within increasingly reticulated relationships.<sup>427</sup>

We also do not spend much time in the physical presence of our physicians. Routinely, we contact them by phone, poorly describe our symptoms, and expect a prescription to be phoned into a pharmacy. Such a practice is viewed as permissible because there is an existing physicianpatient relationship, and the physician has access to some part of our medical record. The prescribing, however, is no less rote than we see in online interactions.

"Traditional" office visits are seldom more robust, with the average primary care visit now lasting approximately fifteen minutes.<sup>428</sup> Patient access to pharmaceutical information, particularly DTC advertising, means that the conversation is as likely to start with a patient's request for a specific drug rather than a physician inquiry as to symptoms.<sup>429</sup> Not to mention the way that managed care compresses the dialogue space and leaves little room for extensive interaction. Many of today's office visits are seldom more didactic than a completed Internet questionnaire. The most compelling argument in favor of the depleted paradigm may be that a bricks-and-mortar physician is less likely to have a financial interest in the dispensing part of the business than her online counterpart.<sup>430</sup> The traditional paradigm is not just collapsing in the medical domain; our regulatory systems themselves recognize that things are not as they once were.<sup>431</sup>

http://www.harrisinteractive.com/news/newsletters/healthnews/HI\_HealthCareNews2003 Vol3\_Iss11.pdf (finding that seventy-two percent of office visits initiated by a patient after DTC exposure led to a prescription being written, and forty-three percent of times for the specific advertised drug).

430. This results in no small part because of prevailing fraud and abuse laws. See infra note 478.

431. See, e.g., ALA. ADMIN. CODE § 540-X-9-.11(2) ("Prescribing for a patient whom the physician has not personally examined may be suitable under certain circumstances. These may include, but not be limited to, admission orders for a patient newly admitted to a healthcare facility, prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment."); N.D. CENT. CODE § 43-15-31.3 (2001) (permitting oral/telephone transmission of prescription information from doctors to pharmacists).

<sup>427.</sup> See FOX & FALLOWS, supra note 54, at 15-16.

<sup>428.</sup> D. Mechanic et al., Are Patients' Office Visits with Physicians Getting Shorter?, 344 NEW ENG. J. MED. 198 (2001).

<sup>429.</sup> See generally Harris Interactive, The Impact of Direct-to-Consumer Advertising of Prescription Drugs on Consumer Behavior, Diagnosis and Treatment, HEALTH CARE NEWS, June 23, 2003,

#### 3. Imperiled Next Generation Models

Some medical boards clearly equate questionnaire prescribing with the most undesirable forms of Internet prescribing. For these regulators, the questionnaire is an artifice, an attempt to fool regulators and patients into believing that individuated diagnosis precedes the shipment of dangerous drugs across state borders. Therefore, for the boards to crack down on questionnaire prescribing is to move against the worst excesses of the trade, cynical pill-mills that jurisdiction hop to avoid health and safety scrutiny. The analysis gets more interesting, however, when we examine how a state board reacts to questionnaire prescribing integrated into an e-health model that seems to lack some or all of these undesirable indicia, such as "online doc-in-a-box,"<sup>432</sup> e-businesses,<sup>433</sup> and, potentially, "second opinion" sites.

MyDoc.com<sup>434</sup> was first launched in Indiana and then briefly expanded to Illinois in April 2002.<sup>435</sup> Originally a division of Swiss-based Roche diagnostics,<sup>436</sup> it was sold to U.S. Health Services in 2003, a unit of Standard Management Corp., which markets pharmaceutical products and services to consumers.<sup>437</sup> MyDoc.com's business model was somewhat unique in that it was owned by a well-known healthcare company and charged on a pay as you go, annual subscription, or employer-paid subscription basis.<sup>438</sup> It also

433. See, e.g., VirtualMedicalGroup, at http://www.virtualmedicalgroup.com/ (last visited Apr. 17, 2004). It promises:

You are in the right place if you want to experience quality health care. VirtualMedicalGroup Board Certified physicians who are licensed in your home state, treat minor, non-emergent medical conditions in the privacy of your own home or office. We have been in business for over three years - longer than anyone on the web - as a result of our focus on patient confidentiality, convenience and quality care.

#### Id.

434. The website for MyDoc.Com (formerly at http://www.mydoc.com) is no longer accessible.

435. Mave Davis, Internet Doctors Make a Move to Illinois, CHI. TRIB., May 5, 2002, at 6A.

436. Online Firms Tout Cyber Physicians; But Some Docs Question Virtual Visits, CRAIN'S CHI. BUS., Aug. 5, 2002, at SR11; see supra note 421 and accompanying text (discussing of doc-inbox medicine).

437. Roche Diagnostics Unloads MyDoc.com; U.S. Health Services Corp. Buys Internet Doctor Service and Plans To Keep It Operating, INDIANAPOLIS STAR, June 13, 2003 at 1C.

438. MyDoc.Com (on file with author).

<sup>432.</sup> If patients are not already asking the question, "What's your email address, doctor?," they will be soon. Dorothy L. Pennachoi, *What's Your Email Address, Doctor*?, 80 MED. ECON. 66 (2003).

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had features that distanced it from the typical Internet pill-mill. First, it treated or prescribed only to residents of Indiana. Second, it employed physicians who were board-certified in Indiana and, unlike the "pill-mills," their identities were disclosed on the website.<sup>439</sup> Third, it refused to prescribe controlled substances or lifestyle drugs<sup>440</sup> and referred complex inquiries to specialists or the patient's existing physician. Fourth, the site featured "next generation" questionnaire prescribing that is better described as questionnaire triaging. Once a patient completed a questionnaire, it was analyzed by an expert system that could then pose additional online questions to the patient. The attending physician could then follow-up in real-time to acquire further information. Finally, any prescribed drugs were not supplied directly by the site; a prescription was communicated to a pharmacy chosen by the patient.<sup>441</sup>

While MyDoc.com prospered in Indiana—at least briefly,<sup>442</sup> when it attempted to commence business in Illinois, the State Department of Professional Regulation issued a cease-and-desist order in October 2002 on the basis of "unlicensed practice of medicine including, but not limited to, treating patients over the Internet and prescribing medication to patients over the Internet without the benefit of performing a physical examination on the patient."<sup>443</sup> The company complied with the order.<sup>444</sup> The medical establishment commended Illinois's action; the AMA stated that it "applauds the efforts of state authorities to aggressively police Web prescribing sites that bypass medical safeguards with disclaimers that suggest a physical examination or review of reliable medical history are <sup>9</sup>irrelevant to the safety of the patient." <sup>445</sup>

Even more benign than virtual walk-in centers are web-based "second opinion" services. In this model, a patient makes web contact with an online medical consultancy, many of which are affiliated with large teaching or research hospitals such as the Cleveland Clinic,<sup>446</sup> and

443. Ill. Dep't of Prof'l Regulation, Disciplinary Report for October 2002,

http://www.ildpr.com/news/discpln/0210\_dis.pdf (last visited May 17, 2004).

444. See Ann Carrns, Illinois Orders Indiana Web Site To Stop Offering Medical Service, WALL ST. J., Oct. 30, 2002, at D4.

445. Tyler Chin, Firm Treating Strangers by Web Shut Out by Illinois, AMNews, Nov. 4, 2002.

446. See E-Cleveland Clinic, at http://www.eclevelandclinic.com (last visited Apr. 17, 2004); see also Virtual Medical Group, at http://www.virtualmedicalgroup.com/ (last visited

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<sup>439.</sup> Id.

<sup>440.</sup> Id.

<sup>441.</sup> Davis, supra note 435.

<sup>442.</sup> Jeff Swiatek, *Illinois Sidelines MyDoc.com Service*, INDIANAPOLIS STAR, Oct. 31, 2002, at 1C.

authorizes access to her medical record and a credit card charge ranging from \$500 to several times that amount.<sup>447</sup> A consultant reviews the record and emails a diagnosis back to the patient. One such system has published a retrospective review demonstrating improved response times compared to traditional second-opinion references, but only a small number of dissenting diagnoses.<sup>448</sup>

Such second opinion sites have opportunistic characteristics in that a prior relationship with the consulting physician is unlikely. Also, they tend to feature record review rather than a physical examination. However, such services tend not to get involved in prescribing, and their record review process furthers continuity of care by involving or at least copying their opinions to the patient's existing physician.<sup>449</sup> It has also been argued that physical contact with the patient is less important in second opinion consultation cases, where most of the analysis flows from review of blood work, scans, and pathology tests and primarily concerns treatment options rather than core diagnoses.<sup>450</sup>

# VI. RETHINKING THE REGULATION OF INTERNET PRESCRIBING AND DISPENSING

This Article does not argue for anything less than a rigorous drug approval system, a licensure system for physicians and pharmacists, and robust enforcement of gatekeeper and quality standards. It accepts with only limited reservations (such as cases of protectionist discrimination or where there are less restrictive means) that it is entirely legitimate for states to enforce their licensure systems and professional standards in a way that has an impact on Internet prescribers and dispensers both inside and outside their borders.

Rather, this Article argues that the current regulatory matrix is inefficient, incoherent, and imprecise in its targeting. It is inefficient because the general deterrence model that the state regulators use (stinging pill-mills where they can find them in the vain hope that others

Apr. 17, 2004); MDExpert.com, at http://www.mdexpert.com (last visited Apr. 17, 2004).

<sup>447.</sup> MDExpert.com quotes fees ranging from \$2800 to \$3200 depending on complexity. MDExpert.com, *Frequently Asked Questions about MEDExpert, at* www.mdexpert.com (last visited Apr. 17, 2004).

<sup>448.</sup> Iris Kedar et al., Internet Based Consultations To Transfer Knowledge for Patients Requiring Specialised Care: Retrospective Case Review, 326 BRIT. MED. J. 696 (2003).

<sup>449.</sup> See Daniel Costello, Virtual Second Opinions, L.A. TIMES, Dec. 30, 2002, at F1.

<sup>450.</sup> See Tara Parker-Pope, Virtual Second Opinions: When the Web Can Be Better than Seeing a Local Doc, WALL ST. J., Aug. 12, 2003, at D1.

will be deterred) does not map well to a technologically sophisticated underground online industry that continually changes its real space and cyberspace identities and locations. It is an enforcement model that is ultimately doomed because the demand side is robust and unconvinced that the regulators have a valid moral imperative. The vast majority of patients want less expensive<sup>451</sup> and more responsive services; increasingly, they want to buy their medical services and pharmaceuticals online and are unconvinced that traditional distribution channels are any better attuned to their needs.

The current model is incoherent due to the over-complexity of the regulatory matrix. State, federal, and self-regulatory bodies administer an overlapping series of systems that are united in conservatism and tunnel vision. At the extremes, they exhibit parochialism and even technophobia. Their models are imprecise because they are not derived from forwardlooking national or local health information infrastructure planning. As such, they derive their mandates from an outdated model of healthcare delivery and not from a conceptual model that distinguishes between types of online health interaction that should be encouraged rather than chilled or deterred.<sup>452</sup> The model is also operationally flawed. It fails to adequately carve out regulatory approval (or appropriate levels of regulation) for traditional telemedicine, while the blunt tools it uses to identify rogue relationships physician-patient and physical practitioners (i.e., examinations) poorly serve the regulators and regulated alike in the face of next generation delivery models.

The United States is moving inextricably towards a more efficient national healthcare infrastructure that is firmly rooted in technologically-mediated exchanges.<sup>453</sup> The system being built is not only transactional,

<sup>451.</sup> Earlier I discussed today's online market for lifestyle drugs—including patients who may be willing to pay more for the convenience of purchasing such drugs in a covert fashion over the internet. *See supra* paragraph preceding note 101. While these patients have been some of the first to purchase drugs over the Internet, they represent a subset of the overall patient population; going forward an increasing number of patients will consider purchasing their medications online, and this mainstream consumer population will be motivated in significant part by potential cost savings.

<sup>452.</sup> For discussion of chilling in this context, see PUBLIC WORKSHOP, *supra* note 313, at 652.

<sup>453.</sup> The National Committee on Vital and Health Statistics (NCVHS), see U.S. Dep't of Health & Human Servs., Nat'l Comm. on Vital and Health Statistics, at http://ncvhs.hhs.gov/ (last visited Apr. 17, 2004), is responsible for the National Health Information Infrastructure, Health Insurance Portability and Accountability Act of 1996,

Pub. L No. 104-191, § 263, 110 Stat. 1988 (1996). The broad goals of NCVHS are to deliver

requiring correlate security and privacy protections, but will integrate the Institute of Medicine's (IOM) technology-based solutions to medical and medication error.<sup>454</sup> Moving forward requires not only persuading regulators that unlawful cross-border Viagra peddling is distinguishable from the "war on drugs" but also that it is a transitional phenomenon, an experiment in online care that is filling the vacuum created by skepticism regarding technologically mediated care. Improvements in the regulatory matrix, therefore, will necessitate not only far more circumspection about practice models that require policing or deterring, but also affirmative steps to encourage innovation by lawful players.

# A. Improving the Prescribing Regulatory Model

There is little doubt that e-prescribing<sup>455</sup> will become the default interface for prescribing in secondary and tertiary care environments. While supervised by physicians or nurse-practitioners and integrated into sophisticated risk-management systems, prescriptions will increasingly be the product of expert systems rather than traditional physician-patient interactions. Online prescribing will take on a similar role in primary care environments.<sup>456</sup> The current regulatory atmosphere is chilling the development of responsible open or public systems; instead, innovative models are developing more slowly as adjuncts to traditional care models within existing health plans<sup>457</sup> or in proprietary systems like Medem.<sup>458</sup>

information to consumers, patients, and professionals that is to be used to make informed decisions about health and health care. U.S. DEP'T OF HEALTH & HUMAN SERVS., NAT'L COMM. ON VITAL AND HEALTH STATISTICS, NHII WORKGROUP ON THE NAT'L HEALTH INFO. INFRASTRUCTURE, INTERIM REPORT, TOWARD A NATIONAL HEALTH INFORMATION INFRASTRUCTURE (2000), *at* http://ncvhs.hhs.gov/NHII2kReport.htm. States are making their own modest contributions by, for example, permitting electronically created and transmitted prescriptions. *See supra* note 17 (discussing such a provision in Massachusetts law).

454. See, e.g., COMM. ON QUALITY OF HEALTH CARE IN AMERICA, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001) [hereinafter CROSSING THE QUALITY CHASM].

455. For a definition of e-prescribing, see supra note 17.

456. See, e.g., Bye-Bye, Paper Rx? E-Prescribing Could Boost Convenience, Safety—Given Time, WASH. POST, July 1, 2003, at HE01 (using term "e-prescribing" to describe Internet delivery of prescriptions from HMOs and doctors' offices to pharmacies).

457. See, e.g., Virtual Doctors on the Horizon in Seattle, 354 LANCET 9182 (1999) (reporting a Virtual Clinic closed system provided by a Seattle hospital to Microsoft employees).

458. The Medem Network: Connecting Physicians and Patients Online, at http://www.medem.com (last visited May 15, 2004).

Medem was founded in 1999 by the AMA and several other professional associations and is a proprietary, for-profit physician-patient communications network that enables physicians to use secure email and messaging with existing patients.<sup>459</sup> To an extent, Medem is online healthcare's AOL, a halfway house for physicians on the way to e-health.<sup>460</sup>

States will be increasingly forced to recognize the benefits of online care<sup>461</sup> and its importance to the future of safe and efficient healthcare delivery.<sup>462</sup> The challenge, therefore, is to design a regulatory system for Internet prescribing and dispensing that will not chill existing, responsible models of online practice (i.e., traditional telemedicine and home telehealth) or impede the development of millennial delivery models (i.e., those for prescribing and dispensing that are part of our e-health future).

The classic answer to this question is a national licensure system for physicians, but this is an unlikely short or medium term option. States are no more of a mind to forego their licensing powers than the federal government is to expand its regulatory purview.<sup>463</sup> Even if the political and policy climate were more favorably disposed toward such a move, federal licensure would not necessarily solve the Internet prescribing issue. Although a national system would reduce the chilling effect that comes from questions as to whether multiple licenses are required and

459. See Press Release, Medem, Physician Associations Announce Health Care Information and Communications Web Site (Oct. 28, 1999),

460. *Cf.* James Surowiecki, *The Future of AOL: Spin Off and Prosper*, WIRED (October 2002) (suggesting AOL could improve its financial position through innovation if Time Warner would spin off the division).

461. See, e.g., ALA. CODE § 34-24-500 (2000) ("The Legislature hereby finds and declares that, because of technological advances and changing practice patterns, the practice of medicine . . . is occurring with increasing frequency across state lines and that certain technological advances in the practice of medicine . . . are in the public interest . . . . "; see also HealthyOregon, at http://www.healthyoregon.org/ (last visited Apr. 17, 2004).

462. See CROSSING THE QUALITY CHASM, supra note 454, at 168-69 (listing "Health-Related Applications for the Internet").

463. *Cf.* Medicare Telehealth Validation Act of 2002, S. 2750, 107th Cong. § 2(c)(1) ("[T]he Secretary . . . in consultation with representatives of States, physicians, healthcare practitioners, and patient advocates, encourage and facilitate the adoption of State provisions allowing for multi-state practitioner licensure across State lines."). The same language is adopted in Medicare Telehealth Validation Act of 2003, H.R. 1940, 108th Cong. § 2(c)(1), and the Medicare Prescription Drug Benefit Bill, S. 1, 108th Cong. § 450H(b)(1) (2003).

http://www.medem.com/press/press\_medeminthenews\_detail.cfm?ExtranetPressNewsKey =1 (last visited May 15, 2004).

inconsistent regulation, federal licensure by itself does not go to the root issues of opportunistic relationships and suspect care.

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Short of national licensure, however, the states can still build a better mousetrap. They must begin by recognizing that, today, the case for regulatory heterogeneity and the disfavoring of technologically-mediated care is quite weak. State regulators can work cooperatively with one another—witness the work of the Federation of State Medical Boards<sup>464</sup>— and develop a uniform licensure and practice code. This code should adopt a standardized test for the "practice of medicine" and set common standards and limitations for online interactions.

The most immediate standardization must come from closed (as contrasted to public Internet) systems, telemedicine, and telehealth applications such as home monitoring. The closed nature of these systems immunizes them from the problems associated with opportunistic interactions, and they are far less likely to involve prescribing. The old telemedicine consult model may no longer be accurate, and nationally consistent standards of consent and record-keeping may be appropriate. There is no reason, however, to chill these practices with inconsistent state regulations or standards that discriminate between chosen technologies and those that feature interstate, as opposed to intrastate, interactions. As with other proposals discussed herein, regulatory scrutiny is required not only for the direct cross-border issues but also for more indirect changes designed to protect consumers engaging in online medicine and promote confidence in the systems that develop. For example, privacy protections for online patients not obviously covered by the PIHI regulations are required. It is unlikely that the United States will move anytime soon to a full collection-centric privacy model. However, both federal<sup>465</sup> and state<sup>466</sup> legislators have considered bills that would remove some of the voluntarism presently found in the publication of privacy policies, for example, by mandating compliance with published privacy policies and disclosure of breaches of privacy or security.

Open (or public Internet) systems are more problematic given the

<sup>464.</sup> See, e.g., FED'N OF STATE MED. BDS., REPORT OF THE SPECIAL COMMITTEE ON PROFESSIONAL CONDUCT AND ETHICS (2000),

http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/internet\_use\_gu idelines.htm; FED'N OF STATE MED. BDS., REPORT OF THE AD HOC COMMITTEE ON TELEMEDICINE (1996),

http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/telemed.htm.

<sup>465.</sup> See, e.g., Online Personal Privacy Act of 2002, S. 2201, 107th Cong. (2002).

<sup>466.</sup> See, e.g., California Online Privacy and Disclosure Act of 2002, A.B. 2297 (Cal. 2002).

potential for opportunistic relationships and sub-standard care. The emerging regulatory touchstones for lawful interaction (an existing physician-patient relationship and physical examination) are too restrictive and chill the development of next generation models. There are less restrictive means to outlaw pill-mills, regulate responsible practice, and encourage innovation. Such standards should be the criteria for a uniform online practice certification.

As argued above, there is little literal magic in the requirement of a "physician-patient relationship." Rather, in this context, regulators are (or should be) concerned about the absence of "continuity of care." Therefore, continuity of care, or rather its deconstructed elements, should be made a requirement for online systems. Rather than demanding an extant relationship (a requirement not imposed on bricks-and-mortar walk-in centers), harmonized state laws should require online providers to establish contact with the patient's existing record and assume the correlate responsibility of adding to that record. Online providers must also show a commitment to continuing or follow-up care.

Similarly, there are less restrictive ways for harmonized state standards to achieve the goals that underlie the requirement of a physical examination. Positive identification of both patient and physician can be achieved using digital certificates.<sup>467</sup> The therapeutic aspects of physical presence can be approximated by establishing protocols for the nonphysical interactions, such as the development of model questionnaires which would include questions that allow for cross-checking responses. There should always be a requirement that the online system is only an initial step, a triage, and the physician has to establish an appropriate system for individual follow-up, by phone, email, or messaging. Such standards must factor in the availability and use of "physical," but technologically-mediated, examinations, such as those being incorporated in telehealth appliances in the home or integrated into mobile devices such as cell phones.

As part of the incubation of, and experimentation with, online care, there should be limitations placed on its utilization. Protocols should address the situations when the online interaction must be halted and the patient referred to a bricks-and-mortar provider. Equally, we must move away from a monolithic approach to online care. Some diagnoses and

<sup>467.</sup> See, e.g., Steve Gold, Site Employs Biometrics, Newsbytes, at

http://www.computeruser.com/newstoday/00/04/18/news6.html (Apr. 18, 2000) (detailing use of BioNetrix biometrics technology to authenticate the identities of doctors ordering patient prescriptions over the Internet from the online pharmacy).

some prescribing may be more consistent with technologically-mediated care than others. An online practice certificate should be conditioned on specialized training and restricted to developed protocols that place limits on the types of treatment and any resultant prescribing. Such a model can be adapted from that applied to nurse-practitioners. Similarly, online practice and prescribing can be limited by protocol, and prescribing can be further limited to a specific formulary of legend drugs or the exclusion of controlled substances.<sup>468</sup> Current overreaching pharmacy regulations that require the dispenser to be satisfied that prescribing was preceded by a physical examination could be reworked to prohibit the filling of an online prescription for a non-protocol drug or by a certified practitioner (a practitioner having undergone the appropriate training).

# B. Reforming Online Dispensing

Such a system of online practice certification and limitation by protocol does not require FDA action. The protocol or formulary prescribing limitations, however, could be encouraged and reinforced if the drug approval process adapted the controlled substances schedule approach<sup>469</sup> to all prescription pharmaceuticals. If sub-categories of ordinary prescription drugs were developed, the FDA and manufacturers could then evolve warning and labeling requirements that would better meet the needs of online prescribing.

Continuing to require multi-state licensing of pharmacies is a much closer case. There is a good argument that we should move away from a paternalistic paradigm and allow patients more choice, including interstate supply.<sup>470</sup> Such a paradigm shift in how we view patient choice in the drug arena is not unheard of. For example, the learned intermediary rule that requires drug warnings to be delivered to physicians rather than patients is riddled with exceptions when robust drug information is or could be delivered directly to patients through package inserts<sup>471</sup> or DTC advertising.<sup>472</sup>

A relaxation of cross-border traffic for pharmaceutical dispensing, however, should not be unconditional. Through a model act,<sup>473</sup> the states

<sup>468.</sup> See, e.g., ALA. CODE § 34-21-87 (1975).

<sup>469.</sup> See, e.g., UNIFORM CONTROLLED SUBSTANCES ACT (1994).

<sup>470.</sup> Brushwood, supra note 268, at 95-96.

<sup>471.</sup> See, e.g., Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985); Samuels v. American Cyanamid Co., 495 N.Y.S.2d 1006 (Sup. Ct. 1985).

<sup>472.</sup> See, e.g., Perez v. Wyeth Laboratories Inc., 734 A.2d 1245 (N.J. 1999).

<sup>473.</sup> This action was likely guided by the NABP. See, e.g., NAT'L ASS'N OF BDS. OF

must commit themselves to regulating the online pharmacies physically located within their borders.<sup>474</sup> In a 180-degree switch from the current regulatory model, pharmacies with interstate businesses could be required to have an exporting state's certificate requiring, for example, additional reporting and available online post-dispensing advice. The states should establish a clearinghouse for complaints about licensed interstate pharmacies and make those complaints and other quality and performance information publicly available, mimicking the models emerging for informing patients about hospital ratings,<sup>475</sup> nursing home ratings<sup>476</sup> and malpractice/disciplinary proceedings against physicians.<sup>477</sup> Crucially, online prescribers and dispensers should be prohibited from cross-ownership interests or payments, which would be consistent with mainstream health's approach to self-dealing.<sup>478</sup> Online pharmacies should not be permitted to refer to specific online physicians and vice versa.

As for international dispensing, any move to legalize the Canadian connection should be viewed as a red (and white) herring. The fact that pharmaceuticals are less expensive across the northern and southern borders of the United States is not some accident of pharmacy licensing. Congress and the White House, unlike a majority of consumers,<sup>479</sup> do not

http://www.nabp.net/ftpfiles/NABP01/ModelActJune2003.doc.

474. See, e.g., N.Y. EDUC. LAW § 6808-b (6) (Consol. 2003). The legislation states:

[T]he department shall not prosecute a complaint or otherwise take formal action against a nonresident establishment based upon delivery of a drug into this state or a violation of law, rule, or regulation of this state if the agency having jurisdiction in the state where the nonresident establishment is based commences action on the violation complained of within one hundred twenty days from the date that the violation was reported.

Id.

475. See, e.g., Ceci Connolly, Pilot Test Will Pay Hospitals for Quality: Government Hopes Care Will Improve, WASH. POST, July 11, 2003, at A03.

476. See, e.g., Nursing Home Compare, Medicare, at

http://www.medicare.gov/nhcompare/home.asp (last visited Apr. 17, 2004).

477. See, e.g., Virginia Board of Medicine's Practitioner Information, HealthCareProvider, at http://www.vahealthprovider.com/ (last visited Apr. 17, 2004). See Sandra G. Boodman, Va. Doc Site Adds Key Info, WASH. POST, Oct. 16, 2001, at F2.

478. See, e.g., 42 U.S.C. § 1320a-7b(b) (2000) (enacting criminal penalties for Medicare & Medicaid kickbacks); 42 U.S.C. § 1395nn (2000) (creating federal limits on patient referrals).

479. Harris Interactive, Prescription Drug Prices, Hospital Costs and Doctors' Fees, HEALTH CARE NEWS, June 13, 2003, at

PHARMACY, MODEL STATE PHARMACY ACT AND MODEL RULES OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (2003),

favor price controls and therefore keep pharmaceutical prices high; it may be bad policy for U.S. consumers to contribute to a disproportionate share of pharmaceutical research and development and profit, but the remedy does not lie in the opening of U.S. borders.<sup>480</sup> Canada may have "become the United States' favorite drugstore for seniors—and its *de facto* Medicare drug benefit,"<sup>481</sup> but if price controls are to be introduced, they should be implemented directly, not imported. Opening up the heretofore closed U.S. distribution system is not without risk, though the FDA is probably exaggerating it. However, congressional action is merely a political artifice designed to pressure U.S. pharmaceutical interests and the politicians whom they financially support, and it will do nothing to improve the regulatory atmosphere surrounding interstate online prescribing and dispensing. When the dust has cleared, though, the FDA and DEA need to revisit their personal importation safe harbors and strive for greater clarity in, and better synchronization of, their policies.

# C. Reformulating Self-Regulation

Self-regulatory or non-governmental systems can fill important needs when applied to novel or emerging business models. Because they are intrinsically more nimble and adaptive than governmental systems and unhampered by regulatory gaps or constitutional concerns, they can inform consumer choice and improve an industry's quality values prior to the maturation of formal standards. In commodity markets such as

http://www.harrisinteractive.com/news/newsletters/healthnews/HI\_HealthCareNews2003 Vol3\_Iss09.pdf (noting that fifty-seven percent of those polled think drug prices are unreasonably high and thirty-two percent think that they are somewhat high, while a declining majority of fifty-six percent to thirty-nine percent favors government price controls).

<sup>480.</sup> This observation may be tempered, if not contradicted, by Frank Lichtenberg's arguments that sustained high levels of spending on new drugs disproportionately reduces other health costs. See Scott Hensley, Follow the Money: Money Spent on Latest Drugs Is Worth Cost, Economist Says, WALL ST. J., Sept. 9, 2003, at D6. A Fraser Institute report predicts that "importing Canadian prices generally into the United States would reduce the profits of research based drug makers to such a degree that they would reduce annual investment in research and development (R&D) by US\$5 billion to US\$15 billion, the latter estimate being almost half of global pharmaceutical R&D for 2002." John R. Graham, Prescription Drug Prices in Canada & the US—Part 4, Canadian Prescriptions for American Patients Are Not the Solution, PUBLIC POLICY SOURCES No. 70 (Sept. 2003), at 3, at

http://www.fraserinstitute.ca/admin/books/files/PrescriptionDrugPricesPart4.pdf. 481. Gilbert M. Gaul & Mary Pat Flaherty, *Canada Is a Discount Pharmacy for Americans*, WASH. POST, Oct. 23, 2003, at A17.

Internet prescribing that feature near identical consumer interfaces (ecommerce engines) and formularies but have not yet seen the development of trusted brand names, self-regulatory systems can reduce the acute informational asymmetry suffered by consumers.

Measured against these functions and goals, the current crop of selfregulatory systems has failed Internet prescribing and dispensing. The AMA and NABP have done little more than mirror the approach of traditional governmental regulators, adding another layer of entry barriers that deter innovators. Credit should be given to the NABP for its VIPPS system, which translates state licensure into a low-risk, consumer friendly system for distinguishing between general Internet dispensing and lawful e-pharmacies. Its value, however, is overstated; in a world where consumers want information about the relative safety and value of Internet pharmacies, VIPPS merely confirms the existence of a small number of relatively well-known e-pharmacy brand names. URAC also deserves praise; it has pointed to the future of useful content regulation. It leverages a wellknown accreditation brand to encourage providers to internalize the costs of content quality assurance, without the cost and complexity of other third-party rating systems.

The logic of the AMA-NABP-URAC approach—approving or accrediting only licensed providers—is unassailable. The question is how those organizations and their policy positions or accrediting systems will react to the liberalization of licensure provisions argued for herein. If the states move to a harmonized online practice certificate model or permit shipments from licensed out-of-state pharmacies, the application of established accreditation systems would drive down consumer information costs and accelerate the market's identification of quality and value in online prescribing and dispensing. Synergies with the proposed regulatory innovations are possible and would be cumulative, for instance, if states made URAC and NABP accreditation a condition of (or substitute for) an exporting license.

#### D. Opening Lawful Channels and Reimbursement

The parallel drawn between the "war on drugs" chilling palliative care and the crackdown on Internet medicine is certainly valid,<sup>482</sup> particularly with regard to shared concerns about the supply or diversion of controlled substances. There are even more telling similarities, however, between Internet prescribing and the trading of music files over the Internet using

<sup>482.</sup> See Brushwood, supra note 268, at 78.

peer-to-peer networks. The lesson learned by the music industry was that a clear legal position,<sup>483</sup> vigorous enforcement in the face of consumer demand,<sup>484</sup> and half-hearted alternatives<sup>485</sup> (e.g., Medem and VIPPS) are insufficient to stop an illegal practice.<sup>486</sup> Government regulation and industry angst and denial have to be supplemented with the development of legal alternatives<sup>487</sup> that approximate the traditional interests of stakeholders<sup>488</sup> by leveraging technology (i.e., embedded but not punitive digital rights management in the case of music, digital certificates and restrictive formularies for online medicine) so that lawful markets can develop, driving down prices and increasing consumer satisfaction within a lawful channel.<sup>489</sup>

483. See A&M Records, Inc. v. Napster, Inc., 239 F.3d 1004 (9th Cir. 2001) (holding that acts of uploading and downloading files containing copyrighted music violate the copyright holders' distribution and reproduction rights respectively). But see Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd., 259 F. Supp. 2d 1029 (C.D. Cal. 2003) (finding no contributory or vicarious liability on the part of the distributors of Internet software used by copyright infringers). See generally Kevin Michael Lemley, Protecting Consumers from Themselves: Alleviating the Market Inequalities Created by Online Copyright Infringement in the Entertainment Industry, 13 ALB. L.J. SCI. & TECH. 613 (2003) (discussing problems in protecting the record industry from peer-to-peer file sharing and possible ways to overcome such obstacles).

484. Amy Harmon, Subpoenas Sent to File-Sharers Prompt Anger and Remorse, N.Y. TIMES, July 28, 2003, at C1.

485. Bob Tedeschi, *Downloading Music over the Internet Without Feeling Like a Criminal*, N.Y. TIMES, June 7, 2003, at A14.

486. See PEW INTERNET PROJECT, PEW INTERNET PROJECT DATA MEMO (2003), http://www.pewinternet.org/reports/pdfs/PIP\_Copyright\_Memo.pdf (last visited Apr. 17, 2004) (finding that twenty-six million U.S. adults share and thirty-five million download music files online and that "[t]wo-thirds of those who download music files or share files online say they don't care whether the files are copyrighted or not").

487. *E.g.*, iTunes, *at* http://www.apple.com/music/store/ (last visited Apr. 17, 2004); BuyMusic.com, *at* http://www.buymusic.com/ (last visited Apr. 17, 2004).

488. "This is a very ugly issue for the pharmaceutical industry," said Humphrey Taylor, chairman of The Harris Poll at Harris Interactive. "As importation of drugs grows—and it looks set to grow a lot more—drug companies run a big risk of making more enemies as they fight to prevent importation. This would fuel the growing backlash against the industry." Harris Interactive, *Drug Companies May Be Headed for a Bruising Battle As Drug Importation Grows*, HEALTH CARE POLL, Oct. 9, 2003,

http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline\_HI\_Health -CarePoll2003vol2\_iss8.pdf.

489. See, e.g., Bob Tedeschi, Services for Downloading Music—Legal and with Making a Profit in Mind—Are Gaining Momentum, N.Y. TIMES, July 28, 2003, at C5; Sandeep Junnarkar,

IV:2 (2004)

As recognized by one state legislature, "The full potential of delivering health care services through telehealth cannot be realized without the assurance of payment for such services and the resolution of existing legal and policy barriers to such payment."490 For online medicine, the key to developing a robust lawful market, countering technophobia, encouraging physician participation, and eventually, AMA and state board buy-in is reimbursement. The current positives are as easy to identify as they are rare. For example, the availability of Medicare payment for teleradiological consults is clearly responsible for the robust state of teleradiology,<sup>491</sup> and in January 2004, the AMA issued a new Current Procedural Terminology (CPT)<sup>492</sup> for billing online care.<sup>493</sup> Overall, development of federal government reimbursement for telehealth has been woefully slow. The Balanced Budget Act of 1997 contained some breakthrough provisions, such as adding codes for reimbursement, but it was too limited because it conditioned reimbursement on certain geographical requirements, shared a single fee between the providers involved, and was not responsive in its listing of eligible presenters to the practicalities of telemedicine. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act 2000<sup>494</sup> increased the number of codes, removed the fee sharing requirement,<sup>495</sup> and increased the population of eligible presenters.<sup>4</sup>

http://news.com.com/2100-1027-5051609.html?tag=nl (last visited Apr. 17, 2004); see also Amy Harmon, What Price Music?, N.Y. TIMES, Oct. 12, 2003, at 2-1; cf. Press Release, Jupiter Research, Jupiter Research Cuts Online Music Forecast, but Market Will Still Quadruple to \$3.3 Billion in 2008 (July 28, 2003), http://www.internet.com/corporate/releases/03.07.28newjupresearch.html (last visited Apr. 17, 2004).

490. Neb. Rev. Stat. § 71-8502(4) (2003).

491. GUIDE TO ASSESSING TELECOMMUNICATIONS FOR HEALTH CARE, supra note 8, at 42.

492. Physicians' Current Procedural Terminology. See generally Am. Med. Ass'n, CPT Process – How a Code Becomes a Code, at http://www.ama-

assn.org/ama/pub/category/3882.html (last updated Nov. 3, 2003).

493. CPT codes were released on January 1, 2004 and will be implemented by July 1, 2004. Am. Med. Ass'n, Category III CPT Codes, *at* http://www.ama-

assn.org/ama/pub/article/3885-4897.html (last visited Apr. 17, 2004).

494. 42 U.S.C. § 1395m (2000).

495. See, e.g., 42 U.S.C. § 1395m(A)(B) (2000).

496. The U.S. Code provides that:

Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

See, e.g., 42 U.S.C. § 1395m(C) (2000).

Buy.com Founder Launches Music Service, CNET News.Com, July 22, 2003, at

Whether such a funding mandate translates into services depends, however, on the states,<sup>497</sup> and their programs remain quite modest.<sup>498</sup> As a result, telemedicine programs, in particular, tend to be short-lived.<sup>499</sup> Most years, congressional bills seek to nudge the system along,<sup>500</sup> but public sector financing of online care remains modest at best.

Investing public funds in technologically-mediated care is economically and politically difficult. The shift of some services from traditional to more efficient e-health models will not take place overnight, and it will not feature direct or immediate cost substitution.<sup>501</sup> As a result, there are likely to be overlaps and, potentially, increases in costs during the transition, or even long-term as patients respond positively to new services.<sup>502</sup> As with HIPAA's Electronic Data Interchange (EDI) model,<sup>503</sup> we must invest now and look for cost-savings later. And, while the public purse is strained, we need to remove regulatory hurdles that discourage private services from entering the telehealth market.

497. See Ctrs. for Medicare & Medicaid Srvs., Medicaid and Telemedicine, at http://cms.hhs.gov/states/telemed.asp (last visited Apr. 17, 2004).

498. See Legislative, Legal and Policy Issues in Telemedicine & Telehealth, TIE, at http://tie.telemed.org/legal/state/#bills (last visited Apr. 17, 2004); cf. CAL. HEALTH & SAFETY CODE § 1374.13 (West 2003); CAL. WELF. & INST. CODE § 14132.72 (West 2003); CAL. WEFL. & INST. CODE § 14132.73 (West 2003); see also COLO. REV. STAT. ANN. § 10-16-123 (West 1999); O.C.G.A. § 50-5-191 to -199 (2002). See generally Ctrs. for Medicare & Medicaid Servs., States Where Medicaid Reimbursement of Services Utilizing Telemedicine is Available, at http://cms.hhs.gov/states/telelist.asp (last visited Apr. 17, 2004).

499. Claudio Cipolat & Michael Geiges, *The History of Telemedicine, in* CURRENT PROBLEMS IN DERMATOLOGY 7 (G. Burg Karger ed., 2003).

500. See, e.g., Medicare Telehealth Validation Act of 2003, H.R. 1940, 108th Cong. (2003).

501. See, e.g., P. B. Jacklin et al., Virtual Outreach: Economic Evaluation of Joint Teleconsultations for Patients Referred by Their General Practitioner for a Specialist Opinion, 327 BRIT. MED. J. 84 (2003).

502. Alan Greenspan, Chairman of the Federal Reserve, has said:

[W]e know very little about how rapidly medical technology will continue to advance and how those innovations will translate into future spending. To be sure, technological innovations can greatly improve the quality of medical care and can, in theory, reduce the costs of existing treatments. But because medical technology expands the range of treatment options, it also has the potential of adding to overall spending—in some cases, significantly.

Hearing Before the House Comm. on the Budget, 108th Cong. 6-7 (2004) (statement of Alan Greenspan, Chairman, Board of Governors of the Federal Reserve System).

503. See supra note 387.

#### VII. CONCLUSION

The transformation of U.S. healthcare delivery into a more technologically adept model is an immensely complex undertaking. It is also a fragile process. There are powerful stakeholders whose dominance is threatened by disruptive new technologies. These stakeholders' reactions to the cram-down style of regulation used in the HIPAA privacy rules and the way technical compliance rules were substituted for general principles that could have found broader acceptance should suggest to regulators that they may want to adopt alternative approaches in the future.

The introduction of the HIPAA's Electronic Data Interchange, the work of the Institute of Medicine and the Agency for Healthcare Research and Quality, and a growing patient demand for online medical information suggest that e-health has passed its tipping point. Contrary to the fears of many and the exaggerations of some, e-health is not a replacement for traditional healthcare delivery. It will impact primary, secondary, and tertiary care differently, and will be more effective with regard to some types of diagnosis, treatment, and care than with others. Only through controlled experimentation in an innovative environment will the correct mix of traditional and technological services and regulations be discovered.

Much of today's prescribing and dispensing activity on the Internet is not just unlawful, it is bad medicine. Clumsy regulation, however well intended, seriously impedes innovation and experimentation, while the parochial and technophobic attitudes that drive some of the regulatory activity in this area are also unhealthy. As a result, overbroad medical and pharmacy board statutes, regulations, and policies are chilling traditional telemedicine and slowing innovation in safer online models.

Following the dot.com implosion, investments in consumer e-health businesses became relatively dormant. In the interim, consumer expectations and familiarity with the Internet as a source of medical information and services have grown exponentially. When the investments return—and they are expected to return<sup>504</sup>—our regulatory systems will need to embrace this new consumer-generated enthusiasm and improve their tools for distinguishing the online wheat from the chaff.

<sup>504.</sup> See Gautum Naik, England Plans Major Revamp of Health Care, WALL ST. J., Dec. 3, 2003, at B1 (noting that 2002 U.S. health-care computer spending increased 9.3% to \$23.6 billion); see also Steve Lohr, Investment in Technology Is Roaring Softly Back, N.Y. TIMES, Nov. 1, 2003, at C1; Michelle Kessler, Health Data Mandate Gives Tech a Boost, USA TODAY, June 8, 2003, at B1.

# Genetic Diagnosis and Intellectual Property Rights: A Proposal To Amend "The Physician Immunity Statute"

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It is difficult to overstate the extent of the revolution in medicine that is currently underway.<sup>1</sup> Across therapeutic areas, critical links between genes and disease are emerging and proving to be further-reaching than anticipated.<sup>2</sup> Researchers have realized that genetics can play a contributory role in the pathology of diseases long believed to be nongenetic, such as infectious disease.<sup>3</sup> Improved understandings of the genetic bases of disease have raised prospects of novel therapies that have the potential to prevent or cure previously untreatable conditions.<sup>4</sup>

Arguably, this increased understanding of genetics has had its greatest impact in diagnostics where "molecular diagnostic tests . . . can provide . . . presymptomatic testing for late-onset disorders" and "can be used for population based screening to predict future genetic disease or assess the risk for complex conditions such as cancer, cardiovascular diseases, and

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<sup>1.</sup> For a general genetics reference text, see EMERY AND RIMOIN'S PRINCIPLES AND PRACTICE OF MEDICAL GENETICS (David L. Rimoin et al. eds., 4th ed. 2002) [hereinafter PRINCIPLES AND PRACTICE].

<sup>2.</sup> One area in which "[m]olecular genetic testing is increasingly available [is] pediatric practice." Comm. on Genetics, Am. Acad. of Pediatrics, *Molecular Genetic Testing in Pediatric Practice: A Subject Review*, 106 PEDIATRICS 1494, 1497 (2000) [hereinafter Am. Acad. of Pediatrics].

<sup>3.</sup> For example, the role of genetics in the progression of HIV to AIDS is a topic of current research. For an overview of the role of genetics in infectious disease, see Shelley Segal and Adrian V.S. Hill, Genetic Susceptibility to Infectious Disease, 11 Trends Microbiology 445 (2003).

<sup>4.</sup> For a review in the context of conditions affecting the Central Nervous System, see R. Tinsley & P. Eriksson, *Use of Gene Therapy in Central Nervous System Repair*, 109 ACTA NEUROLOGICA SCANDINAVICA 1 (2004).

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neurodegenerative disorders in otherwise healthy people."<sup>5</sup> Genetic diseases and syndromes such as Alpert's Disease, Crouzon's disease, Von Recklinghausen's disease, hemophilia A, myotonic dystrophy, muscular dystrophy, hemochromatosis, and Canavan Disease can now all be diagnosed, even prenatally, with a high degree of accuracy, using molecular probes or polymerase chain reaction (PCR) technology.<sup>6</sup> Pre-implantation diagnosis of embryos may in the future allow for the eradication of such diseases altogether.<sup>7</sup> Although each of these diseases is very rare, in the aggregate they constitute a significant disease burden in the pediatric population; over five percent of all live born children will develop disease with a significant genetic contribution before the age twenty-five.<sup>8</sup> Moreover, many of these diseases individually have a markedly increased incidence in select populations, such as Jews of Ashkenazi origin.<sup>9</sup> For families afflicted with these rare conditions, the availability of

6. In each of these cases, the gene responsible for the disease has been identified, and a test has been developed and brought to market that directly examines the patient's DNA to determine if the suspected mutation is present. It is estimated that ten to twelve new molecular diagnostic tests become available each year. Am. Acad. of Pediatrics, *supra* note 2, at 1494. However, there are limits to the utility of genetic testing. Not all genetic diseases are best diagnosed by molecular tests: Cystic fibrosis, the most common genetic disease among Caucasians (one in twenty-five is a carrier), is not suited to molecular diagnosis because the number of mutations causing the disease is too high, making genetic screening currently impractical. Am. Acad. of Pediatrics, *supra* note 2, at 1495. For a complete list of genetic tests available, as well as a directory of laboratories offering testing, see http://www.genetests.org.

PCR stands for polymerase chain reaction and is the chemical reaction by which minute samples of DNA can be amplified into enough genetic material to be readily analyzed. Paul Rabinow, *What Is PCR*?, University of California, Berkeley, *at* http://sunsite.berkeley.edu/pcr/index.html (last visited May 1, 2004).

7. Pre-implantation genetic diagnosis is a technique that relies on genetic testing of embryos obtained through in vitro fertilization prior to 'implanting' the embryos back into the mother's uterus. Thus, the likelihood that a child will be born with the disease can be greatly reduced by implanting only embryos that are free from disease. For an overview of the current status of the development of this technique, see Anuja Dokras, *Pre-Implantation Genetic Diagnosis, at* http://www.hygeia.org/poems5.htm (last visited Apr. 25, 2004).

8. D.L. Rimoin et al., *Nature and Frequency of Genetic Disease, in* PRINCIPLES AND PRACTICE, *supra* note 1, at 55, 56.

9. Genetic diseases often have higher incidence in genetically isolated populations. For example, Ashkenazi Jews (Jews of Eastern European descent) are more likely to suffer from Tay-Sachs, Canavan's disease, and several other disorders. Individuals of Ashkenazi Jewish heritage are advised to be screened for these diseases prior to having children. *See* 

<sup>5.</sup> Am. Acad. of Pediatrics, supra note 2, at 1494, 1494.

genetic tests that can be used to determine whether adults are carriers of disease<sup>10</sup> or to diagnose an unborn child may influence family planning decisions and therefore be of the utmost importance.

The cost of this rapid progress has been borne by both the public, via the National Institutes of Health, and by private enterprises, which have invested research dollars into developing quick, simple, and accurate means to diagnose genetic diseases. As an incentive (and reward) for efforts to discover the genes responsible for disease, the United States offers protected intellectual property rights. However, while the goal of the patent system is indisputably to promote the generation and dissemination of new knowledge and techniques, patents can paradoxically lead to a decrease in the availability of genetic-based tests.<sup>11</sup> In Part I of this Article, I trace the major contours of the development of gene patenting in the United States and discuss the Physician Immunity Statute,<sup>12</sup> a statute designed to ensure that the patenting of medical procedures does not impair the treatment of patients. As I argue below, the protections of the statute, in its current form, do not go far enough. In Part II, I illustrate the problems raised by the limitations of the Physician Immunity Statute by examining Canavan disease, the patent on the gene that encodes for it, and enforcement of that patent. Canavan disease is an incurable metabolic disorder, the gene for which was discovered in 1993 by Dr. Reuben Matalon.<sup>13</sup> The gene was patented by Miami Children's Hospital, which

National Tay-Sachs & Allied Disease Association, Inc., at

http://www.ntsad.org/ntsad/intromap.htm (last visited Apr. 14, 2004).

<sup>10.</sup> For diseases caused by recessive genes, both copies of an individual's gene must have the error that causes the disease. Individuals who have one gene with the error and one "normal" gene are called carriers. They do not themselves generally have the disease, but they can pass it onto their children. J. Cook, *Mendelian Inheritance, in* PRINCIPLES AND PRACTICE, *supra* note 1, at 104, 109. It is important to distinguish carriers of genetic diseases from carriers of infectious disease, who may transmit the disease simply through close contact with individuals.

<sup>11.</sup> A body of legal scholarship recognizes and explores the possibility that patent regimes might hinder innovation and limiting access to inventions. See, e.g., Michael Heller & Rebecca Eisenberg, Can Patents Deter Innovation?, 280 SCIENCE 698 (1996); Clarisa Long, Proprietary Rights and Why Initial Allocations Matter, 49 EMORY L.J. 823 (2000); Arti K. Rai, The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era, 2001 U. ILL. L. REV. 173.

<sup>12. 35</sup> U.S.C. § 287(c) (2000).

<sup>13.</sup> What Is Canavan Disease?, Canavan Foundation, at

http://www.canavanfoundation.org/canavan.php (last visited Apr. 25, 2004); see also Mary Kugler, Gene Patent: For Mankind's Good, or For Profit?, About.com, at

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subsequently enforced the patent, leading to a lawsuit filed by the families of Canavan-afflicted children.<sup>14</sup> Canavan disease provides a particularly compelling example of the potential problems with gene patents for several reasons. The gene's discovery involved research initiated by—and initially funded by—the afflicted families.<sup>15</sup> Therefore, the Canavan story reflects an exception to the usual patent paradigm where a pharmaceutical company speculates on a technology by expending significant financial resources on research and development. In addition, since there is no treatment, let alone cure, for Canavan's disease, genetic testing of the parents and/or prenatal screening represent the only options for parents who do not want to have a child with this devastating condition; these techniques allow parents either to avoid pregnancy or to terminate affected embryos.

A solution fashioned by the legislature that could ensure patients' access to genetic testing information while recognizing the biotechnology companies' financial interests in using gene patents to develop treatments and cures for genetic diseases would represent a crucial step forward in the genetic revolution. In Part III of the Article, I offer a proposal to amend the Physician Immunity Statute that would allow patients unfettered access to diagnostic testing for any known gene sequence, whether patented or not. Specifically, I argue that the provisions of the Physician Immunity Statute that prevent enforcement of patent infringement actions against physicians performing patented procedures or methods of diagnosis be applied to genetic diagnoses as well.

# I. THE PATENT PROCESS

Congress is authorized by Article I, Section 8 of the United States Constitution to issue patents "[t]o promote the Progress of Science and Useful Arts."<sup>16</sup> The patent system has been described as a kind of bargain between the inventor and society, in which monopoly rights are granted to the inventor for a limited time in exchange for the disclosure of the invention.<sup>17</sup> By disclosing the invention to the public, the inventor contributes knowledge to the arts and sciences and thereby spurs further

http://rarediseases.about.com/library/weekly/aa011201a.htm (last visited May 1, 2004).

<sup>14.</sup> See infra Section II.B.

<sup>15.</sup> See id.

<sup>16.</sup> U.S. CONST., art. I, § 8, cl. 8.

<sup>17.</sup> See MARGARETH BARRETT, INTELLECTUAL PROPERTY 18 (2d ed. 2001). The current patent term is twenty years. 35 U.S.C. § 154 (2000).

innovation, including efforts to design around the patent. In order to allow competitors to engage in such innovation, however, the patent must give notice as to the scope of the invention through the use of specific and particular claims.

Current statutory requirements regarding patents were passed into law in the Patent Act of 1952.<sup>18</sup> Five statutory requirements for patentability are that the invention be of patentable subject matter,<sup>19</sup> that the invention be "non-obvious,"<sup>20</sup> that it have utility,<sup>21</sup> that it be adequately disclosed,<sup>22</sup> and that it be precisely claimed.<sup>23</sup> In exchange for disclosure, the patent holder gains the right to exclude others from making, selling, offering for sale, using, or importing the patented object in the United States.<sup>24</sup> In order to enforce these rights, a patent holder can sue for infringement of the patent.<sup>25</sup>

# A. Gene Patents

In 1980, the Supreme Court opened the door to gene patenting by clarifying that biological materials could fall within the purview of ordinary patent protection.<sup>26</sup> Since then however, the practice of gene patenting has generated much controversy.<sup>27</sup> Scholars have challenged the practice of

18. Act of July 19, 1952, ch. 950, 66 Stat. 792 (codified at 35 U.S.C.).

19. 35 U.S.C. § 101 (2000).

20. Id. § 103.

24. Id. §§ 101-112, 271 (2000).

25. Infringement occurs when a patented invention is made, used, imported, offered for sale, or sold by someone other than the patent holder (or licensee). Infringement can be either literal, where the infringing product is exactly the same as the patented product, or by equivalence, where the differences between the patented invention and the infringing product are too minor to constitute successful "design around" the patent. *See id.* § 271 (2000).

26. Diamond v. Chakrabarty, 447 U.S. 303 (1980) (granting a patent for a genetically modified oil-dissolving microbe). The Court asserted in *Diamond* that "Congress intended statutory subject matter to include 'anything under the sun that is made by man.'" *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82=1923, at 6 (1952)). The Court noted that the same language was used by P.J. Federico, "a principal draftsman of the 1952" legislation, in his testimony about the legislation before the House. *Id.* at 309 n.6. In *Diamond*, the bacteria in question had been modified and thus constituted a creation. *Id.* 

27. See generally Barbara Looney, Should Genes be Patented? The Gene Patenting Controversy:

<sup>21.</sup> Id. § 101.

<sup>22.</sup> Id. § 112.

<sup>23.</sup> Id.

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issuing patents on genes on policy grounds, and they have employed various moral,<sup>28</sup> medical,<sup>29</sup> ethical,<sup>30</sup> and scientific<sup>31</sup> arguments in opposition to the practice of issuing gene patents and to the withholding of data that might lead to those patents. Many argue against gene patents out of the fear that over-reaching DNA patents will enable patent holders to encroach on what is considered the "heritage of humanity,"<sup>32</sup> with consequent deleterious effects on patient care and privacy.

The United States Patent and Trademark Office (PTO) has responded to such concerns by assuring the public that "the concern that a person whose body 'includes' a patented gene could infringe the patent is misfounded. The body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form."<sup>33</sup> Currently, the PTO sees little difference between DNA molecules and other chemical compounds.<sup>34</sup> In 2001, the PTO issued "a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the 'utility' requirement of 35 U.S.C. 101."<sup>85</sup>

Arguably, the patentability of Expressed Sequence Tags (ESTs), DNA fragments that can be used as "molecular probes," was "the most controversial issue addressed by the new guidelines."<sup>36</sup> The 2001 guidelines make clear that ESTs are not categorically ineligible for patent protection,

28. For a brief survey of religious groups' position statements on gene patenting, see Ronald Cole-Turner, *Religion and Gene Patenting*, 270 SCIENCE 52 (1995).

29. Eliot Marshall, Is Data Hoarding Slowing Assault on Pathogens?, 275 SCIENCE 777, 777 (1997).

30. Id.; see also Rebecca Eisenberg, Intellectual Property at the Public-Private Divide: The Case of Large Scale cDNA Sequencing, 3 U. CHI. L. SCH. ROUNDTABLE 557 (1996).

31. Out of over 2000 faculty researchers surveyed, a statistically significant higher proportion of genetic researchers (nearly one in six) refused to share research results with colleagues. David Blumenthal et al., Withholding Research Results in Academic Life Science, 277 JAMA 1224, 1224, 1227 (1997); see also Erin G. Campbell et al., Data Withholding in Academic Genetics: Evidence from a National Survey, 287 JAMA 473 (2002).

32. Universal Declaration on the Human Genome and Human Rights, U.N. Educational, Scientific, and Cultural Organization, 29th Sess., 29 C/Resolution 19 (1997).

Legal, Ethical, and Policy Foundations of an International Agreement, 26 L. & POL'Y INT'L BUS. 231 (1994).

<sup>33.</sup> Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

<sup>34.</sup> Id. at 1094.

<sup>35.</sup> Id. at 1092.

<sup>36.</sup> The Fate of Gene Patents Under the New Utility Guidelines, 2001 DUKE L. & TECH. REV. 8 [hereinafter Fate of Gene Patents].

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but also affirm that "[1]ike any descriptive property, a DNA sequence itself is not patentable. A purified DNA *molecule* isolated from its natural environment, on the other hand, is a chemical compound and is patentable if all of the statutory requirements are met."<sup>37</sup> In particular, the guidelines sought to operationalize the judiciary's conception of the utility requirement by "requir[ing] the disclosure of at least one specific, substantial, and credible utility."<sup>38</sup> Although it was not entirely clear how these criteria would apply to "a given EST," the disclosure of a number of factors, such as "the sequence of the corresponding complete mRNA sequence, protein coding sequence or genomic sequence," "the function of the protein encoded by the corresponding mRNA," and "the phenotype of a mutation in the corresponding gene," could all conceivably solidify a claim for patent protection of an EST.<sup>39</sup>

Since patents are by definition exclusive, there is no positive burden on the patentee to use the invention; a patent simply grants the right to exclude others, including the right to restrict the licensing of the invention for non-economic reasons. Applied to diagnostics, the issuance of a patent practically creates a right to exclude patients from being diagnosed. Of particular importance in relation to diagnostic tests based on gene patents is the right of the patent holder to decrease access to prenatal screening, whether as a consequence of the patentee's pecuniary interest or to further a non-economic objective.

Concerns that the patenting of genes would limit the availability of diagnostic testing are a relatively recent phenomenon. In fact, the first 150 years of patent jurisprudence in this country did not recognize the patentability of medical procedures, treatments, or methods of diagnosis.<sup>40</sup> However, by the 1950s, the prohibition against the patenting of medical procedures began to erode,<sup>41</sup> and by the early 1990s, the medical community began to become concerned about the potential impact such patents could have on the delivery of health care and research. While the

<sup>37.</sup> Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 cmt. 8.

<sup>38.</sup> Id. cmt. 9.

<sup>39.</sup> Fate of Gene Patents, supra note 36.

<sup>40.</sup> Robert M. Portman, Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress, 4 U. BALT. INTELL. PROP. L.J. 91, 92 (1996).

<sup>41.</sup> Ex parte Scherer, 103 U.S.P.Q. 107 (BNA) (Pat. Off. Bd. App. 1954) (holding that claims for a medical treatment could be patented). The opposite trend was developing in the rest of the world. As of 1996, over eighty countries, as well as the European Union, exempt medical procedures from patent protection. Thus the Physician Immunity Statute can be seen as harmonizing U.S. law with that of other nations. Portman, *supra* note 40, at 92.

medical community secured some protection from Congress, the protections were not as great as they could have been or, as I will argue below, as great as they should have been. I turn to the history of these protections—and their limitations—in the next Section.

#### B. The Physician Immunity Statute

The rallying cry about the need for protections from patent infringement suits for the medical community came when Dr. Samuel Pallin sued Dr. Jack Singer for infringement of Pallin's patented procedure for use in cataract surgery.<sup>42</sup> Pallin v. Singer was the first case in which a physician sued another physician for infringement of a medical procedure patent; as a result, the medical community became concerned about the deleterious consequences such litigation would present should such patents become widespread.

Largely as a consequence of the *Pallin* litigation, the AMA adopted an ethical resolution in 1994 "vigorously condemning" the patenting of medical procedures and pledging to "work with Congress to outlaw" such patents.43 Soon after the AMA took this position, a coalition of medical and interest groups, the "Medical Procedure Patent Coalition," was formed with the goal of persuading Congress to pass a legislative solution to the problem of procedure patents.<sup>44</sup> Not surprisingly, the Coalition met with fierce resistance from the biotechnology and pharmaceutical lobbies. The biotechnology lobby, in particular, felt threatened by what it considered a "foolhardy" attempt to address the perceived problem through legislation, fearing that the legislation as initially proposed would adversely affect the industry's ability to bring new therapeutic methods, such as Cephalon's innovative use of the drug IGF-1, to market.<sup>45</sup> Claiming that the legislation would "sever the critical lifeline" between the industry and the medical community,<sup>46</sup> industry representatives were able to convince the Coalition to accept compromise legislation that specifically exempted

<sup>42.</sup> Pallin v. Singer, 36 U.S.P.Q.2d 1050 (BNA) (D. Vt. 1995). Dr. Pallin's lawsuit was ultimately unsuccessful.

<sup>43. 1994</sup> ANNUAL MEETING, AMA, Substitute Resolution 2.

<sup>44.</sup> See Portman, supra note 40.

<sup>45.</sup> The Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the House Judiciary Subcomm. on Courts and Intellectual Prop., 104th Cong. 98 (1995) (prepared statement of Frank Baldino, Jr., President and CEO of Cephalon, Inc.). Baldino testified "on behalf of Cephalon and the Biotechnology Industry Organization." Id. at 94.

<sup>46.</sup> Id. at 93.

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"biotechnology" patents from the legislation,<sup>47</sup> and the result<sup>48</sup> was adopted into law.<sup>49</sup> Thus, while the Physician Immunity Statute exempts "medical practitioner[s]" from liability for patent infringement for performing a qualified "medical activity," the Statute specifies that a "medical activity" does not include the "practice of a process in violation of a biotechnology patent."<sup>50</sup>

The legislative history of the Physician Immunity Statute shows that the provisions which exclude the "patented use of a composition of matter in violation of such patent"<sup>51</sup> and "the practice of a process in violation of a biotechnology patent,"<sup>52</sup> respectively, are intended to protect "use patents."<sup>53</sup> For purposes of this provision, the definition of a 'biotechnology patent' includes a patent on a 'biotechnology process' as defined in35 U.S.C. §103(b), as well as a patent on a process of making or using biological materials. Thus, biotechnology patents are wholly exempt from the application of the Physician Immunity Statute. This result reflects the success of the biotechnology lobby's aggressive efforts.<sup>54</sup>

According to widely-held principles of bioethics, physicians should

48. Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67 (1996) (codified at 35 U.S.C. § 287(c) (2000)).

49. 35 U.S.C. § 287(c) (2000).

50. 35 U.S.C. §§ 287(c)(1)-(c)(2)(A) (2000).

51. Id. § 287(c)(2)(A)(ii). This provision is limited by the later § 287(c)(2)(F) to situations in which the use of the composition of matter is directly related to the objective of the procedure.

52. Id. § 287(c)(2)(A)(iii). This provision, unlike § 287(c)(2)(ii), is not constrained by other subsections.

53. A use or utility patent is a patent obtained on an invented composition of matter (as opposed to a design patent, which is a patent on an ornamental design or appearance, or a plant patent, which is a patent on a novel plant). See BARRETT, supra note 17, at 111-371.

54. However, even the biotechnology industry is not without internal dissent. In testimony before the Federal Trade Commission and Department of Justice, Barbara Caulfield, general counsel for the biotechnology company Affymetrix stated that "there should be no patenting of gene sequences, period." *See* Tom Abate, *Do Gene Patents Wrap Research in Red Tape?*, S.F. CHRON., March 25, 2002, at E1.

<sup>47.</sup> For general review of the legislative proposals leading up to H.R. 3610, see Eric M. Lee, 35 U.S.C. § 287 (c)—The Physician Immunity Statute, 79 J. PAT. & TRADEMARK OFF. SOC. 701 (1997). For contrary accounts of the passage of the Physician Immunity Statute and its merits, see Richard P. Burgoon, Jr., Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c), 4 U. BALT. INTELL. PROP. J. 69 (1996); and Portman, supra note 40. Burgoon was chair of the Intellectual Property Committee for the Biotechnology Industry Organization, and Portman represented the Medical Procedure Patent Coalition in its effort to get § 287(c) passed.

respect patients' abilities to make their own decisions about their healthcare; they also have a responsibility to avoid causing harm to patients or failing to prevent harm.<sup>55</sup> Under the principle of autonomy, a patient has the right to be free of interferences in making decisions regarding their own bodies and medical decisions.<sup>56</sup> Any interference in the ability to make such decisions compromises a patient's autonomy. Although there is no general right to diagnosis-there is no a priori absolute right to be diagnosed with a condition any more than an absolute right to health care-no one ought to have the absolute right to deny a patient means of being diagnosed, either. Under the principle of beneficence-the notion that physicians ought to prevent harm<sup>57</sup>—for a caregiver to deny a patient a means of diagnosis, where such a denial might cause the patient harm, would be unequivocally unethical. However, patents allow for precisely this denial. Since the enactment of the Physician Immunity Statute, patented methods of diagnosis-except for biotechnology patents (i.e., gene tests)are exempt from patent enforcement. Thus, the Physician Immunity Statute can be seen as supporting patient autonomy and physician beneficence by removing potential legal barriers to diagnosis.

However, as discussed at greater length below,<sup>58</sup> the exemption for biotechnology patents from the Physician Immunity Statute means that gene patents can limit the ability of doctors to diagnose and research genetic-based diseases. In Part II, I illustrate this danger by discussing the Canavan patent; and in Part III, I argue for an amendment to the Physician Immunity Statute that would limit the ability of patent holders to restrict the use of processes used in the gene-based diagnosis of diseases. The proposed amendment would extend support for the principles of patient autonomy and patient beneficence to genetically-based diagnoses.

# II. THE CANAVAN DISEASE PATENT

As the Council of Scientific Affairs of the American Medical Association has recognized, the patent on the gene for Canavan disease

<sup>55.</sup> TOM L. BEACHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 192 (4th ed. 1994); see Thomas R. McCormick, *Principles of Bioethics*, Ethics in Medicine-Univ. of Wash. Sch. of Med., *at* 

http://eduserv.hscer.washington.edu/bioethics/tools/princpl.html#prin1 (last visited May 17, 2004).

<sup>56.</sup> Id. at 121.

<sup>57.</sup> Id.

<sup>58.</sup> See infra Subsections II.B.3-4 (discussing the limitations on screening and research caused by the Canavan gene patent).

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presents an excellent illustration of the problematic issues raised by the patenting of gene-based diagnostic tests.<sup>59</sup> In its report announcing its position on gene patenting, the Council notes that the Canavan patent raises "serious issues of justice and fairness" and has resulted in the undesirable restriction of access to needed diagnostic testing and research.<sup>60</sup> In this Part, I will take a closer look at the Canavan patent and the issues it raises as an example of the ability of "inventors" to restrict research and limit the availability of genetic testing using the patent system.

# A. The Discovery of the Canavan Disease Gene<sup>61</sup>

Jonathan Greenberg was born in 1981. Although he seemed normal at birth, within a few months his parents became concerned about his development; six months later, he was diagnosed with Canavan disease, an inherited degenerative neurological disease. At the time, there were no screening tests available for parents, nor were there any means of prenatal diagnosis. The Greenbergs subsequently had another child, but their daughter Amy also began to develop the symptoms and signs of the disease.<sup>62</sup>

In 1987, Jonathan's father, Daniel Greenberg, approached Dr. Reuben Matalon, a physician then at the University of Illinois at Chicago, about initiating research with the goal of identifying the Canavan disease gene and ultimately developing a means to prevent or treat it. Daniel Greenberg had previously founded the Chicago chapter of the National Tay-Sachs and Allied Diseases Association (NTSAD); later, in conjunction with NTSAD, he had established a Canavan Registry, which compiled information about families who were carriers of the gene. Daniel Greenberg persuaded Matalon to undertake the research, and together with other families afflicted by Canavan disease, the Greenbergs supported Matalon's research by supplying biological samples, including samples of Jonathan's brain

<sup>59.</sup> COUNCIL ON SCI. AFFAIRS, AM. MED. ASS'N, REPORT NO. 9, PATENTING GENES AND THEIR MUTATIONS (Dec. 2000) [hereinafter COUNCIL ON SCI. AFFAIRS], *available at* http://www.ama-assn.org/ama/pub/article/2036-3603.html (last visited Apr. 14, 2004).

<sup>60.</sup> Id.

<sup>61.</sup> For background information on the Greenbergs and the efforts to find the gene responsible for Canavan disease, see generally Compl., Greenberg v. Miami Children's Hosp. Research Inst., 208 F. Supp. 2d 918 (N.D. Ill. 2002) (No. 00C-6779); Eliot Marshall, *Families Sue Hospital, Scientist for Control of Canavan Gene*, 290 SCIENCE 1062 (2000).

<sup>62.</sup> See Compl. para. 4, Greenberg, 208 F. Supp. 2d 918.

after he died in 1992; family pedigree information; and financial support.69

Although Matalon had not previously engaged in Canavan research, he successfully isolated the Canavan disease gene in 1993.<sup>64</sup> Identification of the gene made widespread, rapid, and accurate screening, as well as prenatal diagnosis,<sup>65</sup> scientifically feasible—opening the door to the hope of an eventual treatment or cure using gene therapy.

Canavan disease is caused by a defect or absence of an enzyme called aspartoacylase. The disease is transmitted as an autosomal recessive trait<sup>66</sup> and is "characterized by spongy degeneration of the white matter of the brain."<sup>67</sup> It is more prevalent in Ashkenazi Jews than in the general population, with the carrier rate among this demographic group as high as 1:36.<sup>66</sup> The clinical manifestations vary, but the disease is uniformly fatal, usually within the first decade of life. The preferred means to diagnose Canavan disease is use of a biochemical assay that can detect the presence of N-acetylaspartic acid, the substrate of the aspartoacylase, in the urine or blood; carrier status can similarly be determined through the use of cultured fibroblasts.<sup>69</sup>

Matalon wrote the entry on Canavan disease in the current edition of

65. Previously, prenatal diagnosis was not possible because there is insufficient aspartoacylase activity in chorionic villi and amniotic cells to render enzyme-based assays of amniotic fluid or chorionic villus samples satisfactory. R. Matalon et al., *Prenatal Diagnosis of Canavan Disease*, 15 J. INHERITED METABOLIC DISEASE 392 (1992). However, researchers continue to make progress toward a genetic test for Canavan disease. *See* C. Janson et al., *Clinical Protocol: Gene Therapy of Canavan Disease: AAV-2 Vector for Neurosurgical Delivery of Aspartoacylase Gene (ASPA) to the Human Brain*, 13 HUM. GENE THERAPY, 1391 (2002).

66. This means that it can skip generations and that if a child's mother and father are both carriers of the gene, the child has a twenty-five percent chance of inheriting the disorder.

67. Sankar Surendran et al., Molecular Basis of Canavan's Disease: From Human to Mouse, 18 J. CHILD NEUROLOGY 604, 604 (2003).

68. Reuben K. Matalon, Aspartic Acid (Canavan Disease), in NELSON TEXTBOOK OF PEDIATRICS (Richard E. Behrman et al. eds., 16th ed. 2000).

69. Fibroblasts are a connective tissue cell type that can easily be cultured from skin. *Id.* It is not altogether clear why biochemical tests are still the preferred means of testing. There are, however, at least two probable explanations: (1) Phenotypic expression (i.e. diminished aspartoacylase activity) is the definition of the disease and, therefore, the "gold standard" of determining whether one clinically suffers from Canavan disease; and 2) Because of the possibility of novel spontaneous mutations, current genetic tests are most likely not one hundred percent sensitive.

<sup>63.</sup> See id. para. 11, 17, 19.

<sup>64.</sup> U.S. Patent No. 5,679,635 (issued Oct. 21, 1997).

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the *Nelson Textbook of Pediatrics*, the most widely used general pediatrics textbook.<sup>70</sup> Under the heading "Treatment and Prevention," Matalon explained, "No specific treatment is available.... Genetic counseling, carrier testing, and prenatal diagnosis are the only methods of prevention."<sup>71</sup> Even when a pediatric patient, as opposed to a fetus, is diagnosed using the biochemical assay, Matalon writes that it is "important to obtain a molecular diagnosis."<sup>72</sup> Characterizing the patient's DNA mutation makes possible the prenatal diagnosis of fetuses with that mutation.

The discovery of the Canavan gene represented a rapid advance in scientific knowledge and the potential (at least from a technological perspective) to prevent a devastating disease. Had this discovery led to widespread, easily accessible testing and research, it could have immediately been considered a modern medical miracle. However, the Miami Children's Hospital Research Institute (MCHRI), the hospital for which Matalon worked when the gene was discovered and the patent assignee, obtained a patent on the Canavan gene. Instead of maximizing the possibility of preventing the disease by allowing the unlimited use of Matalon's invention, MCHRI opted to maximize the licensing revenue it could derive from the discovery. By threatening independent laboratories and universities with infringement actions, MCHRI forced such centers to refrain from offering testing, thus limiting research and the availability of testing. Although the Canavan disease case, in which the parents of a child afflicted with the disease sued MCHRI over the enforcement of the patent, settled in 2003 on terms not available to the public, the facts of the case illustrate the issues at question in the controversy over gene patents.<sup>73</sup>

# B. The Canavan Patent

On October 21, 1997, the U.S. PTO issued patent 5,679,635, entitled "Aspartoacylase gene, protein, and methods of screening for mutations associated with canavan [sic] disease" (the "Canavan patent").<sup>74</sup> The patent specification discloses the cDNA<sup>75</sup> sequence of the wild-type aspartoacylase

<sup>70.</sup> Id. at 376.

<sup>71.</sup> Id.

<sup>72.</sup> Id. at 375. Matalon explains that a proper diagnosis can lead to accurate counseling and aid with future familial prenatal diagnosis.

<sup>73.</sup> Joint Press Release, Canavan Found. (Sept. 29, 2003),

http://www.canavanfoundation.org/news/09-03\_miami.php.

<sup>74.</sup> U.S. Patent No. 5,679,635, supra note 42.

<sup>75.</sup> cDNA stands for "complementary DNA." cDNA is the DNA molecule that is

gene,<sup>76</sup> along with the predominant mutations of the gene that cause Canavan disease. Additionally, the patent teaches<sup>77</sup> methods to screen individuals for the presence of the gene. In exchange for this disclosure, the patentees were granted claims not only on the gene and mutations that they disclosed, but also on *all* human variants of the gene as they exist in nature, whether or not yet discovered or disclosed in the application;<sup>78</sup> any fragment of the gene greater than or equal to 1.1% (sixteen base pairs) of the disclosed sequence;<sup>79</sup> any methods to test for the presence or absence of the gene, or any variant of the gene, in a patient;<sup>80</sup> and any probe which might be useful in detecting or researching the disease.<sup>81</sup> The patentees were also granted claims on basic tools of research, including any and all recombinant vectors,<sup>82</sup> host cells,<sup>83</sup> and methods of producing recombinant protein<sup>84</sup>—i.e., tools absolutely necessary to develop a treatment or cure for the disease.

#### 1. DNA Sequence Claims

The claims of the Canavan patent are disproportionate to what the specification discloses. The heart of the invention in the Canavan patent is the sequence for the aspartoacylase gene, together with the discovery that defective functioning of the gene product leads to the disease. The patent discloses the wild-type sequence of the gene, as well as several mutations of the gene that have been shown to be causative of Canavan disease.<sup>85</sup>

- 82. Id. claims 14-15.
- 83. Id. claims 16-17.
- 84. Id. claims 18-24, 39.
- 85. Id. at General Discussion.

complementary to the messenger RNA transcript of the genomic DNA (gDNA). Practically, cDNA differs from gDNA in that the sequence of the cDNA has been edited by the cellular machinery to remove any introns (i.e., DNA which does not encode proteins) or other intervening sequences that exist in the genomic sequence. See G. Barsh et al., Genome Structure and Gene Expression, in PRINCIPLES AND PRACTICE, supra note 1, at 60, 66, 68, 78.

<sup>76.</sup> A wild-type gene is "[t]he form of an organism that occurs most frequently in nature." For this and other definitions, see Human Genome Information Project, *Genome Glossary, at* http://www.ornl.gov/sci/techresources/Human\_Genome/glossary/ (last visited July 9, 2004).

<sup>77. &</sup>quot;Teaches" is a term of art for the information which the patent discloses in its specification.

<sup>78.</sup> U.S. Patent No. 5,679,635, supra note 64, claims 1-7, 12-13.

<sup>79.</sup> Id. claims 1c, 38.

<sup>80.</sup> Id. claims 25-37, 40-44.

<sup>81.</sup> Id. claims 8-11.
Specifically, using the pedigree data from seventeen non-related Jewish families, the disclosure teaches that eighty-five percent of Canavan patients of Ashkenazi Jewish descent share a point mutation—i.e., a change in a single DNA base out of the 1435 bases that code for the aspartoacylase protein.<sup>86</sup> The causative mutation in another 14.8 percent of patients is another point mutation that causes the premature arrest of the transcription of the gene.<sup>87</sup> The patent additionally discloses various other mutations.<sup>88</sup>

However, in addition to claiming the disclosed sequences-the wildtype gene and specific mutations identified-the Canavan patent broadly claims any and all forms of the gene and/or mutations thereof: Claim 1 of the Canavan patent asserts the generic claim to a human aspartoacylase gene,<sup>89</sup> and in claim 3, the patent goes on to explicitly claim any aspartoacylase gene that "differs by at least one nucleotide from the nucleotide sequence of [the wild-type gene], and is a naturally-occurring allele of human aspartoacylase having an altered biological activity."90 Thus, the Canavan disease patent bars the characterization of a patient's DNA regardless of whether or not the patient has the disease, and even if the patient has a mutation that is not specifically disclosed in the Canavan patent. This is the case because the patent discloses only the most common disease-causing alleles, but claims "allelic variants" in addition to those mutations disclosed.<sup>91</sup> In effect, the patent obtained is on the Canavan locus.<sup>92</sup> In other words, the patentees have extended their disclosure of a handful of mutations known to cause Canavan disease into claims on any and all possible mutations, as well as any different aspartoacylase genes that might exist in humans anywhere, regardless of their effect on the function of the gene-or the fact that they have yet to be discovered. As the specification asserts, "[i]t will be understood by those of skill in the art that allelic or other sequence variations in the DNA... sequence[] of the

90. Id. claim 3.

91. Id.

92. For further discussion of the basic difference between an allele and a locus, see Am. Acad. of Pediatrics, *supra* note 2, at 1494.

<sup>86.</sup> Id.

<sup>87.</sup> Id. at General Discussion, Example 12.

<sup>88.</sup> Id. at General Discussion.

<sup>89.</sup> The claim reads in full: "An isolated nucleic acid molecule comprising: (a) a nucleic acid sequence encoding a human aspartoacylase polypeptide; (b) a nucleic acid sequence fully complementary to nucleic acid sequence (a); or (c) a nucleic acid sequence at least 16 nucleotides in length capable of hybridizing specifically with one of said nucleic acid molecules (a) or (b)." *Id.* claim 1.

[aspartoacylase] gene . . . are included in the present invention."99

The breadth of this claim runs counter to the principle that for DNA patents enough of the sequence must be disclosed to justify the breadth of the claim sought.<sup>94</sup> MCHRI's attempt to broadly claim all aspartoacylase sequences is reminiscent of *Amgen v. Chugai*, where a patent was found invalid because the biotechnology firm Amgen claimed all possible sequences coding for the gene for erythropoietin, but only disclosed the wild-type sequence and a few analogs.<sup>95</sup> However, although MCHRI's patent may be overbroad, the validity of the patent has not been challenged directly. The full breadth of the patent, as issued, would cover any genetic mutation causing Canavan disease, whether or not discovered by Dr. Matalon or other researchers at MCHRI.

## 2. Methods for Screening for Canavan Mutations

The Canavan patent employs two overlapping strategies for obtaining coverage of all means of diagnosing the presence of the Canavan disease gene: Claims 25-37 are "method" or "process" claims,<sup>96</sup> and claims 8-11 cover the DNA molecule probes that are essential to amplifying a patient's DNA in order to utilize those methods or processes.<sup>97</sup> Claim 25 broadly claims a generic method for screening a person for the gene:

A method of screening a subject to determine if said subject is a Canavan carrier or a Canavan patient, comprising (a) providing a biological sample of the subject to be screened; and (b) submitting the sample to an assay for detecting in the biological sample the presence of a wild-type aspartoacylase gene, a mutant aspartoacylase gene or a mixture thereof, wherein said gene has a DNA sequence of claim 1, and wherein detection of a mutant as [sic] aspartoacylase gene indicates that the subject is a Canavan patient.<sup>98</sup>

The patent goes on to specifically claim different methods well known in the art which could be used to test for the presence of the mutant gene, whether by hybridization assay,<sup>99</sup> labeled nucleotide probes,<sup>100</sup> DNA

<sup>93.</sup> U.S. Patent No. 5,679,635, supra note 64, at General Discussion.

<sup>94.</sup> See Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991), cert. denied, 502 U.S. 856 (1991).

<sup>95.</sup> Id. at 1214.

<sup>96.</sup> U.S. Patent No. 5,679,635, supra note 64, claims 25-37.

<sup>97.</sup> Id. claims 8-11.

<sup>98.</sup> Id. claim 25.

<sup>99.</sup> Id. claim 26. Hydridization assays, whether using radionucleotide probes (i.e.,

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hybridization assay,<sup>101</sup> RFLP,<sup>102</sup> heteroduplex analysis,<sup>103</sup> or kits for performing these procedures.<sup>104</sup> The result of these expansive claims is that any attempt to test a person's genetic material for the mutant gene using conventional molecular genetic tools found in any molecular biology laboratory will infringe on the Canavan patent.

## 3. Decreased Availability of Screening

In testimony before Congress, the College of American Pathologists complained of the deleterious effect of patent enforcement on the availability of diagnostic tests generally, stating that forty-eight percent of seventy-four university-based clinical laboratories surveyed had ceased performing or developing a test for either clinical or research purposes because of patent restrictions.<sup>105</sup> That patent enforcement leads to diminished availability for genetic testing has also been shown for another genetic disorder, hereditary haemochromatosis.<sup>106</sup>

In light of these facts, it is not surprising that the enforcement of the Canavan patent also led to diminished availability of testing. Citing negotiations with "major pharmaceutical companies" seeking licensing to offer Canavan tests, MCHRI in November of 1998 began to assert its patent

100. U.S. Patent No. 5,679,635, supra note 64, claim 27.

101. Id. claim 30.

102. Id. claim 31. Restriction fragment length polymorphisms (RFLPs) rely on bacterial enzymes that cut DNA strands at known sequences. When a mutation changes the sequence, the bacterial enzyme no longer can cleave the DNA. Human Genome Information Project, *supra* note 76.

103. U.S. Patent No. 5,679,635, supra note 64, claim 32.

104. Id. claims 33-37, 42, 44.

105. Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. On Courts and Intellectual Property of the House Comm. On the Judiciary, 106<sup>th</sup> Cong. 158-60 (2000) (prepared statement of the Coll. of Am. Pathologists).

106. Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577 (2002). Merz and his colleagues conducted a survey of clinical labs and examined whether the existence of patents on the gene causing haemochromatosis, a blood disorder causing excessive red blood cell production, affected the offering of genetic tests for the disease. They concluded that enforcement of hemochromatosis gene patents caused laboratories to cease offering testing for the gene. *Id.* at 578-79.

radioactively labeled DNA) or other DNA sequence fragments, rely on the double-stranded nature of DNA. They work because single strands of DNA will automatically bind complementary sequences. Thus, labeled DNA fragments can be used to bind larger DNA fragments (i.e., those isolated from a patient). Human Genome Information Project, *supra* note 76.

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rights by sending cease-and-desist letters to centers offering testing without a license; the letters advised the centers of MCHRI's intention to "enforce vigorously our intellectual property rights relating to carrier, pregnancy, and patient DNA tests for Canavan Disease mutations."<sup>107</sup> As a result, community organizations and academic centers previously offering testing were forced to stop doing so or risk liability for patent infringement. Referring specifically to the availability of Canavan disease testing, the AMA concluded in December 2000 that "[t]he ultimate impact [of patent enforcement] is that the test is *currently not available* to many of those who desire it."<sup>108</sup>

Because prior art biochemical assays remain the preferred means of diagnosing Canavan disease in patients once they are born, the most significant effect of the Canavan patent is on prenatal testing, which cannot be done using the prior art methods.<sup>109</sup> Thus, the restriction of testing due to exclusive licensing is most acutely felt where it is currently needed most—in disease prevention.

#### 4. Canavan Patent Restricts Research

While the lack of availability of genetic testing is an undeniably important problem for families who may be carriers of these diseases, another concern raised by the award of gene patents is their potentially chilling effect on innovative attempts to treat or cure genetic disease.<sup>110</sup> Because Canavan disease is caused by an inborn error of metabolism, gene therapy provides the only hope for developing treatment or a cure. Unfortunately, MCHRI was granted claims on the very basic tools of molecular research—the vectors,<sup>111</sup> host cells,<sup>112</sup> and recombinant genes<sup>113</sup>

<sup>107.</sup> See Compl. para. 32, Ex. A, Greenberg v. Miami Children's Hosp. Research Inst., 208 F. Supp. 2d 918 (N.D. Ill. 2002) (No. 00C-6779).

<sup>108.</sup> COUNCIL ON SCI. AFFAIRS, supra note 59. For information about the current availability of Canavan disease testing, see Screening & Testing Centers, Canavan Foundation, at http://www.canavanfoundation.org/screening.php (last visited May 17, 2004). Availability remains limited, id., nearly one year after the Greenberg case was settled, infra text accompanying note 118.

<sup>109.</sup> See supra note 65.

<sup>110.</sup> It is difficult to determine definitively the inhibitory effect of the Canavan patent on research as there is no way to know what projects might have been undertaken were it not for the patent. Under the terms of the settlement agreement, researchers may now use the Canavan disease gene without fear of litigation.

<sup>111.</sup> U.S. Patent No. 5,679,635, supra note 64, claims 14-15.

<sup>112.</sup> Id. claims 16-17.

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absolutely essential to researching a treatment or cure. The patent uses this combination of claims to cover the basic methodologies of genetic research, making it impossible for a worker skilled in the art to research Canavan disease without infringing on the patent. Unlike many other industrialized nations,<sup>114</sup> the United States's recognition of an "experimental use" exception to patent infringement is extremely narrow.<sup>115</sup> Researchers hoping to cure Canavan disease through gene therapy would not be protected from a patent infringement suit, since such research could be viewed as a "commercialization" of the Canavan patent.<sup>116</sup>

In the case of Canavan disease, the families who motivated the Canavan disease research and supplied the biological materials<sup>117</sup> that were necessary for the discovery of the gene filed a complaint alleging breach of fiduciary duty, lack of informed consent, and unjust enrichment. Although there was no remedy for them under U.S. patent law, the families and MCHRI reached a settlement on August 6, 2003, ensuring the free use of the Canavan gene in research to cure the disease. MCHRI will, however, continue to collect royalties on the screening test.<sup>118</sup> It is important to

115. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) (noting that "the experimental use defense is very narrow and strictly limited").

116. For a review of the experimental use doctrine under U.S. law, see Janice M. Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1, 17-32 (2001). Mueller writes:

An experimental use exception has met with little success in the United States . . . The U.S. Court of Appeals for the Federal Circuit has grudgingly recognized the existence of a common law experimental use defense, but characterizes it as 'truly narrow' and applicable only to trifling 'dilettante affairs.' Banished from the experimental use defense is any activity viewed as 'commercialization' or otherwise grounded on profit motive. The current narrow interpretation of the doctrine virtually assures that it cannot be relied on by the rapidly growing number of university and industry collaborations whose research and development efforts are ultimately targeted at the commercialization of new biomedical products.

Id. at 5 (internal citations omitted).

117. See Compl., Greenberg v. Miami Children's Hosp. Research Inst., 208 F. Supp. 2d 918 (N.D. Ill. 2002) (No. 00C-6779).

118. Press Release, Canavan Found., Gene Patent Lawsuit May Radically Affect Research (Sept. 29, 2003), available at http://www.canavanfoundation.org/news/09-03\_miami.php (last visited Apr. 14, 2004).

<sup>113.</sup> Id. claims 18-24.

<sup>114.</sup> For a comparative review of nations' experimental use exception to patents, see Natalie M. Dzerko, A Local and Comparative Analysis of the Experimental Use Exception—Is Harmonization Appropriate?, 44 IDEA 1, 28-70 (2003).

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recognize that this settlement was made possible, in large part, by the particular facts of the Canavan gene discovery, which was funded initially by Canavan families, who then challenged the ownership of the patent on grounds outside the arena of ordinary patent law. Because of the complaint brought by the Greenberg family, all patients suffering from Canavan disease, as well as their families, enjoy the hope that they might benefit from the free use of the gene for research toward a cure. Unfortunately, these facts would apply to few, if any, patients suffering from other genetic diseases; these patients, therefore, will not have the same opportunity to ensure access to research.

Importantly, the effects on scientific research may be more insidious than simply the ability of the patentee to deny a competitor the right to do research. The AMA Council on Scientific Affairs warns of the corrupting influence that licensing agreements, which are beyond the purview of the Patent Office, may have on clinical research. The Council has noted that nothing would prevent a patentee from restricting a license such that the licensee would be "'gagged' regarding findings that question the validity and quality of data."<sup>119</sup>

Whether continued enforcement of the Canavan gene patent would have resulted in less research, less critical examination of the research that did occur, less prenatal screening, or all of the above, the future for potential victims of Canavan disease would have been similarly bleak: Under any of these scenarios, the enforcement of the Canavan patent undoubtedly would result in more children being born with this devastating neurological condition than would be the case if diagnostic testing were freely and widely available. Although the specter of intellectual property rights impeding the discovery of treatments and cures is today counterfactual in the Canavan case, this troubling prospect, along with the more immediately palpable problem of decreased access to screening technologies, is of general concern in the era of gene patents.

## **III. AMENDING THE "PHYSICIAN IMMUNITY STATUTE"**

At its 2000 interim meeting, the American Medical Association (AMA) House of Delegates adopted a resolution declaring that the AMA "supports equitable access to licenses or sublicenses of gene patents for diagnostic genetic tests to any Clinical Laboratory Improvement Act (CLIA)- certified laboratory at a reasonable royalty."<sup>120</sup> Unfortunately, given the practice of

<sup>119.</sup> COUNCIL ON SCI. AFFAIRS, supra note 59.

<sup>120.</sup> COUNCIL ON SCI. AFFAIRS, AMA, REPORT NO. 5, GENE PATENTING: UTILITY

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patentees negotiating exclusive licensing agreements,<sup>121</sup> the lack of controls to ensure widespread licensing,<sup>122</sup> and the legal difficulties that would be incurred by attempts to institute controls such as mandatory licensing,<sup>123</sup> the AMA's proposal for widespread access to diagnostic tests for a "reasonable royalty" is inadequate to remedy the problems posed by patents for gene-based diagnostic tests. The Canavan patent does not exist in a vacuum, nor is its enforcement just a case of moral bankruptcy on the part of one particular hospital. Rather it is a systemic problem that requires an adjustment to the law to cure.

Specifically, the Physician Immunity Statute<sup>124</sup> should be amended so that the exemption for "medical activit[ies]" includes the identification of a patient's genes for purposes of diagnosis or prenatal screening. Such an amendment would define the limits of a patent holder's right to exclude, thereby allowing patients' greater access to the diagnostic tests that play such an important role in the diagnosis and prevention of genetic-based diseases. This proposal brings the scope of patent protection for genetic testing into accord with that of other diagnostic procedures already encompassed by the Physician Immunity Statute.

## A. Amending the Statute

As I argued earlier, the legislative history of the Physician Immunity Statute shows that the exclusion of "biotechnology patent[s]" from the Act's protections was the result of aggressive lobbying on the part of the biotechnology lobby,<sup>125</sup> and the exclusion is broadly defined: A

123. See generally Janice M. Mueller, Patent Misuse Through the Capture of Industry Standards, 17 BERKELEY TECH. L.J. 623, 664-69 (2002) (discussing the use of mandatory licensing as a sanction for failing to disclose patent rights). Although Mueller argues for compulsory licenses of patented technology that becomes an "industry standard," *id.* at 664, this article provides an overview of the historical objections to mandatory licensing schemes.

124. Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67 (1996) (codified at 35 U.S.C. § 287(c) (2000)).

125. See Portman, supra note 40. A use or utility patent is a patent obtained on an

EXAMINATION GUIDELINES (2001), http://www.ama-assn.org/ama/pub/article/print/2036-4968.html (last visited Apr. 14, 2004).

<sup>121.</sup> For an overview of the considerations that enter into patent licensing, see Paul E. Schaafsma, An Economic Review and Suggested Approach for Licensing Patent Applications, 81 J. PAT. & TRADEMARK OFF. SOC'Y 340 (1999).

<sup>122.</sup> For an illustration of how exclusive licensing can have adverse effects, see Peter Mikhail, Hopkins v. CellPro: An Illustration That Patenting and Exclusive Licensing of Fundamental Science Is Not Always in the Public Interest, 13 HARV. J.L. & TECH. 375 (2000).

"biotechnology patent" includes a "biotechnology process," as defined in 35 U.S.C. §103(b), as well as a patent on a process of making or using biological materials.

Thus, included under this exemption are claims, like those in the Canavan patent, premised on standard molecular techniques, such as restriction fragment length polymerase (RFLP) testing, used in the genebased diagnosis of diseases. This result reflects the success of the biotechnology lobby's aggressive efforts.<sup>126</sup> In order to roll back this exemption and ensure greater access to genetic diagnostic tests, I propose the following amendment to 287(c)(2):

Recognizing that the human genome is the common heritage of all humanity, and that genetic diagnostic testing is playing an increasingly important role in the prevention of disease, Section 287(c) of Title 35, United States Code, is amended by replacing § 287(c)(2)(A)(iii) with the following revised subsection: "(iii) the practice of a process in violation of a biotechnology patent, other than for purposes of diagnosis."

In March 2002, Representative Lynn Rivers sponsored legislation similar to that proposed here. The "Genomic Research and Diagnosis Accessibility Act of 2002" included provisions allowing gene sequences to be used for research and diagnosis, and it required the disclosure of DNA sequences at the time an individual applied for a patent.<sup>127</sup> Unfortunately,

invented composition of matter (as opposed to a design patent, which is a patent on an ornamental design or appearance, or a plant patent, which is a patent on a novel plant). See BARRETT, supra note 17, at 111-371.

<sup>126.</sup> However, even the biotechnology industry is not without internal dissent. In testimony before the Federal Trade Commission and Department of Justice, Barbara Caulfield, general counsel for the biotechnology company Affymetrix stated that "there should be no patenting of gene sequences, period." See Tom Abate, Do Gene Patents Wrap Research in Red Tape?, S.F. CHRON., March 25, 2002, at E1.

<sup>127.</sup> Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002), was introduced in the House of Representatives in March of 2002. Section 3 of the bill provided that "the term 'medical activity' means the performance of a genetic diagnostic, prognostic, or predictive test or a medical or surgical procedure.'" It further defined those terms as follows:

<sup>[</sup>T]he term "genetic diagnostic, prognostic, or predictive test" means any test, designed to detect disease, to predict the potential for a medical disorder, or to predict the effectiveness of therapeutics, which uses either an ordered listing of nucleotides comprising a portion of a human or human pathogen genetic code or the proteins encoded by such nucleotides.

the legislation died when Representative Rivers lost her Congressional seat to fellow incumbent Representative John Dingell following redistricting. Nevertheless, there is an increasing awareness of the continued need for a legislative remedy for the growing conflict between patent jurisprudence and the needs of medical researchers and patients.<sup>128</sup>

The simpler proposal offered here more narrowly addresses the specific issue of ensuring physician immunity from patent infringement in the diagnosis of genetic disorders. Such a remedy allows patients at risk of genetic disorders to have unfettered access to diagnostic testing, without being encumbered by the broader issues of the effect of gene patents on research and industry disclosure raised by Representative Rivers's proposal. Although the effect of gene patents on research remains a significant concern, I have deliberately chosen to adopt a more modest approach in my proposal. Indeed, a broader approach, such as the one attempted by Representative Rivers, would be more likely to mobilize the biotechnology lobby and impede the likelihood of the amendment's success.

Moreover, extending the protection from infringement to academic or industrial researchers (or others not engaged directly in patient care) is unnecessary to redress the problem of the negative effect of patents on genetic testing. Rather, the potential for commercial gain from applications other than testing, such as would be obtained though commercial research, would be all the more critical after passage of this proposed amendment eliminating such gains from diagnostic applications. Experience in the pharmaceutical and medical device industries is persuasive that patent protection or, more specifically, the economic incentives associated with such protection are critical to the development of novel therapies.<sup>129</sup> Therefore it is the express intention of this proposal

<sup>128.</sup> See John Barton, Patents, Genomics, Research and Diagnostics, 77 ACAD. MED. 1339 (2002). Professor Barton advocates for a narrow legislative exemption aimed at protecting medical research from patents on ESTs and SNPs, as well as legislative and/or judicial challenges to the Court of Appeals for the Federal Circuit's recent extensions of patentable subject matter.

<sup>129.</sup> It is widely believed that the pharmaceutical industry would not engage in the costly research and development process required for new therapies, if not for the monopoly rights guaranteed by patent protection. While other public policies-including tax incentives and grants of public monies-may also encourage technical innovation, patents continue to be viewed as the essential element. See ORG. FOR ECON. COOPERATION & DEV'T, (2004), CHALLENGES 9 POLICY PATENTS AND INNOVATION: TRENDS AND http://www.oecd.org/dataoecd/48/12/24508541.pdf; Wesley M. Cohen, Patents: Their Effectiveness and Role, Presentation to the FTC/DOJ Hearings on Competition and Intellectual Property Law in the Knowledge-Based Economy (Feb. 20, 2002),

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to maintain the traditional patent incentives in such cases. However, whereas biotechnology patents may well be necessary to ensure the commercial viability of the development of gene therapies (in analogy to pharmaceuticals), molecular diagnostics are more easily developed,<sup>130</sup> and genetic diagnosis is easily performed once a gene has been sequenced.<sup>131</sup>

By limiting the biotechnology patent exemption of § 287(c), the restrictions on diagnostic testing, as in the case of Canavan disease, would be loosened to the benefit of patients. The precise extent of this loosening would have to be worked out in the political process. For example, a Congressional majority might want to impose stricter restrictions on parents' access to fetal genetic information than it would on individuals' access to their own "personal" genetic information. Even if the legislative process, subject to judicial review, were to maintain relatively tight restrictions on access to genetic testing, it is better that those restrictions be controlled by the policy choices of publicly accountable representatives, rather than the individual actions of private parties.

This modification would result in more widely available tests and, consequently, increased prevention of genetic disease. In addition, the proposal would alleviate concerns about the potential gagging effect of licenses, since physicians would be free to perform the diagnostic tests and report their efficacy in journals without the fear of data being subjected to oversight by the licensing company. The potential for licenses to gag

http://www.ftc.gov/opp/intellect/cohen.pdf. There is considerable debate about how to most efficiently achieve costly drug innovation and whether current patent terms are ideal. *See, e.g.*, OXFAM, IMPLAUSIBLE DENIAL: WHY THE DRUG GIANTS' ARGUMENTS ON PATENTS DON'T STAKE UP (2001), at http://www.oxfam.org.uk/what\_we\_do/issues/health/implausible\_denial.htm (last visited May 17, 2004); *see also* Heller & Eisenberg, *supra* note 11. However, there is little question that the costs of developing diagnostics are less than for developing therapeutics, *see infra* note 130 and accompanying text; one can hypothesize that the incentives required are also reduced.

<sup>130.</sup> The timeline for scientific development and regulatory approval of diagnostics is shorter than for therapeutics and the process, overall, is less expensive. However, the revenue potential is smaller for diagnostics than for therapeutics for several reasons, including greater price sensitivity. *See, e.g.*, Robert S. Schifreen, *Molecular Diagnostics: The Challenge for the Future*, IVD TECH., Nov. 2003, at 27.

<sup>131.</sup> For example, one study found that many laboratories offered testing for genes based on published sequence data, before any commercial kits were made available (and not coincidentally before the patents were enforced). Mildred K. Cho, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3 (2003).

physicians is based on a contractual relationship between the physician and the patent holder; thus, in the absence of such an agreement, a physician would be able to publish based on his or her own clinical experience with the test. This would in turn benefit patients, since the doctor-physician relationship requires that patients be able to trust their physicians, and is undermined by third party influences on physician decision making.

#### B. Policy Cost-Benefit Analysis

The biotechnology lobby, in its attack on the original incarnation of the Physician Immunity Statute, argued that gene patents protect companies' investments and therefore have a net effect of increasing research and development, resulting in more diagnostic tests, drugs, and novel therapies.<sup>132</sup> While it is likely that patent protection, generally speaking, does stimulate research and development, several coinciding factors dilute the value of the patent "incentive" not just for gene patents on methods of diagnosis, but for gene patents in general. In the early days of biotechnology, the effort required to clone a gene or elucidate its sequence was staggering.<sup>133</sup> Courts were cajoled into recognizing the substantial amount of labor that scientists put into these "inventions" in order to provide the nascent biotechnology industry with an incentive to continue such tedious work. However, they could not have anticipated that what in the 1980s required Herculean labor would, by the mid-1990s, easily be achieved in a day. The increase in the speed and ease of sequencing has meant that the "innovation" required to patent a gene is not now what it was when Dr. Chakrabarty successfully defended his groundbreaking patent on a genetically-modified oyster before the Supreme Court.<sup>134</sup> With each passing day, as technology becomes more advanced, it requires less and less "innovation" to patent a gene.

134. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

<sup>132.</sup> Hearings on H.R. 1127, supra note 45, at 92, 94-98 (prepared testimony of Frank Baldino, Jr., President and CEO of Cephalon, Inc.).

<sup>133.</sup> At its inception around 1990, it was estimated that the Human Genome Project would take 30,000 person-years to complete, based on the then maximum rate of sequencing of 100,000 base pairs per person per year. PRINCIPLES AND PRACTICE, *supra* note 1, at 291. With the advent of automated high-output sequencing, analysis of the human genome can proceed at a much faster pace now than it could just a few years ago. See Mark Adams et al., Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project, 252 SCIENCE 1651, 1651 (1991). Perhaps even more important is the diminution in the costs of sequencing that comes with automation. Id. at 1651.

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A second consideration is the "gold rush" aspect of gene patenting.<sup>185</sup> The human genome is finite—more so than was at first appreciated<sup>15</sup> and researchers have already completed sequencing the human genome.<sup>137</sup> University scientists "and at least one major pharmaceutical company" have reacted to the attempt by genome companies to appropriate the human genome by dedicating sequence data to the public, creating prior art hurdles for many gene patents.<sup>138</sup> Between the sequences dedicated to the public, and those already "invented," the window for inventors to "invent" human genes is closing. In fact, before the PTO imposed the utility requirements on EST patent claims, many companies had been filing for patent applications on DNA molecules for which no function is known, simply speculating on the possibility that their patented sequence will turn out to be an important one. At least in the initial stage of the genetic revolution, a "gold rush" mentality dominated. Despite the PTO's heightened emphasis on the utility criterion, individuals and enterprises who were attracted to this "patent bonanza" atmosphere might continue to file for intellectual property protection not to further knowledge, but rather to stake a claim to a patch of DNA that the "inventor" hopes will one day yield a mother lode.

Moreover, while the relatively small number of genes being dedicated to the public increases, the number of overlapping, or stacked, patents on genes is likely to increase. Since many "stacked" patents on the same disease gene will increase the licensing costs of the diagnostic test, it is possible, if not likely, that gene- based diagnostic tests will be kept out of the market not by scientific obstacles, but rather by commercial ones.<sup>139</sup> The liberal issuance of "Expressed Sequence Tag" (EST) patents<sup>140</sup>

139. This is what Michael Heller and Rebecca Eisenberg have referred to as the "tragedy of the anticommons . . . in biomedical research." Heller & Eisenberg, *supra* note 11, at 701. "A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream." *Id.* at 698.

140. An EST is a cDNA corresponding to randomly selected messenger RNA isolated from a cell. Because messenger RNA is the transcript of genomic DNA on its way to being "expressed" as protein, the sequences are limited to expressed sequences. It is further called a 'tag' because the procedure generated only a fragment of the cDNA transcript.

<sup>135.</sup> Susan Watts, The Genetic Goldrush, INDEPENDENT (London), Apr. 27, 1994, at 21.

<sup>136.</sup> It contains approximately 30,000 loci. International Human Genome Sequencing Consortium, 409 NATURE 860, 861 (2001).

<sup>137.</sup> Elizabeth Pennisi, Reaching Their Goal Early, Sequencing Labs Celebrate, 300 SCIENCE 409 (2003).

<sup>138.</sup> See Eliot Marshall, Companies Rush to Patent DNA, 275 SCIENCE 780, 781 (1997); Eisenberg, supra note 30, at 559, 561.

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threatened to inordinately dilute the value of a patent on a gene for purposes of diagnosis because ESTs are by definition non-functional fragments of a gene; their main potential commercial utility is to aid in diagnosis.<sup>141</sup> Although patents for bare genetic sequences can no longer be used to claim the underlying gene and protein if their functions are unknown,<sup>142</sup> there remains the problem of overlapping or stacked patents due to polymorphisms or mutations of the same gene. There are literally hundred of mutations of the breast cancer gene, each one potentially patentable.<sup>143</sup> Theoretically, even a handful of disease-causing alleles could each be subject to several patents, so that the number of cross-licenses needed to market a diagnostic test would be unworkable.<sup>144</sup>

Moreover, in addition to these trends, it is too simplistic to argue that private capital provided by biotechnology investors, enticed by the prospect of licensing fees, is absolutely necessary for the discovery of genes and the development of diagnostic tests. The Medical Procedure Patent Coalition argues that the patent "incentive" is unnecessary in medical practice, as "the development of new medical procedures often occurs during the normal course of medical practice and generally does not require significant capital investment."<sup>145</sup> Even if genetic tests are not

142. "If a patent discloses only nucleic acid structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. . . . ESTS which meet the criteria for utility, novelty, and nonobviousness are eligible for patenting when the application teaches those of skill in the art how to make and use the invention." Utility Examination Guidelines, *supra* note 33, at 1093-94 (Jan. 5, 2001); *see also* Tom Hollon, *Gene Patent Revisions To Remove Some Controversies*, 6 NATURE MED. 362, 362 (April 2000).

143. There are approximately460 known, distinct sequence variants of BRCA1 (one of two known breast and ovarian cancer genes). Therese Sørlie et al., Mutation Screening of BRCA1 Using PTT and LOH Analysis at 17q21 in Breast Carcinomas from Familial and Non-familial Cases, 48 BREAST CANCER RES. TREAT. 259, 259 (1998).

144. Cf. Heller & Eisenberg, supra note 11, at 699 (discussing the analogous problem of "concurrent fragments" in pharmaceutical screening).

145. Jenner & Block, Patents for Surgical/Medical Procedures: A Call for Legislative Prohibition, http://www.ascrs.org/advocacy/execsum.html (last visited Apr. 27, 2004).

Human Genome Information Project, supra note 76.

<sup>141.</sup> See, e.g., AM. SOC'Y OF HUMAN GENETICS, PATENTING OF EXPRESSED SEQUENCE TAGS (1991), http://genetics.faseb.org/genetics/ashg/policy/pol-08.htm (recognizing the potential commercial application in the realm of diagnostics but noting that "the utility of ESTs can be seriously questioned. Scientific experience suggests that an EST itself is unlikely to have commercial utility. The [principal] anticipated utility of an EST is simply as a research tool to identify the remainder of the coding region of the gene.").

generally developed "during the normal course of medical practice," these tests may well require less investment of time, money, and talent to develop than other inventions, such as pharmaceuticals. Moreover, as with other medical procedures, researchers may be draw substantial motivation from non-monetary incentives, such as a desire to improve their professional stature or reputation. In addition, in the case of many rare diseases, it is patients, patient support groups, and their doctors who raise money and awareness of the disease seeking a treatment, diagnostic test, or cure. Canavan disease is a formidable example of research driven by patients, not industry. Exempting physicians from patent infringement would have had little, if any, effect on Matalon's discovery of the gene, although it might have spared "Canavan families" the burden of pursuing their lawsuit.

The societal benefit of these private research dollars is further reduced by a corresponding increase in costs associated with gene patenting, which effectively retards research. These costs range from the systemic effects of gene patenting that create commercial incentives that skew academic research<sup>146</sup> away from free disclosure of information to the diminution in research caused by inhibiting basic academic research secondary to increased research costs.<sup>147</sup> The Canavan patent, for example, covers any and all uses of the gene or even fragments of the gene, making research on the Canavan disease gene without a license impossible. In addition, the specter of stacked patents on ESTs may exacerbate these negative tendencies exponentially. Imagine the same facts surrounding the Canavan patent, but where the testing centers were issued cease-and-desist letters from a dozen different genome corporations with claims to parts of the Canavan sequence, or prominent mutations. Given these negative factors, it is not at all clear that the net effect on innovation attributable to gene patents is positive.

There are other costs associated with patents on genetic diagnostic tests. In fact, there are human costs. There can be no question that the enforcement of the Canavan patent claims on diagnostic tests results in more children being born with this preventable genetic disease which causes incredible suffering and hardship on families and which is ultimately uniformly lethal.

Finally, the patent right may be subject to abuse. The fundamental right a patent provides is the right to exclude others from making or using the disclosed invention. Thus, for example, a religious group that fears

<sup>146.</sup> David Blumenthal, Academic-Industrial Relationships in the Life Sciences, 349 NEW ENG.

J. MED. 2452, 2455 (2003); see also Blumenthal, supra note 31.

<sup>147.</sup> See generally Heller & Eisenberg, supra note 11, at 700.

that diagnostic tests will result in more prenatal diagnosis and abortion could purchase patents on childhood diseases to prevent the development of such tests. Alternatively, a company could patent a gene, but then not have the financial resources to exploit its invention and allow the patent to languish.<sup>148</sup>

While patent protection currently leads to monopoly control over a gene, conversely, stacked patents, which each necessitate cross-licensing, potentially dilute the value of any individual patent. The amendment to the Physician Immunity Statute which I propose would obviate entirely the issue of whether one is infringing on one exclusive licensee or two hundred potential licensees by allowing unfettered access to genetic diagnosis. Similarly, should a patent-holder not have the means to develop or market kits to make diagnosis practically feasible, independent labs would be free to do so. Finally, the provision would prevent the patent system from being used as a vehicle for restricting licenses out of noneconomic concerns, such as to prevent pre-implantation diagnosis or family planning.

## **IV.** CONCLUSION

There is no doubt that society benefits from medical advances in its ability to diagnose and treat human ailments in which genetic predisposition is a causal or contributing factor. Society can also benefit from the patenting of genes that can be exploited to develop novel medicines such as Epogen, Amgen's recombinant erythropoietin product, or incorporated into gene therapies. These are examples of beneficent applications of gene patents; so, too, are patents for pharmaceuticals that encourage innovation and research into new drug treatments. The proposed legislation would have no effect on the biotechnology industry's ability to continue to bring such ground-breaking and important inventions to market. For example, gene therapy-attempts to correct the genetic defect through the use of recombinant technology-would not be affected by the proposed legislation. As far as diagnostics are concerned, though, patent protection is not in the public interest. This Article proposes a narrowly tailored approach that would alleviate the problems caused by patents such as the Canavan patent without affecting the ability

<sup>148.</sup> For an overview of the history of suppressed patents (where a company withholds development of a patent for strategic reasons), as well as for a proposal for compulsory licensing of non-used patents, see Kurt Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389 (2002).

of—or incentives for— biotechnology or pharmaceutical companies to develop novel, and patentable, drugs or other therapies.

## COMMENTARIES

## Cloning Matters: How Lawrence v. Texas Protects Therapeutic Research

## Steven Goldberg, J.D.\*

Several states have banned therapeutic cloning,<sup>1</sup> and the federal government is considering legislation that would do the same.<sup>2</sup> Some of

2. Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. § 302(a)(1) (1st Sess. 2003) ("It shall be unlawful for any person ... to perform or attempt to perform human cloning ...."); see also id. § 302(a)(3) ("It shall be unlawful for any person ... to ... receive for any purpose an embryo produced by human cloning or any product derived from such embryo."). The legislation also imposes a maximum penalty of ten years imprisonment for violations of these sections. Id. § 302(c)(1). As the text makes clear, this bill would ban human cloning whether supported by private or public funds. The federal legislation defines "human cloning" in language similar to that used by state legislatures: "Human cloning" is defined as "human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any state of development) that is genetically virtually identical to an existing or previously existing human organism." Id. § 301(1). This bill passed the House of

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<sup>1.</sup> See, e.g., N.D. CENT. CODE 12.1-39-02.02(1)(c) (2003) ("A person may not... receive the product of a human cloning for any purpose ..."). Human cloning is defined as "human asexual reproduction, accomplished by introducing the genetic material of a human somatic cell into a fertilized or unfertilized oocyte, the nucleus of which has been or will be removed or inactivated, to produce a living organism with a human or predominantly human genetic constitution." *Id.* §12.1-39-01. Similar bans are achieved by ARK. CODE ANN. §§ 20-16-1001 to 20-16-1003 (2003) and IOWA CODE ANN. §§707b.1 to 707b.4 (2003). All of these statutes ban both reproductive and therapeutic cloning. On the distinction between reproductive and therapeutic cloning, see *infra* Part I.

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these laws, including the proposed federal legislation, make it a crime not only to engage in therapeutic research on a cloned embryo, but also for a patient to use any medicine derived from such research, even if the cloning took place in a country where the research is lawful.<sup>3</sup> Under the United States Constitution, government action restricting freedom in this way must have at least a rational basis if it is to be upheld in court.<sup>4</sup>

Opponents of therapeutic cloning argue not that medicines derived from therapeutic cloning will be unsafe or ineffective, but rather that the embryonic stem cells used in therapeutic cloning represent potential life that must be protected.<sup>5</sup> I will argue, however, that this concern is not the real reason most individuals oppose therapeutic cloning. Indeed, this

summ2=m& (last visited Apr. 2, 2004); see The Good Kind of Cloning, L.A. TIMES, March 12, 2003, at 2-12. Because this bill would make it unlawful to perform human cloning for any purpose or to receive an embryo produced by human cloning for any purpose, it would ban both reproductive and therapeutic cloning. Denise Grady, Debate over Cloning in U.S. Remains Intense, N.Y. TIMES, February 12, 2004, at B12. For more on the two types of cloning, see infra Part I.

3. Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. § 302(b)-(c)(1) (1st sess. 2003) ("It shall be unlawful for any person . . . to import for any purpose an embryo produced by human cloning or any product derived from such embryo. . . . Any person . . . that violates this section shall be . . . imprisoned not more than 10 years . . . . "). As this text makes clear, there is no exclusion for products received from countries where therapeutic cloning is lawful. *See, e.g.,* Ellen Goodman, *Outlawing Science,* WASH. POST, March 8, 2003, at A23. Similarly, under North Dakota law, a person may not "receive the product of a human cloning for any purpose." *See* N.D. CENT. CODE §§ 12.1-39.01 to 12.1-39-02.02(1)(c) (2003).

4. Both the Due Process and the Equal Protection Clauses require, at a minimum, that legislative classifications be supported by a rational basis. See, e.g., Williamson v. Lee Optical, 348 U.S. 483 (1955); Carolene Products Co. v. United States, 323 U.S. 18 (1944); see also Robert A. Schapiro & William W. Buzbee, Unidimensional Federalism: Power and Perspective in Commerce Clause Adjudication, 88 CORNELL L. REV. 1199, 1255 (2003). The Supreme Court is generally quite deferential to the legislature in applying this standard. Id. At times, however, legislative enactments have been struck down as irrational. See, e.g., Cleburne v. Cleburne Living Ctr., 473 U.S. 432 (1985) (holding that it is irrational for the state to require a residence for the mentally disabled to obtain a special use permit not generally required). In Part III, I will discuss this rational basis review standard in the context of legislation concerning cloning.

5. See infra Part II. Other grounds for opposing therapeutic cloning are also discussed in Part II.

Representatives on February 27, 2003, but it has not passed the Senate. Bill Summary and Status for the 108th Congress, at http://thomas.loc.gov/cgibin/bdquery/z?d108:HR00534:@@@L&

"potential life" argument is ignored daily when some spare embryos produced as a byproduct of routine fertility treatments are destroyed while others are used for research.<sup>6</sup> As I will argue below, this disparate treatment reveals that the real basis for the ban on therapeutic cloning is repugnance at the idea of cloning, driven by a sense that cloning is unnatural. I will conclude this Commentary by arguing that the Supreme Court's recent decision in *Lawrence v. Texas* casts serious doubt on the idea that repugnance alone is an adequate basis for a criminal statute.

## I. THERAPEUTIC CLONING: SOME BACKGROUND

To understand the dispute over therapeutic cloning, it is necessary to understand the scientific terminology that underlies the debate. The term "human cloning" has come to include two distinct activities—reproductive cloning and therapeutic cloning—that begin in the same way: Nuclear material is removed from a woman's egg, and nuclear material from a donor's somatic cells is introduced in its place.<sup>7</sup> The egg then begins to develop in the same manner as a traditional fertilized ovum.

In the context of reproductive cloning, this embryo would be implanted in a uterus and brought to term. No one knows if this procedure will work in humans, and there is real concern that any human born in this way will be severely disabled.<sup>8</sup> The latter concern justifies regulation of reproductive cloning, much as the possibility of birth defects justifies the regulation of thalidomide.<sup>9</sup>

With therapeutic cloning, there is no intention of bringing the embryo to term. After a few weeks, the stem cells are removed for research, with the hope that this research will contribute to progress in the development of treatments for individuals suffering from diabetes, Alzheimer's, and

8. Id. at 356-57; see also Coby S. Nixon, Note, Human Cloning and the Commerce Power: In Light of United States v. Lopez, Congress Can—But Should Not—Regulate Human Cloning, 37 GA. L. REV. 295, 306 (2002).

9. See, e.g., Ruth Lynn Deech, Clones, Ethics and Infertility or Sex, Sheep and Statutes, 2 QUINNIPIAC HEALTH L.J. 117, 127-28 (1998-1999). The state statutes and the proposed federal statute under consideration in this Commentary all ban reproductive cloning. See supra notes 1-2.

<sup>6.</sup> See infra Part II.

<sup>7.</sup> The description of reproductive and therapeutic cloning provided in this Part is based on Suzanne H. Rhodes, Comment, The Difficulty of Regulating Reproductive and Therapeutic Cloning: Can the United States Learn Anything from the Laws of Other Countries?, 21 PENN. ST. INT'L L. REV. 341, 343 (2003).

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other ailments.<sup>10</sup> On February 12, 2004, South Korean scientists announced that they had derived stem cells from a cloned human embryo, moving the promise of therapeutic cloning closer to reality." While research remains to be done, Dr. Hwang Wee Suk, the leader of the South Korean team, is motivated by the possibility that such research will benefit patients, particularly by improving cell regeneration therapy.<sup>12</sup> His efforts were inspired in part by a newlywed couple he met at a Seoul hospital. During their honeymoon the husband fell, severely damaging his spine; Hwang believed the husband "was badly in need of treatment which human embryo research could help provide."13 In the United States, in the wake of the Korean breakthrough, Dr. Ron McKay, a stem cell scientist at the National Institute of Neurological Disorders and Stroke, reported that it was now easier than previously thought to extract stem cells from cloned human embryos.<sup>14</sup> McKay illustrated the potential benefits when he spoke of a scientist "who had died in her 40's from breast cancer"; he noted that if her tissues had been cloned to make human embryonic stem cells, those stem cells could have then been used in cancer research.<sup>15</sup>

## II. POSSIBLE JUSTIFICATIONS FOR BANNING THERAPEUTIC CLONING

What is the justification for banning therapeutic cloning? The legislation cannot be justified on the ground that it seeks to prohibit unsafe or ineffective treatments, as the bans are not tailored in this way. Under the existing state laws<sup>16</sup> and the proposed federal law,<sup>17</sup> the use of medicines derived from such cloning is a crime, even if the medicines are proven to be safe and effective. Indeed, under the proposed federal law, the importation of such medicine from any jurisdiction that permits

<sup>10.</sup> Michael J. Sandel, *The Anti-Cloning Conundrum*, N.Y. TIMES, May 28, 2003, at A19. Some researchers believe that stem cells from cloned embryos will have more therapeutic promise than stem cells from embryos that come from fertilization because using "material cloned from a patient's own DNA... might reduce or eliminate immune response problems." Roger H. Taylor, *The Fear of Drawing the Line at Cloning*, 9 B.U. J. SCI. & TECH. L. 379, 383 (2003).

<sup>11.</sup> Rick Weiss, Mature Human Embryos Cloned, WASH. POST, Feb. 12, 2004, at A01.

<sup>12.</sup> Anthony Faiola, Dr. Clone: Creating Life or Trying To Save It?, WASH. POST, Feb. 29, 2004, at A01.

<sup>13.</sup> *Id.* 

<sup>14.</sup> Gina Kolata, Cloning Creates Human Embryos, N.Y. TIMES, Feb. 12, 2004, at A1.

<sup>15.</sup> *Id*.

<sup>16.</sup> See supra note 1.

<sup>17.</sup> See supra note 2.

therapeutic cloning, such as the United Kingdom, is also a crime punishable by up to ten years in prison.<sup>18</sup>

Do individuals have a right to use potentially life-saving medicine unless the government has a rational basis for prohibiting its use? I believe that they do. In at least a few cases, the United States Supreme Court has protected the rights of patients to control their health. For example, when the Supreme Court, in Vacco v. Quill,<sup>19</sup> rejected a constitutional right to assisted suicide, every justice on the Court affirmed a patient's right to receive medicine to relieve pain, even if such treatment would hasten the individual's death. Justice Rehnquist, in his opinion for the Court, distinguished sharply between a doctor who assists a suicide and one who provides "aggressive palliative care."20 He further noted, "[I]n some cases, painkilling drugs may hasten a patient's death, but the physician's purpose and intent is, or may be, only to ease his patient's pain."21 The concurring opinions reiterated the right to pain relief. Justice O'Connor stressed that "[t]here is no dispute that dying patients in Washington and New York can obtain palliative care, even when doing so would hasten their deaths."22 Justice Stevens, noting that the Supreme Court had previously upheld a right to refuse treatment,<sup>23</sup> wrote that "[a]voiding intolerable pain" was also a vital liberty interest.<sup>24</sup> Justice Souter drew precisely the same distinction between "assistance to suicide, which is banned, and practices such as termination of artificial life support and death-hastening pain

18. Human Cloning Prohibition Act of 2003, H.R. 534,  $108^{ch}$  cong. § 302 (b)-(c)(1) (1<sup>st</sup> sess. 2003) ("It shall be unlawful for any person... to import for any purpose... any product derived from such embryo.... Any person... that violates this section shall be ... imprisoned not more than 10 years...."); see also Ellen Goodman, Outlawing Science, WASH. POST, March 8, 2003, at A23. On the legality of therapeutic cloning in the United Kingdom, see Nicholas Wade, Stem Cell Studies Advance in Britain, N.Y. TIMES, Aug. 14, 2001, at A1.

19. 521 U.S. 793 (1997) (holding that the Equal Protection Clause does not create a right to assisted suicide).

20. Id. at 802.

21. Id.

22. Id. at 737-38 (O'Connor, J., concurring). Justices Ginsburg and Breyer joined in this portion of O'Connor's concurrence. Id. at 736.

23. Id. at 742 (Stevens, J., concurring in the judgments). Justice Stevens explained, "In Cruzan v. Director, Mo. Dept. of Health ... the Court assumed that the interest in liberty protected by the Fourteenth Amendment encompassed the right of a terminally ill patient to direct the withdrawal of life-sustaining treatment." Id. at 742. Stevens also noted, "The Cruzan case demonstrated that some state intrusions on the right to decide how death will be encountered are ... intolerable." Id. at 745.

24. Id.

medication, which are permitted."25

If the government cannot arbitrarily deny an individual access to death-hastening pain medication, it is at least arguable that it cannot deny access to potentially life-saving medicine without a rationale. Of course, the absence of a valid reason to ban pain medication does not, in itself, demonstrate that there is no rationale for banning therapeutic cloning. I will discuss below the rationales that have been offered for such a ban.<sup>26</sup> The *Vacco* case simply supports the plausible proposition that the government cannot arbitrarily ban therapeutic cloning.

Nor does *Vacco* stand alone. For example, the Court has held that the state cannot arbitrarily forbid a woman from choosing an abortion procedure, even one that would otherwise be illegal, when it is necessary to protect her health.<sup>27</sup> This suggests yet again that the Court will ask for a rational justification when the government bans a safe and effective medicine derived from therapeutic cloning.

This means, of course, that it is important to determine whether a rational basis exists for such a ban. To do this, it is necessary to consider what possible justifications exist for the criminalization of therapeutic cloning. Several commentators have suggested that allowing therapeutic cloning increases the likelihood that we will someday come to accept reproductive cloning, and that this provides sufficient justification for the ban.<sup>28</sup> But our government does not have a free hand to regulate lawful activities because they might someday lead to unlawful ones. Otherwise little would be free from government regulation. Abortion cannot be banned because it might bring about the acceptance of infanticide. As the

28. See, e.g., Janet L. Dolgin, Embryonic Discourse: Abortion, Stem Cells, and Cloning, 31 FLA. ST. U. L. REV. 101, 112, 148 (2003); Cass R. Sunstein, Is There a Constitutional Right To Clone?, 53 HASTINGS L.J. 987, 1004 (2002). It is hard to see how this justifies the ban on importing medicines produced by therapeutic cloning from those countries where such cloning is legal, since the U.S. ban would have no direct impact there. Indeed, the generally more liberal attitude toward embryo research in the United Kingdom as compared to the United States has spurred such research in the U.K. Sarah Baxter, Give Us a Miracle, SUNDAY TIMES (London), July 22, 2001.

<sup>25.</sup> Id. at 809-10 (Souter, J., concurring in the judgment).

<sup>26.</sup> See infra notes 28-33 and accompanying text.

<sup>27.</sup> Stenberg v. Carhart, 530 U.S. 914, 936-38 (2000) (holding that the state cannot ban "a particular abortion procedure" without a health exception for the mother when this procedure may at times be the safest for the mother). Another indication that the Court gives weight to an individual's right to receive medicine is provided in the prison context. See Estelle v. Gamble, 429 U.S. 97, 103-04 (1976) (holding that the government must provide medical care for those it incarcerates).

Supreme Court has said, a state may not "prohibit possession of chemistry books on the ground that they may lead to the manufacture of homemade spirits."<sup>29</sup> It is no great feat to write legislation that bans reproductive cloning while allowing therapeutic cloning; indeed, some states have passed laws that do just that.<sup>30</sup> If our society remains committed to prohibiting reproductive cloning, it can prohibit it without stamping out therapeutic cloning as well.

The other justification for banning therapeutic cloning turns on the status of the stem cells that are used in the process. For many Americans, these cells represent either human life or potential human life.<sup>31</sup> For those with this view, banning therapeutic cloning is identical or similar to banning research on human subjects.<sup>32</sup> It does not matter that such research could lead to medical breakthroughs.<sup>33</sup> Our respect for human personhood is such that we require consent before we do research on people.<sup>34</sup> Since no consent is possible from embryonic stem cells and since the cells may be destroyed as part of the research process, these critics argue that therapeutic cloning should be banned.<sup>35</sup>

As I just indicated, this objection rests on the belief that embryonic stem cells are entitled to the protections we extend to life or potential life. The most immediate problem with this argument is that it does not reflect societal or legal attitudes, even in the states that have banned therapeutic cloning. As many observers have pointed out, there is an enormous contradiction between the concerns about therapeutic cloning and the

32. Id.

33. See supra note 10.

34. See, e. g., MICHAEL H. SHAPIRO ET AL., BIOETHICS AND LAW: CASES, MATERIALS AND PROBLEMS 198-231 (2003).

<sup>29.</sup> Stanley v. Georgia, 394 U.S. 557, 567 (1968) (holding that the state may not prohibit possession of obscene materials on the ground that such possession may lead to antisocial conduct).

<sup>30.</sup> See, e.g., CAL. HEALTH & SAFETY CODE §§ 24185-24187 (Deering 2003); R.I. GEN. LAWS §§ 23-16.4-1 to 23-16.4-3 (2001); see also John A. Robertson, Two Models of Human Cloning, 27 HOFSTRA L. REV. 609, 614 (1999); R. Alta Charo, The Ethics of Control, 2 YALE J. HEALTH POL'Y L. & ETHICS 143, 155 n.45 (2001). See generally States Show Washington the Way To Go on Stem Cells, NEWSDAY, March 19, 2003, at A28.

<sup>31.</sup> See generally Consuelo G. Erwin, Note, Embryonic Stem Cell Research: One Small Step for Science or One Giant Leap Back for Mankind?, 2003 U. ILL. L. REV. 211; Clarke D. Forsythe, Legal Perspectives on Cloning: Human Cloning and the Constitution, 32 VAL. U. L. REV. 469 (1998).

<sup>35.</sup> See, e.g., Erwin, supra note 31; Forsythe, supra note 31.

broad acceptance of assisted reproductive technologies.<sup>36</sup> In hundreds of clinics across the United States, would-be parents use *in vitro* fertilization techniques in which sperm and egg are brought together outside of the womb, and numerous embryos are created, only some of which are then implanted and brought to term.<sup>37</sup>

The disposition of the "spare embryos" that almost invariably result from *in vitro* fertilization illustrates that they are not treated as human life or potential human life. They are often destroyed, either because that is the wish of the would-be parents, or because, in cases where the parents' desires are unknown, the fertility clinic destroys them.<sup>38</sup> In many cases, they are frozen alive through a process called cryopreservation, and their ultimate fate is uncertain.<sup>39</sup>

One might argue that therapeutic cloning is more objectionable than in vitro fertilization because the former creates embryos with the intention of destroying them after the research is completed. In the case of fertility clinics, however, the goal is to create human life, and the creation of spare embryos is only an unfortunate byproduct of that goal. In other words, it might strike some people as worse to create an embryo explicitly for medical research purposes.<sup>40</sup>

There are a number of problems with this distinction. First, it is perfectly predictable that spare embryos will result from fertility treatments, so the demise of these embryos is not at all surprising.<sup>41</sup> Secondly, *in vitro* fertilization is not always successful.<sup>42</sup> Thus, the argument reduces to the belief that destroying several embryos is acceptable in the hope of producing healthy life. But if that is so, it would seem to justify therapeutic cloning, as well; there, too, embryos are destroyed, but it is with the goal of producing healthy life. Indeed, if therapeutic cloning lives up to its promise, it may save countless lives, both embryonic and full-

42. The national average for pregnancy rates from *in vitro* fertilization is estimated to be thirty percent. See Amy Dockser Marcus, Treatments Work To Reduce Risky Multiple Births, HOUSTON CHRON., Feb. 23, 2003, at A4. Even with the most advanced screening techniques, the success rate for *in vitro* fertilization for women over thirty-eight does not exceed fifty percent. Carey Goldberg, Screening of Embryos Helps Avert Miscarriage, BOSTON GLOBE, June 13, 2003, at A1.

<sup>36.</sup> See, e.g., Rhodes, supra note 7, at 349; Sandel, supra note 10.

<sup>37.</sup> See, e.g., SHAPIRO ET AL., supra note 34, at 625-41.

<sup>38.</sup> Id.

<sup>39.</sup> Mailee R. Harris, Stem Cells and the States: Promulgating Constitutional Bans on Embryonic Experimentation, 37 VAL. U. L. REV. 243, 244-45 (2003).

<sup>40.</sup> Sandel, supra note 10.

<sup>41.</sup> Harris, supra note 39.

term.43

It is important to note that not all spare embryos from fertility clinics are destroyed; some have been used to create stem cell lines that are used for scientific research.<sup>44</sup> In August 2001, after much deliberation and publicity, President Bush announced that federal funding would be allowed for research on existing stem cell lines, but not for new lines created from spare embryos after the date of his announcement.<sup>45</sup> The President, because he gave weight to the view that embryos are potential life, did not want to encourage the creation of stem cell lines for research purposes.<sup>46</sup> However, by only withholding federal funding, he permitted such research to continue, so long as private funding is available. And stem cell research on non-cloned embryos has, in fact, continued since President Bush's announcement. On March 3, 2004, Harvard researchers announced that they had used private funding to create seventeen new stem cell lines for research purposes, more than doubling the world's available supply.<sup>47</sup> Eleven million dollars in private funding is supporting similar research at the University of California at San Francisco, while Harvard plans to raise one hundred million dollars to continue its efforts.<sup>48</sup>

Thus, the inconsistency between the effort to ban therapeutic cloning and the acceptance of privately funded stem cell research on non-cloned embryos is clear. The proposed federal legislation criminalizes not only the importation of any medicine produced by human cloning anywhere in the world,<sup>49</sup> but also research on cloned human embryos no matter whether privately or publicly funded.<sup>50</sup> Why should it be a crime to use your own money to do stem cell research on cloned embryos, but perfectly lawful to use your own money to do stem cell research on spare embryos from fertility clinics?

This question reveals what really is at stake here: Cloning matters. It is opposition to cloning that fuels the drive to criminalize promising science. It is not a concern for potential life, as some opponents of such research

<sup>43.</sup> Sandel, supra note 10.

<sup>44.</sup> See Rick Weiss & Justin Gillis, New Embryonic Stem Cells Made Available, WASH. POST, March 4, 2004, at A02 (discussing the creation of stem cell lines from human embryos donated by a fertility clinic).

<sup>45.</sup> For a transcript of President Bush's speech on stem cell research, see *The President's* Decision, N.Y. TIMES, Aug. 10, 2001, at A16.

<sup>46.</sup> Id.

<sup>47.</sup> Weiss & Gillis, supra note 44.

<sup>48.</sup> Id.

<sup>49.</sup> See supra note 3.

<sup>50.</sup> See supra note 2.

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suggest. How could that be the reason, when we know that the law permits research on spare embryos, which represent as much potential for life as cloned embryos? Cloning matters; and, in an important sense, this has been clear from the beginning of the debate about therapeutic cloning.

## **III. CLONING MATTERS AND THE LAWRENCE RESPONSE**

Leon R. Kass, the Chairman of the President's Council on Bioethics, is the most articulate opponent of all forms of human cloning. He grounds his opposition in the "repugnance" that so many feel toward cloning, and he argues that "repugnance is the emotional expression of deep wisdom, beyond reason's power fully to articulate it."<sup>51</sup> He observes that most opponents of human cloning describe it as "Offensive. Grotesque. Revolting. Repugnant. Repulsive."<sup>52</sup> He extends his criticism to both reproductive and therapeutic cloning.<sup>53</sup>

Kass has voiced an important truth: Many share a profound feeling that cloning an embryo is unnatural and unsettling. In opposing both therapeutic and reproductive cloning, one member of the House of Representatives called them "ghoulish,"<sup>54</sup> while a Bush Administration official called them "repugnant."<sup>55</sup>

But is repugnance alone an adequate basis for a governmental ban on medicines derived from therapeutic cloning? The Supreme Court's recent decision in *Lawrence v. Texas* suggests that it is not. In *Lawrence*, the Court struck down a Texas law that criminalized homosexual sodomy.<sup>56</sup> As was widely noted, Justice Kennedy's opinion for the Court affirmed the liberty interest all individuals have in engaging in intimate sexual conduct.<sup>57</sup> Less widely noted, but equally important, was the respect the Court's opinion showed for those who oppose homosexuality. The Court did not trivialize

52. Kass, supra note 51, at 686 (internal quotation marks omitted).

53. Id. at 685-86.

54. The Good Kind of Cloning, L.A. TIMES, March 12, 2003, at 2-12 (quoting Rep. Sue Wilkins Myrick).

55. Richard Willing, U.N. Plan Would Ban Cloning To Create Human Baby, USA TODAY, Sept. 23, 2002, at A3 (quoting legal adviser to the U.S. U.N. mission Carolyn Willson).

56. Lawrence v. Texas, 123 S. Ct. 2472 (2003).

57. Id. at 2484.

<sup>51.</sup> Leon R. Kass, The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans, 32 VAL. U. L. REV. 679, 687 (1998). Kass submitted these views to a congressional subcommittee considering cloning legislation. See Cloning: Legal, Medical, Ethical, and Social Issues: Hearing Before the House Subcomm. on Health and Environment of the Comm. on Commerce, 105th Cong. 119 (1998).

their concerns, but argued instead that feelings of repugnance toward a practice, even when shared by a majority of the community, cannot overcome the beliefs of the minority:

The condemnation [of homosexuality] has been shaped by religious beliefs, conceptions of right and acceptable behavior, and respect for the traditional family. For many persons these are not trivial concerns but profound and deep convictions accepted as ethical and moral principles to which they aspire and which thus determine the course of their lives. These considerations do not answer the question before us, however. The issue is whether the majority may use the power of the State to enforce these views on the whole society through operation of the criminal law.<sup>58</sup>

Of course, there are differences between the issues decided in *Lawrence* and the ones at stake in the debate about cloning. But the similarities are striking: Prohibiting a ban on therapeutic cloning shows no disrespect to the views of those who find cloning profoundly unnatural; such a ban simply says that those views alone cannot provide the rational basis necessary to justify a criminal ban on therapies that may save lives.

The similarities extend to Justice O'Connor's concurrence in Lawrence. O'Connor did not agree with the five Justices who joined the Court's opinion which held that Texas had violated the liberty interests of gays.<sup>59</sup> But she found the Texas statute unconstitutional on other grounds. O'Connor noted that in Texas sodomy was a crime if engaged in by samesex couples, but was perfectly legal when engaged in by opposite-sex partners. She found that such an irrational distinction violated the Equal Protection Clause.<sup>60</sup> It is noteworthy that O'Connor did not rely on equal protection cases in which the Court applied strict scrutiny to legislation creating racial distinctions.<sup>61</sup> She simply applied the more deferential "rational basis review" applicable when "challenged legislation inhibits personal relationships,"<sup>62</sup> yet, even under this deferential standard, she found the statute unconstitutional.

Here again, while there are differences between the two situations,

<sup>58.</sup> Id. at 2480.

<sup>59.</sup> Id. at 2484 (O'Connor, J., concurring in the judgment).

<sup>60.</sup> Id. at 2484-88 (O'Connor, J., concurring in the judgment).

<sup>61.</sup> See, e.g., McLaughlin v. Florida, 379 U.S. 184, 191-92 (1964) (contrasting the deference accorded to ordinary legislative classifications with the far more demanding "strict scrutiny" of racial classifications).

<sup>62.</sup> Lawrence v. Texas, 123 S. Ct. 2472, 2485 (O'Connor, J., concurring in the judgment).

there is a remarkable parallel with the cloning dispute. Imagine two patients: one who would benefit from a drug that came from research on spare embryos and another who wanted to use a drug that came from research on cloned embryos. Why should the first be free to take the medicine while the second one goes to jail? Once more, *Lawrence* suggests that repugnance at cloning is not an adequate answer.

This still does not exhaust the similarities between *Lawrence* and the cloning dispute. In *Lawrence*, for example, the Court's opinion found it significant that other countries did not criminalize the sexual conduct at issue, and Texas had not shown that it had an interest that was "somehow more legitimate or urgent."<sup>63</sup> The same point might be made about therapeutic cloning, where research proceeding overseas may lead to treatments, and the United States has not demonstrated why it has an urgent need to prevent its citizens from receiving such treatments.<sup>64</sup>

Lawrence did not come out of nowhere. In 1996, the Supreme Court, in *Romer v. Evans*, struck down an amendment to the Colorado constitution that prohibited all governmental action designed to protect gays from discrimination.<sup>65</sup> Justice Kennedy's opinion for the Court said this amendment could be upheld if it simply bore "a rational relation to some legitimate end,"<sup>66</sup> but the amendment failed even that modest test because it was "inexplicable by anything but animus" toward gays.<sup>67</sup> As Lawrence demonstrates, repugnance is no better a justification.

#### IV. CONCLUSION

The United States government, at both the federal and state level, faces a choice: It can ban therapeutic cloning, or it can allow it to proceed. A ban is an unwise policy of doubtful constitutionality. Preventing the development and importation of medicine derived from therapeutic cloning does not serve valid policy goals. Rather, it is based on a sense of

66. Id. at 631.

<sup>63.</sup> Id. at 2483.

<sup>64.</sup> On the regulation of therapeutic cloning abroad, see Rhodes, *supra* note 7. Rhodes notes that the United Kingdom and Japan allow therapeutic cloning, while Germany avoids the inconsistency in American policy by banning all genetic research on embryos. *Id.* at 351-55.

<sup>65.</sup> Romer v. Evans, 517 U.S. 620 (1996).

<sup>67.</sup> Id. at 632. The failure of the Colorado amendment to survive the deferential rational basis test was unusual, but not unprecedented. See Robert C. Farrell, Successful Rational Basis Claims in the Supreme Court from the 1971 Term Through Romer v. Evans, 32 IND. L. REV. 357 (1999).

repugnance that should not drive public policy. Thus, therapeutic cloning should be allowed in the United States.

Allowing therapeutic cloning does not necessitate allowing reproductive cloning. Patients seeking medical treatment may be limited in their search if the treatment is not safe or effective. Reproductive cloning can be banned for this reason. But a ban on therapeutic research before we know whether it will lead to safe and effective therapies, and a ban on importing medicines derived from therapeutic cloning even if such medicines are safe and effective, cannot be justified on this ground. Indeed, virtually any form of scientific and medical research can be turned to unlawful ends, but no one seriously believes that we should abandon science and medicine as a result.

Additionally, therapeutic cloning cannot be banned because of the status of the cloned embryos that are involved. We allow private research on non-cloned embryos that are a by-product of routine *in vitro* fertilization; in fact, we even allow such non-cloned embryos to be destroyed. It is irrational to treat cloned embryos differently.

It is not surprising that these arguments for banning therapeutic cloning are unpersuasive. They are unpersuasive because they conceal the central reason why opponents condemn cloning: They find it repugnant. However heartfelt that feeling is, it cannot serve as a legitimate basis for criminal statutes that deprive patients of the opportunity to receive potentially life-saving medicines. Our courts have allowed patients access to pain relief that hastens death and to controversial abortion procedures despite public opposition. As *Lawrence* demonstrates, repugnance alone cannot provide a rational basis for legal distinctions that harm individuals.

Cloning matters. It matters in the sense that it explains the motivation behind the proposed bans. But it also matters in the sense that therapeutic cloning is a promising avenue to innovative treatments for serious diseases. This avenue should not be blocked before its true value as a research tool can be conclusively determined.

# Putting International Research Ethics Guidelines To Work for the Benefit of Developing Countries

## James V. Lavery, Ph.D.\*

It has become increasingly well-recognized in recent years that an equitable distribution of the benefits of research is an important component of international research ethics.<sup>1</sup> International research ethics guidelines, in particular the World Medical Association's *Declaration of Helsinki*,<sup>2</sup> the Council for International Organizations of Medical Sciences's (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*,<sup>3</sup> and the United Nations Joint Programme on AIDS's (UNAIDS) *Ethical Considerations in HIV Preventive Vaccine Research*,<sup>4</sup> have begun to assign investigators and their sponsors the task of ensuring and realizing research-related benefits for host country research subjects and their communities. These agreements impose these obligations through three primary requirements: the negotiation of agreements about the conditions under which the research subjects' post-trial access to effective research interventions, and the establishment of efforts to build the

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<sup>1.</sup> Fair Benefits for Research in Developing Countries, 298 SCIENCE 2133, 2133-34 (2002) [hereinafter Fair Benefits]; Leonard H. Glantz et al., Research in Developing Countries: Taking "Benefit" Seriously, HASTINGS CENTER REP., Nov. 1998, at 38, 38-42.

<sup>2.</sup> WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2002), http://www.wma.net/e/policy/pdf/17c.pdf (last visited May 1, 2004).

<sup>3.</sup> COUNCIL FOR INT'L ORGS. OF MED. SCIS. (CIOMS), INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2002), http://www.cioms.ch/frame\_guidelines\_nov\_2002.htm (last visited May 22, 2004).

<sup>4.</sup> UNAIDS, ETHICAL CONSIDERATIONS IN HIV PREVENTIVE VACCINE RESEARCH 15-16 (2000), http://www.unaids.org/EN/other/functionalities/advancedSearch.asp (last visited Apr. 18, 2004).

capacity of researchers and their institutions in host countries to participate as full partners in the research.<sup>5</sup> Although the ethical need for such obligations is indisputable, these obligations present the possibility of expanding the role of investigators in a way that might be unrealistic and therefore of limited effectiveness in ensuring the fair distribution of research benefits. Despite these reasonable concerns about feasibility, investigators may be particularly well placed to play an enhanced role in maximizing the benefits of research in low- and middle-income countries (LMIC) as a result of their unique position in the global health workforce.

In this Commentary I argue that, under appropriate circumstances and with the appropriate training and support, investigators may be able to play a critical role in ensuring that communities in LMIC that participate in international collaborative research derive a fair share of the benefits of the research and thereby avoid being exploited. More specifically, I argue that the main activities that are required by collaborative partnership in research—engagement and negotiation—also serve as the basic means by which a fair distribution of research benefits may be achieved. If investigators can be assured appropriate training and supportive mechanisms, and if some necessary changes in research ethics review can occur, investigators may collectively represent a potent global force for ensuring access to research benefits.

## I. THE NEED TO AVOID EXPLOITATION

The past decade has seen an unprecedented expansion in international health research, particularly clinical drug and vaccine trials funded by sponsors in high-income countries (HIC) and conducted in lowand middle-income countries (LMIC).<sup>6</sup> At any given time in locations

<sup>5.</sup> For a detailed discussion of prior agreements, see Alice K. Page, *Prior Agreements in International Clinical Trials: Ensuring the Benefits of Research to Developing Countries*, 3 YALE J. HEALTH POL'Y L. & ETHICS 35 (2002). For a recent discussion of post-trial obligations in international guidelines, see WORLD MED. ASS'N, WMA SECRETARIAT REPORT ON THE REVISION OF PARAGRAPH 30 OF THE DECLARATION OF HELSINKI (2003),

http://www.wma.net/e/ethicsunit/pdf/secretariat\_report\_rev\_paragraph30.pdf (last visited Apr. 2, 2004); and WORLD MED. Ass'N, DOCUMENTATION FOR THE PREPARATION OF NOTE OF CLARIFICATION ON PARAGRAPH 30 OF THE REVISED DECLARATION OF HELSINKI, http://www.wma.net/e/ethicsunit/pdf/preparation\_clarification\_paragraph30.pdf (last visited Apr. 2, 2004). For capacity-building requirements, see CIOMS, *supra* note 3, at Guideline 20; and UNAIDS, *supra* note 4, at 15-16.

<sup>6.</sup> Solomon R. Benatar, Avoiding Exploitation in Clinical Research, 9 CAMBRIDGE Q. HEALTHCARE ETHICS 562, 562-65 (2000).

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around the world, there are thousands of researchers from institutions, agencies, and private companies in HIC conducting research in LMIC.<sup>7</sup> The proportion of international health research that is funded by private industry sponsors has also increased. In 1992, private pharmaceutical companies accounted for about forty-four percent of global spending on health research,<sup>8</sup> and a decade later the proportion has been estimated at nearly half of the seventy billion dollars spent globally on health research.<sup>9</sup> Greater awareness of this expansion of private interests, in particular, has helped to focus attention on global health disparities and the vastly disproportionate levels of funding devoted to research on the diseases that burden HIC compared to those of LMIC.<sup>10</sup>

The recognition of the nature and extent of disparities in health and health research funding has also framed a long-standing debate over the ethics of international research. At the core of this debate is the question of what investigators and sponsors from HIC owe to the subjects of clinical research conducted in LMIC, where the entitlements to, and availability of, healthcare are often inferior to those in the sponsoring HIC.<sup>11</sup> The debate has resulted in heightened awareness of the potential for international health research to be exploitative of host country communities and populations.<sup>12</sup> Although exploitation is a difficult concept to define

7. The World Bank classifies economies into low-income, middle-income, and highincome groups based upon per capita gross national income (GNI). Low-income and middle-income economies, which are also sometimes referred to as developing economies, are those whose per capita GNI is less than \$9206. All of the African nations fall under this category, as well as the majority of countries in Central and South America, Central and Southern Asia, and Eastern Europe. High-income countries (those with per capita GNI greater than \$9206) include those in North America and Western Europe, as well as some Asian and Middle Eastern nations, such as Australia, Bahrain, China, Israel, Japan, Taiwan, and the United Arab Emirates. For more detailed information, see WORLD BANK, CLASSIFICATION OF ECONOMIES,

http://www.worldbank.org/prospects/gep2003/classification.pdf (last visited Apr. 2, 2004).

8. See Benatar, supra note 6, at 563.

msf.org/documents/fatal\_imbalance\_2001.pdf (last visited Apr. 18, 2004).

12. See Benatar, supra note 6.

<sup>9.</sup> MSF Access to Essential Medicines Campaign, Drugs for Neglected Diseases Working Group, A Survey of Private Sector Drug Research and Development: Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases 16-20 (2001) [hereinafter Survey], http://www.accessmed-

<sup>10.</sup> Global Forum for Health Res., The 10/90 Report on Health Research xi (2000).

<sup>11.</sup> Solomon R. Benatar & Peter A. Singer, A New Look at International Research Ethics, 321 BRIT. MED. J. 824, 824-26 (2000).

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precisely,<sup>13</sup> it has been described as an unfair distribution of the benefits of research in the context of international collaborative research.<sup>14</sup> The definition continues to garner attention<sup>15</sup> and is likely to be refined further over time.

Whatever the appropriate definition of exploitation, the history of international health research is blemished by poor performance in the transfer of benefits to the communities in LMIC that have served as the proving grounds of interventions of interest, particularly novel drugs and vaccines.<sup>16</sup> Most privately-funded research involves the testing of drugs and interventions that will be sold exclusively in HIC and, as such, will serve only to widen disparities in global health and health research funding. Currently, Africa, which is home to roughly fourteen percent of the world's population and its greatest burden of disease, including just under thirty million people living with HIV/AIDS,<sup>17</sup> accounts for less than two percent of the world market for drugs.<sup>18</sup> North America, Europe, and Japan, collectively with less than 1.5-times the population of Africa, account for more than forty times more, or eighty percent, of the global market.<sup>19</sup>

## II. BACKGROUND

## A. The Current Emphasis in International Research Ethics

In response to the debate about exploitation in international heath research, and the research involving drug and vaccine trials in particular, there has been a rapid and concerted expansion of major international research ethics guidelines<sup>20</sup> and a proliferation of commissioned analyses

17. Global Estimates for Adults and Children, End 2003, UNAIDS, http://www.unaids.org/wad/2003/Epiupdate2003\_en/Epi03\_11\_en.htm#P251\_74233 (last visited Apr. 2, 2004).

18. Amy Kapczynski et al., *Global Health and University Patents*, 301 SCIENCE 1629, 1629 (2003).

<sup>13.</sup> See generally ALAN WERTHEIMER, EXPLOITATION 10-12 (1999) (examining the complexity of the concept of exploitation).

<sup>14.</sup> See Fair Benefits, supra note 1, at 2133.

<sup>15.</sup> See JENNIFER HAWKINS & EZEKIEL J. EMANUEL, EXPLOITATION IN MULTINATIONAL CLINICAL RESEARCH (forthcoming 2005).

<sup>16.</sup> Reidar K. Lie, *Justice and International Research, in* BIOMEDICAL RESEARCH ETHICS: UPDATING INTERNATIONAL GUIDELINES. A CONSULTATION 27 (Robert J. Levine & Samuel Gorowitz eds., 2000).

<sup>19.</sup> See SURVEY, supra note 9, at 16.

<sup>20.</sup> See supra notes 2-4 and accompanying text.

of the related ethical issues.<sup>21</sup> High-profile national and international bodies have conducted many of these analyses. The latest flurry of guidelines and analyses has focused squarely on the unfair distribution of benefits of research and emphasized the critical role of procedural safeguards against the exploitation of host country populations. Yet, the implications of this current emphasis are poorly understood. Guidelines on three main issues—negotiation of prior agreements, capacity-building, and post-trial obligations—are of interest here, since they may be most likely to involve considerable expansion of investigators' current roles.

Current international guidelines (e.g., the *Declaration of Helsinki*, the CIOMS *Guidelines*, and the UNAIDS *Ethical Considerations*) include provisions that require researchers from HMIC to negotiate with the host country collaborators about the conditions under which the research will be conducted, including what benefits are expected to accrue to the host communities, prior to the start of the research. They also include provisions about the assurance of on-going access to any intervention demonstrated to be effective through the course of the study. These assurances are commonly known as "post-trial obligations." The guidelines also state that, in the course of research activities, opportunities must be found to enhance the capacity of the LMIC collaborators and their institutions to conduct and be full partners in research.<sup>22</sup>

Since the main guidelines lack specificity about how the responsibility for these provisions should be divided between investigators and research sponsors, it is not yet clear whether, or to what extent, current mechanisms of review will enable Institutional Review Boards (IRBs) or Research Ethics Committees (RECs) in HIC to assess the extent to which current investigators are executing these provisions, or whether they will instead have to begin to require new formal demonstration that the requirements have been met. While this question has received little attention to date, the answer is of considerable consequence: On the one hand, these obligations could prove to be burdensome, and even deleterious to the research effort; on the other hand, if investigators were able to meaningfully fulfill these obligations, the benefits to LMIC could be significant. Whether the

<sup>21.</sup> See U.S. NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH (2001),

http://www.georgetown.edu/research/nrcbl/nbac/human/overvoll.pdf; U.K. NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF RESEARCH RELATED TO HEALTHCARE IN DEVELOPING COUNTRIES (2002),

http://www.nuffieldbioethics.org/filelibrary/pdf/errhdc\_fullreport.pdf.

<sup>22.</sup> See, e.g., CIOMS, supra note 3, at Guideline 20.

benefits to LMIC exceed the costs to investigators—and how the costs to investigators could be minimized while ensuring the effectiveness of these obligations—are questions I take up later in this Commentary.

## **B.** Guidelines and Legal Requirements

Rules and conventions governing research with human subjects are managed differently in different countries. In the United States, these rules are codified into federal regulations that must be followed by institutions and investigators to ensure their eligibility to receive public funding for their research activities.<sup>23</sup> In contrast, international guidelines such as the Declaration of Helsinki, the CIOMS Guidelines, and the UNAIDS Ethical Considerations are not legally binding documents.<sup>24</sup> Instead, they represent different (and occasionally conflicting) perspectives about what principles and actions are necessary for research to be considered ethical. Each reflects the perspective of its constituent groups (e.g., national medical associations, in the case of the Declaration of Helsinki), and the force of the guidelines depends in large measure on current global opinion about the moral authority of the promulgating agencies. In this respect, the guidelines cannot be considered to be requirements in the same sense that the U.S. federal regulations can. However, ethics is largely about the establishment and justification of conventions of practice, and in this sense it is worth remembering that some of the specific provisions of the U.S. regulations,<sup>25</sup> such as the requirement of review by an independent committee, were required in a moral sense by the Declaration of Helsinki prior to their formal adoption into U.S. law.

The converse may be true to some extent as well. For example, Jonathan Moreno has argued that the increasingly intense regulation of research involving human subjects in the United States risks eliminating whatever is left of investigators' discretion to make ethical judgments about the protection of human subjects,<sup>26</sup> and could reduce research ethics to a rote exercise of ensuring compliance with the letter of the law. For many, this trend has progressively undermined the moral authority of the regulations. What is left, particularly in the context of international

<sup>23.</sup> See 46 C.F.R. § 46.101 (2003).

<sup>24.</sup> David P. Fidler, "Geographical Morality" Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries, 42 HARV. INT'L L.J. 299, 324-28 (2001).

<sup>25. 45</sup> C.F.R. § 46.109(a) (2003).

<sup>26.</sup> Jonathan D. Moreno, Goodbye to All That: The End of Moderate Protectionism in Human Subjects Research, HASTINGS CENTER REP., May-June 2001, at 9, 9-17 (2001).
collaborative research, is an awkward marriage between non-binding international guidelines with some reasonably legitimate claims to moral authority in the protection of human subjects<sup>27</sup> and legally required regulations that some view as having diminishing moral authority.

Arguably, however, the tension between these types of documents may not be as great as it initially appears to be. Despite the prevailing culture of regulatory compliance described by Moreno, the regulations themselves require judgment, particularly with respect to the balance of risks and benefits, and the international guidelines provide principles and analyses that may help the IRBs to make these judgments in their reviews of international research, particularly collaborative research in LMIC. To the extent that the international guidelines diverge on important substantive issues, their value for IRBs may be reduced. But for prior agreements, capacity-building, and post-trial obligations, there is at least some agreement in principle among the guidelines, even if the specific responsibilities and details of implementation remain somewhat underdeveloped. Although there may be other strategies that could help improve the effectiveness of U.S. IRBs in their review of international research,<sup>28</sup> these strategies may add little substantive content to the existing guidance on prior agreements, post-trial obligations, and capacity-building.

# III. ENGAGEMENT, NEGOTIATION, AND AN EXPANDED ROLE FOR INVESTIGATORS

Although the guidelines vary in the extent to which they describe specific responsibilities for various parties, the obligations associated with prior agreements, post-trial obligations, and capacity-building are generally directed toward research sponsors and other groups who may have the means and authority to commit resources to satisfy these requirements.<sup>29</sup>

<sup>27.</sup> It is important to recognize that some see this authority as having been compromised to some extent by contentious recent revisions. See Heidi P. Forster et al., The 2000 Revision of the Declaration of Helskini: A Step Forward or More Confusion? 358 THE LANCET 1449, 1449-52 (2001).

<sup>28.</sup> See, e.g., Eric M. Meslin et al., International Research Ethics: Building Capacity from the Ground Up (2004) (unpublished manuscript, on file with Yale Journal of Health Policy, Law, & Ethics) (discussing efforts to "develop[] a collaborative approach . . . for conducting research that is sensitive to local values and consistent with accepted principles of research ethics" between a U.S. university and a partner research institution in Africa).

<sup>29.</sup> For example, the CIOMS Guidelines state that "Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that . . . any intervention or product developed, or knowledge

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There is a logic to a broad base of accountability, but it tends to obscure the way that these obligations are satisfied in practice. Research sponsors may be actively engaged in some of these activities, particularly in largescale and high-budget research projects, but for smaller research projects, they are typically carried out on a day-to-day basis by the investigators themselves with only limited involvement from the agencies sponsoring the research. And so, although the guidelines may not explicitly ascribe the ethical responsibilities for these requirements to investigators, those responsibilities generally fall to investigators because of the way the allocation of responsibilities in research works in practice.

Generally speaking, the specific activities in question may be thought to fall under the rubric of collaborative partnership, a set of activities whose ethical relevance to international research is increasingly recognized,<sup>30</sup> but whose practices are only beginning to be described in

generated, will be made reasonably available for the benefit of that population or community." CIOMS, *supra* note 3, at Guideline 10. Also on the topic of ensuring availability, the UNAIDS Vaccine Guidelines state that

[t]his discussion should include representatives from relevant stakeholders in the host country, such as representatives from the executive branch, health ministry, local health authorities, and relevant scientific and ethical groups. It should also include representatives from the communities from which participants are drawn, people living with HIV/AIDS, and NGOs representing affected communities.

Furthermore, the discussion concerning availability and distribution of an effective HIV vaccine should engage international organizations, donor governments and bilateral agencies, representatives from wider affected communities, international and regional NGOs and the private sector. These should not only consider financial assistance regarding making vaccines available, but should also help to build the capacity of host governments and communities to negotiate for and implement distribution plans.

UNAIDS, *supra* note 4, at 14. Although the Declaration of Helsinki focuses explicitly on the obligations of the physician investigator, paragraph 30, which deals with ensuring on-going access, does not ascribe responsibility to any specific party. However, the main thrust of the paragraph suggests a role for the research sponsors and other parties such as those listed in the UNAIDS Guidelines: "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study." WORLD MED. ASS'N, *supra* note 2, at 4.

30. See, e.g., Bernard Lo & Ronald Bayer, Establishing Ethical Trials for Treatment and Prevention of AIDS in Developing Countries, 327 BRIT. MED. J. 337, 337-38 (2003); see also J. V. Lavery et al., Ethical Issues in International Environmental Health Research, 206 INT'L J. HYGIENE & ENVTL. HEALTH 453, 457-58 (2003) (discussing the significance of community-based approaches in international environmental health research).

detail sufficient to guide the activities of investigators.<sup>31</sup> There are many specific aims of collaborative, or community, partnership, but there are only a few general mechanisms through which it achieves ethical ends, such as ensuring the fair distribution of benefits. Collaboration requires *engagement* with host-country researchers, institutions and governments in LMIC; it requires the sharing, through dialogue, of the relevant concerns, aspirations, motivations, and opportunities that will establish the common goals necessary for research to proceed. But engagement itself does not settle issues about how the various interests of stakeholders in the research (e.g., the investigators, research subjects, community, institutions, and governments) can and should be met, and under what conditions the research activities are most likely to satisfy these multiple interests. Thus *negotiation*, the task of forging agreement on the specific ways in which the relevant interests will be satisfied in the course of the research, is also a critical aspect of collaboration.

Investigators and sponsors from HIC often enjoy relatively high levels of access to senior officials in healthcare and politics in LMICs hosting the research. This access provides opportunities for their engagement and negotiation activities to make a difference for the health of the populations that participate in their research. However, precisely how these opportunities should be sought and managed, especially by less experienced HIC investigators, who lack the extensive contacts and whose relevant skills may be underdeveloped, is not currently a prominent subject of ethical guidance. Although some of the few examples of engagement and negotiation that have been captured in the literature to date involve large-scale multi-million dollar trials with complex and often competing interests among sponsors, communities, and governments, it would be misleading to adopt these trials as paradigm cases.<sup>32</sup> More representative, and collectively also of greater potential impact, are the many thousands of HIC investigators in smaller research initiatives throughout the world, who lack regular recourse to logistical support teams, lawyers, and high ranking host-country officials. If the guidelines are intended to apply equally-or at least proportionately-to their research activities, their circumstances will require specific consideration.

<sup>31.</sup> Ezekiel J. Emanuel et al., What Makes Clinical Research in Developing Countries Ethical?: The Benchmarks of Ethical Research, 189 J. INFECTIOUS DISEASES 930, 931-32 & tbl. 1 (2004).

<sup>32.</sup> In her discussion of prior agreements, Page discusses large scale prior agreements using examples from the World Health Organization, the International AIDS Vaccine Initiative, and the California-based company VaxGen, whose candidate AIDS vaccine "AIDSVAX" was first to Phase III efficacy testing. Page, *supra* note 5, at 54-64.

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In some respects, it seems unremarkable that investigators are assumed to be the most appropriate protagonists for these collaborative dramas. They are the most knowledgeable about the aims, feasibility, and relevance of the research, and therefore best placed to tell the stories that engagement requires. Additionally, investigators from HIC often begin this process with established relationships with some host country collaborators that they have met through training or professional activities, and therefore may have an "in" with the relevant communities and authorities in the host country, even before initiating a broader engagement. The idea that the investigators from HIC should assume leadership roles with respect to satisfying the current research ethics guidelines related to exploitation and fair distribution of benefits is a reasonable one. But the idea that researchers should shoulder the lion's share of responsibility for effecting these improvements through their work is a potentially insidious one and deserves to be promulgated carefully and deliberately.

# IV. "ROLE EXPANSION" AND ITS IMPLICATIONS

If investigators are intended to be the principal purveyors of fair distribution of research benefits in accordance with the current guidelines, and if the ethical motivation behind the guidelines is the same for smallscale research projects as for large ones, then it seems that some expansion of investigators' current roles is inevitable. "Role expansion" in this sense may be a reasonable and feasible extension of the core functions and opportunities of investigators. Moreover, if it is exercised with sufficient care and integrity, it might represent an as yet poorly recognized dimension of human resources mobilization in global health. However, to be utilized to full effect these roles must be made explicit and supported in meaningful ways by research sponsors and institutions. Thoughtful researchers should greet the potential for "mission creep" with some trepidation. Three concerns, in particular, deserve some separate consideration: the potential for dilution of investigators' impact, the fit between the activities required by role expansion and investigators' training, and the unwitting relief of others' obligations.

### A. Dilution of Investigator Impact

The main issue related to dilution of investigators' impact is whether, on balance, investigators trying to follow the current requirements in international research ethics can do so without jeopardizing the conduct of their research or the quality of the evidence it generates. In effect, this is a concern about the scarcest of resources: time. The main activities associated with the current requirements (i.e., engagement and negotiation) will entail even more tasks in schedules that, for many investigators, are already far beyond comfortable management. Investigators, particularly those in the public sector, have heavy demands in reading, academic writing, research grant preparation, reviewing, teaching and mentoring, and committee work, in addition to the myriad demands of designing, conducting, interpreting, and presenting the research itself. For researchers in global health, these demands are often split between institutions on different continents. Concern about adding additional responsibilities to these already busy schedules is clearly warranted.

But it is necessary to look beyond the immediate concern about additional demands on time. It is certainly true, for example, that most investigators conducting collaborative research in LMICs are concerned about-indeed deeply motivated by-the potential impact of their research in the service of improving global health. Rather than diluting their impact by robbing them of invaluable research time, the new requirements might force investigators to consider and even embrace different practices, some of which might actually enhance the impact of their work. It is plausible that requiring investigators to think through the potential benefits of their research in greater detail (i.e., what these benefits are, or could be, and how they might be realized) could enhance the influence of their research, rather than dilute it. In other words, the requirements themselves might force investigators to critically examineand perhaps find wanting-their current approaches to ensuring that their efforts result in benefits for research subjects and their communities. Of course, there are many investigators who already take these issues very seriously and do an exemplary job. But the historical lack of benefits to LMIC from international health research is evidence enough that existing practices are insufficient.

# B. The Fit Between Researcher Training and the New Requirements

Precisely what are researchers being asked to do under the current requirements? Above, I have provided a simplified account that focuses on the two main types of activity associated with prior agreements, capacitybuilding, and post-trial obligations: engagement and negotiation. On the surface, these may appear to be quite ordinary and common tasks, and it may be tempting for researchers and perhaps also drafters of international research ethics guidelines to underplay their importance and complexity. But in fact, each of these activities might also be the topic of a separate course in an international MBA program or in training for foreign

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diplomatic service. Each requires some theoretical foundation, enormous skill, and significant experience if it is to be performed effectively and reliably; together, they could easily consume a huge proportion of a researcher's time—at least through certain critical periods of the research. But although these activities may be well represented in the curricula of schools of law, business administration, and international relations, they are not part of the current landscape in research training programs, even in schools of tropical medicine and hygiene, where the value of these activities might be expected to be better appreciated.<sup>33</sup> The result is that investigators are insufficiently prepared to perform the very tasks that may be necessary to meet the great expectations of current international research ethics guidelines.

Despite these challenges, it is critical to recognize that many researchers are currently performing these, or very similar, roles in the research they conduct in LMIC throughout the world, though the extent of these activities is not known and likely varies with the nature and scale of the research. Although their current effectiveness with respect to these roles is not clear, the community of HIC investigators currently working in LMIC clearly represents an inchoate resource whose potential impact on global health could be great.

### C. The Responsibilities of Others

It is a common fear in capacity-building efforts in LMIC—especially those with poor governance and leadership—that foreign workers, including health researchers, engaged in efforts to make the country better may simply be taking on work that the governments, private sector, and civil society of the host country should be doing and from which they should be benefiting.<sup>34</sup> It is less frequently realized that researchers might be able to utilize their standing to encourage otherwise reluctant or

<sup>33.</sup> In fact, schools of public health and tropical medicine are well placed to incorporate some of these issues into existing programs. A cursory internet search of a few of the world's best known schools identifies courses on topics such as consultation techniques, communication strategy, team management and leadership, and negotiation, though not with an explicit focus on ethics and research benefit sharing.

<sup>34.</sup> James Pfeiffer, International NGOs and Primary Health Care in Mozambique: The Need for a New Model of Collaboration, 56 SOC. SCI. & MED. 725, 725-38 (2003). Pfeiffer focuses on development aid activities conducted by NGOs, but focuses on a number of NGOs, such as USAID, Family Health International and Pathfinder, which regularly sponsor and/or conduct research. He discusses baseline studies, surveys and evaluations as typical activities. *Id.* at 733.

uninterested authorities to get involved in the funding, conduct, or application of research for the benefit of their communities. The fact that this rarely occurs—at least in the straightforward way implied—does not make the point irrelevant. In fact, the history of a dismal failure to realize fair benefits for host countries through research is itself likely to be a potent deterrent for many potential collaborators from LMIC. But as examples of benefits to host country populations from international research emerge, those benefits—even modest ones—will reinforce the value of the current ethical guidelines; when that happens, some of the well-deserved skepticism may begin to recede and open up new space for creative and constructive dialogue. In fact, this possible change may reflect the true potential of the current ethical guidelines, and if so, investigators surely have much to contribute in this respect.

### V. CAN THE NEW GUIDELINES ACHIEVE THEIR INTENDED EFFECT?

# A. The Magnitude of the Problem

It is important at the outset to recognize the magnitude of the that prior agreements, capacity-building, and post-trial problem obligations aim to address. Although these mechanisms are meant to be applied to health research of all kinds, the global struggle to control HIV/AIDS offers an instructive example of the overwhelming magnitude of the challenge to realize research-related benefits for participating communities. UNAIDS currently estimates that it would cost between seven to ten billion dollars per year to achieve effective control of HIV/AIDS in low- and middle-income countries.35 The WHO Commission on Macroeconomics and Health estimated that the research and development costs alone for scaling up national health care systems to avert eight million deaths per year globally-many from HIV/AIDS-would be three billion dollars per year by 2007, or approximately eleven percent of its projected total grant assistance of twenty-seven billion dollars for that year. The CMH also proposed 1.5 billion dollars in support for the Global Fund for Health Research and an additional 1.5 billion dollars annually for research and development activities through existing institutions.<sup>36</sup>

<sup>35.</sup> United Nations, Calculating the Cost of an Effective Global Campaign Against HIV/AIDS, *at* http://www.un.org/ga/aids/ungassfactsheets/html/fscost\_en.htm (last visited Apr. 3, 2004).

<sup>36.</sup> COMM'N ON MACROECONOMICS & HEALTH, WORLD HEALTH ORG., MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT 13-14 (2001), http://www.un.org/esa/coordination/ecosoc/docs/RT.K.MacroeconomicsHealth.pdf.

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Effective control of HIV/AIDS globally will require research on treatment, prevention strategies, health services and policy, palliative care and epidemiology, to name a few specific dimensions. But the scale and diversity of the necessary research agenda also reinforces the idea of the vast collective potential for individual investigators to effect improvements in the transfer of research benefits.

### B. Evaluation of Impact

It is conceivable that the current emphasis in international research ethics guidelines could have important implications for the way benefits accrue to LMIC from research collaboration. Any evidence of the effectiveness of these guidelines in reducing exploitation by improving the transfer of research benefits would clearly enhance the perceived value of research ethics in global health, a perception that has suffered from the protracted and occasionally arcane debate over standards of care.<sup>37</sup> Accordingly, the evaluation of these new requirements is a challenge that must be taken seriously. A more concerted effort by global research funders, perhaps in conjunction with the World Medical Association, CIOMS, and UNAIDS, could help to clearly establish the feasibility and value of these new requirements, including their impact on the exploitation of LMIC populations. Along these lines, an international database of prior agreements as well as long-term follow-up on the outcomes of research, including the distribution of benefits, would not only help host countries to document and evaluate the benefits of collaboration, but would also help HIC public sponsors of international research to justify their activities to the governments that allocate their funding. Additionally, this type of information would serve as a valuable resource for U.S. and other HIC IRBs/RECs, which often lack experience reviewing international health research.

# VI. CHANGES IN RESEARCH ETHICS REVIEW

The guidelines, on their own, are insufficient to alter well-established practices by both investigators and the committees that review the ethical acceptability of their research. In the case of international guidelines like the *Declaration of Helsinki* and the CIOMS *Guidelines*, the lack of meaningful enforcement mechanisms makes this challenge even greater. Therefore,

<sup>37.</sup> On some of the reasons behind the difficulty in resolving the disagreements in the standard of care debate, see Alex J. London, *The Ambiguity and the Exigency: Clarifying* 'Standard of Care' Arguments in International Research, 25 J. MED. & PHIL. 379, 379-97 (2000).

other changes in research ethics review are necessary to create meaningful change in this area.

## A. The Need for Cultural Change

The current emphasis in the guidelines must be reinforced by cultural changes in research ethics review, particularly in the sponsoring country institutions. IRBs and the relevant regulatory authorities in the United States, in particular, must find ways to move beyond the current preoccupation with informed consent and protectionist postures<sup>38</sup> to grapple more realistically with issues of beneficial impact and social value in research. It is here that ethically significant improvements are most likely to be realized, rather than in marginal improvements to informed consent.

In part, these issues are given short-shrift in research ethics review precisely because they involve complex and difficult judgments about the balance between protecting human subjects, on the one hand, and taking bolder steps to improve the value of research for host country populations, on the other. IRBs need to begin to invest more time and energy into examining, and asking investigators difficult questions about, the potential social value of the research they review, and in particular the nature and extent of the benefits that they reasonably expect to accrue from their research activities. Emerging frameworks and concrete benchmarks for collaborative partnership might be particularly valuable in this respect.<sup>39</sup>

Where researchers are not forthcoming about how they see their research activities leading to benefits for the populations under study, IRBs should be proportionately circumspect about the value of the research. Importantly, this should not prejudice IRBs against preliminary studies, Phase I trials, or other studies for which the immediate benefits may be more difficult to anticipate. Rather, it should mark a change in the culture and attitude of IRBs away from unduly intense scrutiny of techniques, such as informed consent, that may, in fact, offer limited protection from exploitation<sup>40</sup> to greater emphasis on areas such as the planning and distribution of benefits of research that might prove to be more effective at reducing exploitation. Regulatory authorities, such as the Office for Human Research Protections (OHRP) in the United States, could play an

<sup>38.</sup> See Moreno, supra note 26.

<sup>39.</sup> See Emanuel et al., supra note 31, at 930-32.

<sup>40.</sup> Christine Pace et al., What We Don't Know About Informed Consent, SciDevNet, at

http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierreaditem&dossier=5&type=3 &itemid=189&language=1 (last visited Apr. 3, 2004).

important role in facilitating this cultural evolution by emphasizing the importance, and regulatory requirement, of judgments in research ethics review and by supporting programs to encourage increased sophistication and excellence in these judgments by IRBs.<sup>41</sup>

### **B.** Supportive Teams

If it is accepted that researchers are well-placed to participate in the engagement and negotiation activities that the current international guidelines specify, and yet are unlikely to be maximally effective in these endeavors on their own, then the question becomes: How might investigators best be supported in satisfying these requirements? It is conceivable that expert teams could be developed with skills and experiences related to the core functions of engagement and negotiation. These teams might be attached to an international agency whose recognized mandate involves the protection of human subjects in research. They might be available to investigators and sponsors for consultations related to individual studies or research programs and would bring to bear the relevant expertise, experiences and, ideally, knowledge of local culture and politics, in lending assistance for research in LMIC. It is perhaps more likely that the cost of these services could become allowable research expenses if there was agreement among the world's major health research funding bodies on their value. Given the importance of relationships in facilitating engagement and forging trust in negotiations,<sup>42</sup> it is conceivable that sponsors could even enhance the value of their investments in health research by providing some appropriate funding programs aimed explicitly at relationship building and engagement. The fact that these proposals currently sound far-fetched and impractical should not disqualify them outright from further consideration. It may be that it is precisely the lack of this type of supportive mechanism, along with the laissez faire application of international guidelines on research benefits, that has permitted international health research to flourish for so long without meaningful benefits to LMICs.

<sup>41.</sup> See United 45 C.F.R. § 46.111a(2) (2003). This regulation discusses the responsibility of Institutional Review Boards with respect to risk and benefit in research, which states that IRBs must determine that "[r]isks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result." *Id.* 

<sup>42.</sup> Page, *supra* note 5, at 65 (emphasizing the importance of the strength of the collaborators' relationships and mutual commitment to shared goals, since many agreements proceed slowly on a verbal basis).

## C. Training for Investigators

It is a relatively recent phenomenon that researchers are required to complete training in research ethics as a condition of receipt of federal research funding in the United States,<sup>43</sup> a requirement that holds equally for domestic research and research conducted in LMIC. Although some innovative training programs are emerging that focus on international research issues for U.S. investigators, most focus on the U.S. regulations and emphasize what investigators are required to do to be compliant with them. Programs that teach skills and strategies related to engagement and negotiation within the context of research ethics training have not yet emerged, but may be worthy of careful consideration. But whatever the status of existing programs, there is clearly an opportunity to enhance investigators' relevant skills in innovative ways and to design rigorous evaluations of such training that might help to gauge its impact on exploitation in LMIC.

# CONCLUSION

Researchers applying the current international research ethics guidelines might represent a critical and under-appreciated human resource pool for improvements in global health. They are uniquely positioned to provide leadership in engagement with host country communities and the ensuing negotiations about the specific conditions under which the research will proceed, including the planned distribution of expected benefits. These social mechanisms are the means to fulfilling the current international research ethics guidelines related to prior agreements, capacity-building, and assurance of on-going access to beneficial interventions. The ethical end that they serve is the reduction of exploitation in international health research through fair distribution of its benefits in small-scale, as well as large-scale, studies. With improved training and supportive mechanisms, some evolution in the culture of research ethics review, and a serious effort to evaluate the impact of current international guidelines, these guidelines will not be the source of deleterious, pointless role expansion for investigators. Instead, they will contribute to an important end: The development of improvements in the

<sup>43.</sup> See NAT'L INSTS. OF HEALTH, REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS (June 5, 2000), http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

benefits to LMIC communities that participate in international collaborative research.

# **CASE STUDY**

## **QUESTION:**

# How Do International Trade Agreements Influence the Promotion of Public Health?

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Juan Rovira, Ph.D.

# How Do International Trade Agreements Influence the Promotion of Public Health?—An Introduction to the Issue

### Jason Andrews and Samantha Chaifetz

The past two years have seen a substantial proliferation in international trade liberalization agreements. Even as the World Trade Organization (WTO) has continued to expand its membership, there has been a remarkable increase in other bilateral and multilateral trade agreements.<sup>1</sup> The United States, in particular, has been actively pursuing bilateral agreements around the world—from recently signed agreements with Chile and Singapore to continued negotiations with Morocco, Saudi Arabia, South Africa, and other countries.

Concomitant to this trend are concerns about how WTO member nations will be able to import or produce affordable pharmaceuticals without violating trade policies. This has led to extensive debate at WTO ministerial meetings, in academic journals, among non-governmental organizations, and even in domestic courtrooms. As a result, heightened attention is now being paid to the question of how—and, perhaps, whether—countries can successfully protect their health interests while expanding free trade.

In this issue of the Yale Journal of Health Policy, Law, and Ethics, we offer several perspectives on the ways in which trade agreements are likely to affect domestic health promotion. We hope that this collection of short essays will shed light on this important issue—furthering our understanding of how health and trade interests intersect for both developing and developed countries. Moreover, we hope that these diverse responses to this Case Study topic will illuminate how countries are—or ought to be—analyzing the implications of these trade agreements for their own health care systems.

<sup>1.</sup> For example, regional agreements include the Free Trade Area of the Americas (FTAA) and the Central American Free Trade Agreement (CAFTA). Recent agreements have been added to the already existing structures of the North American Free Trade Agreement (NAFTA) and the African Growth and Opportunity Act (AGOA).

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There are many questions about the relationship between trade interests and health interests that have only just begun to be explored. In addition to the ongoing debate surrounding intellectual property and access to pharmaceuticals, other nexuses between trade and health have started to garner attention, such as the regulation of environmental consequences of trade, the implications of trade protections for tobacco and firearms, the effects of job creation and reduction of wage inequality on access to health care, and the consequences of privatization of previously public structures (such as hospitals) as a result of prohibitions on trade restrictions. While the contributions to this Case Study focus on the issue of access to pharmaceuticals, we hope that these essays will help to encourage a continuing dialogue on not only this issue, but also all others related to the linkage between trade and health. It is a dialogue whose time has come.

# The "Good Old Days" of TRIPS: The U.S. Trade Agenda and the Extension of Pharmaceutical Test Data Protection

## Susan Scafidi, J.D.\*

Intellectual property rights carry significant implications for world health. In 1994, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) placed pharmaceuticals among the forms of technology that constitute patentable subject matter.<sup>1</sup> Over the past ten years, non-governmental organizations, governments, and international institutions have increasingly acknowledged that this mandated inclusion influences the availability of new drugs, at least within the member nations of the World Trade Organization (WTO).<sup>2</sup>

The nature of this effect, however, remains open to debate. Whether pharmaceutical patents provide financial incentives that support private research and development, as the industry attests, or allow monopoly pricing and production that hinder the ability of poor nations to address health crises, such patents have become an unavoidable feature of global medicine. The TRIPS-driven harmonization of intellectual property protection across borders is likely to continue into the foreseeable future.

Although negotiations regarding the expansion of patent rights for pharmaceuticals have been highly contested—with conflicts frequently

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<sup>1.</sup> See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27.1, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement] (establishing that patents are available in all fields of technology), available at http://www.wto.org/english/tratop\_e/trips\_e/t\_agm0\_e.htm.

<sup>2.</sup> See generally Susan K. Sell, TRIPS and the Access to Medicines Campaign, 20 WIS. INT'L L.J. 481 (2002) (offering a political perspective on the TRIPS Agreement and its implementation).

arising between developed and developing countries<sup>3</sup>—the TRIPS Agreement represents the result of extensive multilateral discussion. For example, while the TRIPS Agreement requires a twenty-year minimum patent term,<sup>4</sup> it allows countries to offer "limited exceptions to the exclusive rights conferred by a patent" and includes provisions for compulsory licensing of patented inventions under limited circumstances.<sup>5</sup> In the years since the TRIPS Agreement entered into force, this discussion has continued, resulting in new statements on pharmaceutical patents and public health issues in the 2001 Doha WTO Ministerial Declaration,<sup>6</sup> the concurrent Declaration on the TRIPS Agreement and Public Health,<sup>7</sup> and, most recently, in an implementation agreement regarding the compulsory licensing of patented pharmaceutical products.8 WTO member nations have also agreed to extend the transition period for least-developed countries to comply with those elements of the TRIPS Agreement related the protection of pharmaceuticals.9 However imperfect these to compromises, and whatever their eventual effect on global health, the new agreements are intended to address the concerns of developing and leastdeveloped member nations. In this sense, the ongoing TRIPS process represents a victory of collective bargaining power.

Recent U.S. bilateral and regional free trade agreements (FTAs), by contrast, do not offer trading partners an equivalent opportunity to influence either the text or the implementation of intellectual property

http://www.wto.org/english/thewto\_e/minist\_e/min01\_e/mindecl\_e.htm.

7. World Trade Org., Doha WTO Ministerial 2001, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter TRIPS Public Health Declaration], available at

http://www.wto.org/english/thewto\_e/minist\_e/min01\_e/mindecl\_trips\_e.htm. The TRIPS Public Health Declaration affirms that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to secure access to medicines for all." *Id.* at para. 4.

8. World Trade Org., General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Sept. 1, 2003), available at http://www.wto.org/english/tratop\_e/trips\_e/implem\_para6\_e.htm. The agreement describes the acceptable circumstances for compulsory licensing and for the export and import of such goods.

9. TRIPS Public Health Declaration, supra note 7, at para. 7.

<sup>3.</sup> Id.

<sup>4.</sup> TRIPS Agreement, supra note 1, at art. 33.

<sup>5.</sup> Id. at art. 30-31.

<sup>6.</sup> World Trade Org., Doha WTO Ministerial 2001, Ministerial Declaration, WT/MIN(01)/DEC/1 (Nov. 20, 2001), available at

provisions. The Office of the United States Trade Representative (USTR) is engaged in a systematic effort to increase international intellectual property protection, one country at a time.<sup>10</sup> This effort is not limited to the global consensus ostensibly embodied in the TRIPS Agreement, but extends to additional protections in areas such as digital rights management and the establishment of criminal sanctions infringement." Most significantly from a public health perspective, the USTR seeks to supplant ambiguous provisions in TRIPS with concrete substantive minima in FTAs for the protection of regulatory test data, or the otherwise undisclosed scientific studies submitted to regulatory agencies in the process of seeking approval to market pharmaceuticals. The legal status of this test data is of paramount importance to the manufacturers of generic pharmaceutical products, who reference the existence of brand-name pharmaceutical test data in order to obtain postpatent marketing approval for their own, less expensive versions of the same drugs. This indirect reliance, in turn, affects the price of generic pharmaceuticals and the degree of public access to these medicines. Although the United States has engaged in ongoing consultations with Argentina on this intellectual property and public health matter under the aegis of the WTO Dispute Settlement Understanding, it has thus far declined to submit the question of what constitutes adequate test data protection under TRIPS to a WTO panel,<sup>18</sup> preferring instead to enshrine

10. See OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2003 SPECIAL 301 REPORT (May 1, 2003), http://www.ustr.gov/reports/2003/fullreport.pdf.

11. Id.

12. See id.; North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 605 (1993) [herinafter NAFTA Agreement], available at

http://www.ustr.gov/regions/whemisphere/nafta.shtml; United States - Singapore Free Trade Agreement, May 6, 2003, 42 I.L.M. 1026 (2003) [hereinafter Singapore FTA], *available at* http://www.ustr.gov/new/fta/Singapore/final.htm; United States - Chile Free Trade Agreement, June 6, 2003, 42 I.L.M. 1026 (2003) [hereinafter Chile FTA], *available at* http://www.ustr.gov/new/fta/Chile/text/index.htm; Central American Free Trade Agreement, Jan. 28, 2004, (draft text) [hereinafter CAFTA Agreement], *available at* http://www.ustr.gov/new/fta/Cafta/text/index.htm; and United States - Morocco Free Trade Agreement, Mar. 31, 2004 (draft text) [hereinafter Morocco FTA], *available at* http://www.ustr.gov/new/fta/Morocco/text/index.htm.

13. World Trade Org. Dispute Settlement Body, Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, Argentina - Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals, WT/DS171/3, Argentina -Certain Measures on the Protection of Patents and Test Data, WT/DS196/4 (June 20, 2002); Office of the United States Trade Representative, Dispute Settlement Update (Mar. 9, 2004),

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its favored interpretation in various bilateral and regional FTAs.

This brief Case Study describes the treatment of pharmaceutical regulatory test data under both TRIPS and recent U.S. FTAs and argues that there has been an increasing elaboration of protective legal structures in the latter. While individual countries may perceive benefit in expanding their protection of test data, such public health analysis should not take place under the pressure of free trade negotiations.<sup>14</sup> The TRIPS Agreement and its implementation may be far from ideal, but its transparent, multilateral approach to intellectual property harmonization offers technology-importing nations greater influence over evolving issues like pharmaceutical test data protection than the often unequal free trade negotiation process.

### **UNDERSTANDING TEST DATA PROVISIONS**

### TRIPS ARTICLE 39.3

The first step in understanding the contested international treatment of pharmaceutical test data is to analyze the relevant provision of the TRIPS Agreement. Protection for pharmaceutical test data in TRIPS is cast as an extension of the provisions regarding "unfair competition" found in Article 10*bis* of the Paris Convention for the Protection of Industrial Property.<sup>15</sup> Under this general rubric, Article 39 of TRIPS provides for the protection of "undisclosed information" or trade secrets. The provision regarding test data, Article 39.3, is the result of a compromise among

available at http://www.ustr.gov/enforcement/update.pdf [hereinafter Dispute Settlement Update].

The WTO Dispute Settlement Body can interpret TRIPS provisions but is not authorized to expand protection, and it has avoided the temptation to fill gaps in the Agreement. J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries*?, 32 CASE W. RES. J. INT'L L. 441, 446-49 (2000).

<sup>14.</sup> Even in the United States the expanded protection of test data is a relatively recent development, driven largely by the perceived inadequacy of the patent system to provide financial incentives for the development of certain pharmaceuticals with limited markets. The United States first attempted to address this issue in 1982 with the passage of the Orphan Drug Act, 21 U.S.C. §360cc (2004).

<sup>15.</sup> Paris Convention for the Protection of Industrial Property, art. 10*bis.* The TRIPS Agreement refers directly to the Paris Convention, which was established in 1883 for the protection of non-literary or artistic intellectual property and is the earliest direct precursor to TRIPS.

differing submissions from several participating nations.<sup>16</sup> The final version reads as follows:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.<sup>17</sup>

Among the several undefined terms in Article 39.3, the issues of what constitutes a "new chemical entity" and how to define the limits of "unfair commercial use" appear to be the most pressing.<sup>18</sup>

TRIPS requires that member nations provide test data protection only for "new chemical entities," which at a minimum should exclude substances that have previously received regulatory approval. In the pharmaceutical context, this provision would arguably not require protection for new combinations, dosages, applications, or formulations of existing drugs, even if they required submission of additional test data to gain marketing approval.<sup>19</sup> This limitation, even if assumed, does not clarify whether "new" indicates novelty in the patent sense or merely a fresh submission for marketing approval, either in the member state or worldwide. Under the most restrictive (and least likely) interpretation, a new chemical entity would have to represent a novel patentable invention, and only such products would be entitled to test data protection. An interpretation more consistent with the intent of the countries that originally sought the test data provision would require protection for all previously undisclosed, first-time marketing approval submissions, whether or not the chemical entity were eligible for patent protection.<sup>20</sup> Further

<sup>16.</sup> See JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 197-99 (2000); G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT'L. L. & BUS. 1, 5-20 (2003).

<sup>17.</sup> TRIPS Agreement, supra note 1, art. 39.3.

<sup>18.</sup> See WATAL, supra note 16, at 203-06; Skillington & Solovy, supra note 16, at 25-28, 29-35; Carlos M. Correa, Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals, 3 CHI. J. INT'L. L. 69, 74-75, 76-79 (2002).

<sup>19.</sup> Correa, supra note 18, at 75.

<sup>20.</sup> See id. at 74-75.

evidence that TRIPS Article 39.3 is unclear as to the definition of "new" includes recent U.S. FTAs that either eliminate the modifier entirely or include separate provisions for new and pre-existing chemical products.<sup>21</sup> Under the TRIPS Agreement, then, member states are free to adapt their understanding of the category of "new chemical entities" to suit national health care policy.

Much of the discussion of "unfair commercial use" under Article 39.3 involves the question of whether third parties can rely on protected undisclosed test data to obtain marketing approval for their own products. In particular, a company seeking to market a generic drug can avoid vast, inefficient expenditures of time and money if it is able to simply submit evidence of bioequivalence (equal potency and availability to the body) with a previously approved chemical entity in order to support its own application. In this case, the government entity that required submission of the original test data has not disclosed it to the third party or even necessarily made "use" of the test data, much less unfair commercial use. Instead, it may be argued that the government has merely affirmed the interchangeability of the two compounds in a manner consistent with public health concerns regarding access to medicines.<sup>22</sup> This narrow interpretation of what constitutes unfair commercial use in the context of pharmaceutical test data is controversial. Whether or not a health agency actually consults data on safety and efficacy before approving an equivalent drug or merely remains aware that such data exists, a later application submitted without independent test data could not meet government standards without the existence of the original test data. The third party applicant thus derives commercial advantage from a regulatory process that makes use of undisclosed test data, arguably an unfair benefit. National health policies seek to balance this alleged unfairness with the public benefits of a robust generics industry.

Early versions of Article 39.3 contained a specific requirement that would have precluded third parties from relying on undisclosed test data to facilitate the approval of competing products for a "reasonable" period of time.<sup>23</sup> Some commentators have argued that temporal exclusivity provisions are the only way to ensure protection against unfair commercial use consistent with the TRIPS Agreement.<sup>24</sup> Given that TRIPS Article 39.3

<sup>21.</sup> See infra notes 29-49 and accompanying text.

<sup>22.</sup> Correa, *supra* note 18, at 80 (discussing Bayer v. Canada (Attorney General), [1999] 1 F.C. 553).

<sup>23.</sup> WATAL, supra note 16, at 197-99; Skillington & Solovy, supra note 16, at 5-20.

<sup>24.</sup> See, e.g., Skillington & Solovy, supra note 16, at 33.

is silent with respect to the type of substantive minima required for other areas of intellectual property protection, it is unclear that member states could be forced to provide specific periods of absolute test data protection. Aside from ongoing consultations with Argentina,<sup>25</sup> the United States's preferred method of limiting third party reliance on pharmaceutical test data is the inclusion of multi-year periods of exclusive use in its free trade agreements.<sup>26</sup> Apparent flexibility in the interpretation of TRIPS is thus curtailed by the greater obligations required by parallel instruments.

## U.S. Free Trade Agreements

The extent to which the United States was forced to compromise on the issue of pharmaceutical and agricultural chemical test data protection in the TRIPS Agreement is apparent from both historical accounts of the original TRIPS negotiation process<sup>27</sup> and the more extensive protection mandated by bilateral and multilateral FTAs. Representative examples of FTAs with more extensive intellectual property provisions than TRIPS include the North American Free Trade Agreement (NAFTA), enacted shortly before the TRIPS Agreement, and recent agreements or proposed agreements with Singapore, Chile, Central American nations, and Morocco. The progression from NAFTA, which includes test data provisions that the United States tried and failed to incorporate into TRIPS, to the most recent agreements illustrates the increasingly protectionist objectives of the USTR. The newest FTAs attempt not only to close the loopholes of TRIPS with respect to test data protection, but also to extend the term of patent protection for pharmaceutical products in order to account for the period of regulatory review.<sup>28</sup>

The NAFTA Agreement, like TRIPS, treats test data as a form of trade secret, focusing initially on nondisclosure and then, if disclosure occurs, on the prevention of unfair commercial use.<sup>29</sup> Protection is limited to agricultural and chemical products containing "new chemical entities," although as in TRIPS there is no effort to define "new."<sup>30</sup> With regard to the reliance of generics companies on protected data to obtain marketing approval, NAFTA requires exclusivity for a "reasonable period," defined as

30. Id.

<sup>25.</sup> Dispute Settlement Update, supra note 13.

<sup>26.</sup> See infra notes 28-49 and accompanying text.

<sup>27.</sup> See Sell, supra note 3.

<sup>28.</sup> See infra notes 38-42 and accompanying text.

<sup>29.</sup> NAFTA Agreement, supra note 12, at art. 1711(5).

"normally" at least five years and conditioned upon both the nature of the data and the effort and expenditure required to produce it.<sup>31</sup> Should a third party attempt to rely on test data submitted in another NAFTA country, the exclusivity period runs from the date of the first marketing approval cited.<sup>32</sup> However, NAFTA provisions specifically authorize "abbreviated approval procedures" for competing products following the exclusivity period, effectively limiting claims of unfair commercial use.<sup>33</sup> Despite U.S. efforts, TRIPS includes no such temporal exclusivity requirement. There is no distinction in either NAFTA or TRIPS between pharmaceutical and chemical products.

In contrast to NAFTA, concluded a decade earlier, the United States -Singapore Free Trade Agreement (Singapore FTA) does not invoke trade secret protection for test data. Instead, Singapore and subsequent FTAs include special provisions for "certain regulated products," such as pharmaceuticals.<sup>34</sup> The Singapore FTA provides that "information regarding the safety and efficacy of a pharmaceutical or agricultural chemical product" shall be excluded from third party reliance in marketing approval for five and ten years, respectively.<sup>35</sup> There is no mention of the effort expended in producing the "information," nor is there a requirement that the products be "new." The flexible five-year presumption in NAFTA is transformed in the Singapore FTA into fixed periods of five years for pharmaceuticals and ten for agricultural chemicals,<sup>36</sup> a shift reflected in subsequent U.S. FTAs.

In addition, several provisions in the Singapore FTA effectively lengthen the terms of test data protection and pharmaceutical patent protection. Unlike NAFTA, the period during which test data submitted in another country cannot be used for marketing approval without consent runs not from the date of the foreign approval, but from the later of the foreign approval date or the domestic approval date for the original product.<sup>37</sup> Additional efforts to lengthen the effective term of protection for pharmaceutical and agricultural chemicals under the Singapore FTA include the requirement that the exclusivity period for data pertaining to patented products be allowed to continue past expiration of the patent

<sup>31.</sup> *Id.* at art. 1711(6).

<sup>32.</sup> Id. at art. 1711(7).

<sup>33.</sup> Id. at art. 1711(6).

<sup>34.</sup> Singapore FTA, supra note 12, at art. 16.8.

<sup>35.</sup> Id. at art. 16.8(1).

<sup>36.</sup> Id.

<sup>37.</sup> Id. at art. 16.8(2).

term, should the patent expire before the end of the exclusivity period.<sup>38</sup> The Singapore FTA also introduces a provision, for pharmaceuticals only, for patent term extensions to compensate for "unreasonable curtailment of the patent term as a result of the marketing approval process."<sup>39</sup> Finally, pharmaceutical patent holders are entitled to notification of the identity of "any third party requesting market approval effective during the term of the patent," as well as assurance that such marketing approval will not be granted during the patent term without consent.<sup>40</sup> These pharmaceutical patent extensions, which appear in neither NAFTA nor TRIPS, are included in later FTAs as well.<sup>41</sup>

The draft United States - Chile Free Trade Agreement (Chile FTA), Central American Free Trade Agreement (CAFTA), and United States -Morocco Free Trade Agreement (Morocco FTA) each continue to refine the definition of a "new" pharmaceutical or agricultural chemical product and how to measure the duration of test data protection. The Chile FTA and CAFTA define "new" products as those that have not been previously approved,<sup>42</sup> rather than new or novel in the patent sense; CAFTA also specifies that the products not have received marketing approval in the individual member country.43 With respect to third party marketing approval on the basis of previously submitted test data, both the Chile FTA and CAFTA echo the Singapore FTA's exclusivity periods of five years for pharmaceuticals and ten for agricultural chemicals.<sup>44</sup> In addition, CAFTA provides that the exclusivity period shall run from the date that the original applicant received marketing approval in the individual CAFTA member country-rather than in any foreign country-although CAFTA members may condition this term of protection on the original applicant seeking approval in the member country within five years of the foreign application.45

The Morocco FTA goes beyond earlier agreements by protecting, in addition to the basic category of regulatory test data for new pharmaceutical and agricultural chemical products, a separate body of new

42. Chile FTA, supra note 9, at art. 17.10(1); CAFTA, supra note 9, at art. 15.10(1)(c).

<sup>38.</sup> Id. at art. 16.8(3).

<sup>39.</sup> Id. at art. 16.8(4)(a).

<sup>40.</sup> Id. at art. 16.8(4)(b-c).

<sup>41.</sup> CAFTA refers to this grant as "restoration" rather than "extension" of the patent term. CAFTA, *supra* note 12, at art. 15.10.

<sup>43.</sup> CAFTA, *supra* note 9, at art. 15.10(1)(c).

<sup>44.</sup> Chile FTA, supra note 9, at art. 17.10(1); CAFTA, supra note 9, at art. 15.10(1)(a).

<sup>45.</sup> CAFTA, supra note 9, at art. 15.10(1)(b).

clinical information required for the approval of (not necessarily new) other than information pharmaceutical products, related to bioequivalency.<sup>46</sup> Like the Singapore and Chile FTAs and CAFTA, the Morocco FTA grants exclusivity periods for pharmaceutical and agricultural products of five and ten years, respectively, measured in this case from the date of original approval within the contracting country.<sup>47</sup> For new clinical information, which might pertain to previously reviewed or approved pharmaceuticals, the period of protection is limited to three years.<sup>48</sup> In addition, protection of new clinical information is conditioned upon the requirement that its origination involve "considerable effort."49 Although the language regarding effort echoes NAFTA and TRIPS, the division between new products and new clinical information indicates the development of an additional category of protected information that could affect the availability of existing pharmaceutical chemicals approved for new applications.

#### CONCLUSION

From the early suggestion in NAFTA that original applicants should enjoy a "reasonable period" of exclusivity with respect to reliance on pharmaceutical test data to standardized periods of protection and expansive definition of what constitutes a "new" product, the mechanism of free trade agreements has allowed the United States to establish international levels of protection far beyond the original, deliberately ambiguous TRIPS consensus on trade secrets. While some countries may enjoy benefits similar to those that the United States identified in creating its own domestic protections for test data,<sup>50</sup> others may not yet have reached the stage at which incentives to invest in the creation of clinical data for new drug approval outweigh the need to facilitate marketing of competing versions on an expedited basis. The serial free trade negotiation process, particularly between nations with unequal bargaining power, is an unlikely forum for development of comprehensive, balanced policies on health care. It is, however, an opportunity for the United States to advance elements of intellectual property protection that exceed worldwide norms. This apparent divide-and-conquer strategy on the part of

<sup>46.</sup> Morocco FTA, *supra* note 9, at art. 15.10(1-2).

<sup>47.</sup> Id. at art. 15.10(1).

<sup>48.</sup> Id. at art. 15.10(2).

<sup>49.</sup> Id.

<sup>50.</sup> See Skillington & Solovy, supra note 16, at 8-11.

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the United States circumvents the multilateral nature of TRIPS negotiations, decreases opportunities for the flexible interpretation of TRIPS by member nations, effectively lengthens the terms of pharmaceutical patents, and threatens to create a de facto global standard that may adversely affect the development of generic pharmaceutical production capacity. Although the TRIPS regime represents a global compromise that required many nations to increase intellectual property protections only with great reluctance, recent U.S. FTAs make TRIPS look like the good old days.

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# The Interaction of Increased Trade and the Decentralization of Health Care Delivery in Nepal: A Suggestion for Reform

## Nephil Matangi Maskay, Ph.D.\*

#### INTRODUCTION

As levels of international trade and investment have increased, national economies that were once relatively isolated have become increasingly connected as participants in one global economy. This phenomenon is reflected in the growing number of bilateral and multilateral agreements, as well as the rising membership in the World Trade Organization (WTO)—a global multilateral organization which has facilitated the trend toward greater trade in goods and services.<sup>1</sup> The continuing increase in WTO membership suggests that member states have found their participation in the organization to be beneficial. However, the effect of WTO membership on domestic health issues has received relatively little attention. This may be in part because there is little evidence of direct links between the health of a nation and economic development.<sup>2</sup> Yet the two are connected, albeit indirectly; this connection occurs primarily through the ability of good healthcare delivery to produce a productive workforce.<sup>3</sup>

This Case Study puts forward a perspective on health related issues

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<sup>1.</sup> The WTO was established on January 1, 1995 and to date has 148 members. World Trade Organization, *at* http://www.wto.org (last visited Apr. 14, 2004).

<sup>2.</sup> There have been some recent exceptions. See WORLD HEALTH ORG.,

MACROECONOMICS FOR HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT (2001). 3. WILLIAM HSIAO, WHAT SHOULD MACROECONOMISTS KNOW ABOUT HEALTH CARE

POLICY?: A PRIMER (International Monetary Fund Working Paper No. 00/136, 2000).

from the eyes of Nepal—the youngest member of the WTO—whose protocol of accession<sup>4</sup> was approved by consensus at the fifth Ministerial in Cancun<sup>5</sup> and recently ratified by Nepal.<sup>6</sup> With a per capita income of approximately \$236<sup>7</sup> and a low human development index,<sup>8</sup> Nepal is one of the first "least developed" countries<sup>9</sup> to enter the WTO through the regular process of accession.<sup>10</sup> The protocol of accession reflects Nepal's acceptance of the principles of the WTO, as well as the wide range of commitments Nepal has made in multilateral agreements concerning goods and services with the objective of facilitating trade. The health and social services sector in Nepal is certainly not immune to the broad impact of WTO membership.<sup>11</sup> For example, there is ongoing discussion of TRIPS (Trade-related Aspects of Intellectual Property Rights), one of the

4. The protocol of accession is the membership treaty and lists the member's commitments. *See* WORLD TRADE ORG., UNDERSTANDING THE WTO 100 (3d ed. 2003) [hereinafter WORLD TRADE ORG., UNDERSTANDING], *available at* http://www.wto.org/english/thewto\_e/whatis\_e/tif\_e/understanding\_e.pdf; *see also* WORLD TRADE ORG., DOC. WT/ACC/NPL/16, REPORT OF THE WORKING PARTY ON THE ACCESSION OF THE KINGDOM OF NEPAL TO THE WORLD TRADE ORGANIZATION (2003).

6. Milan Mani Sharma, *Government Ratifies WTO Membership*, KATHMANDU POST, March 24, 2004, at 2, *available at* http://www.kantipuronline.com/kolnews.php?&nid=9410.

7. NEPAL MINISTRY OF FINANCE, ECONOMIC SURVEY 7 (2003), *available at* http://www.mof.gov.np/publication/budget/2003/index.php.

8. UNITED NATIONS DEVELOPMENT PROGRAM, HUMAN DEVELOPMENT REPORT 2003 (2003).

9. The United Nations uses countries' per capita gross domestic products (GDP) to designate which countries to designate as "least developed." The threshold for inclusion is generally \$900, but the United Nations also considers weak human resources (as measured by life expectancy at birth, per capita calorie intake, combined primary and secondary school enrolment, and adult literacy) and the level of economic diversification. *See* Press release, U.N. Conference on Trade & Development, Least Developed Countries at a Glance (June 18, 2002),

http://www.unctad.org/Templates/webflyer.asp?docid=2929&intItemID=1634&lang=1.

10. Cambodia is another one of the "least developed" countries to be approved to enter the WTO through the regular accession process. *See* Press Release, World Trade Org., Ambition Achieved as Ministers Seal Cambodia Membership Deal (Sept. 11, 2003), http://www.wto.org/english/news\_e/pres03\_e/pr354\_e.htm; *id.* 

11. WORLD TRADE ORG., DOC. S/C/W/50, HEALTH AND SOCIAL SERVICES: BACKGROUND NOTE BY THE SECRETARIAT (1998); see also Rupa Chanda, General Agreement on Trade in Services: Implications for Social Policy Making, 38 ECON. & POLITICAL WEEKLY 1567 (2003).

<sup>5.</sup> Press Release, World Trade Org., WTO Ministerial Conference Approves Nepal's Membership (Sept. 11, 2003),

http://www.wto.org/english/news\_e/pres03\_e/pr356\_e.htm.

multilateral agreements between WTO members, and the influence that its provisions on medical patents, such as those held by pharmaceutical companies, have on the public health community.<sup>12</sup> Proponents of these agreements believe that the presence of greater service suppliers, both domestic and foreign, will enhance the productivity and efficiency of the health sector. The hope is that enhanced productivity and efficiency will in turn contribute to better healthcare in the nation. Since the Nepalese economy is largely agrarian, labor input is highly important;<sup>18</sup> as a result, the overall health of the Nepalese population has a significant influence on the state of the economy and on economic development.

The primary focus of this Case Study is the component of the WTO agreement dealing with trade in health services, as covered under the General Agreement on Trade in Services (GATS), and its interaction with current domestic reforms aimed at decentralizing the public health care system. This Case Study argues that the interaction of decentralization and increased trade, coupled with current domestic conflict in Nepal, could result in significant short-term costs. Modifying the decentralization process should help minimize the short-term costs, so that the long-term benefits of increased trade can be realized.

### I. GATS AND TRADE IN HEALTH SERVICES

Using the GATS definitions, trade in health services can be supplied in four different ways: 1) cross-border delivery of health service supplies that are not present in the domestic economy through telemedicine or telediagnosis; 2) consumption of health services abroad when domestic consumers travel to a foreign country to receive health services; 3) commercial presence, such as a foreign service provider establishing a joint venture health institution in the domestic economy; and 4) movement of people, such as health care professionals, between countries.<sup>14</sup> There are both benefits and costs to each of these possible trade mechanisms.<sup>15</sup>

The potential benefits of the first mechanism (e.g., telemedicine) are,

<sup>12.</sup> WTO Members Expected To Agree on TRIPS & Health Pre-Cancun, BRIDGES, Aug. 28, 2003, at http://www.ictsd.org/weekly/03-08-28/story2.htm.

<sup>13.</sup> Shiva Raj Adhikari et al., Nepalese Health Policies: Some Observations from an Economic Development Perspective, 14 ECON. REVIEW: OCCASIONAL PAPER 55 (2002), available at http://www.nrb.org.np/red/publication/Economic\_Review\_Occasional\_Paper\_No\_14-Nepalese\_Health-Policies.pdf.

<sup>14.</sup> Rupa Chanda, Trade in Health Services, 80 BULL. OF THE WORLD HEALTH ORG. 158, 160 (2002).

<sup>15.</sup> Id. at 159-61.

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among other things, that it allows health services to cater to remote areas, helps alleviate human resource constraints, and provides cost-effective surveillance of disease. The potential cost is the reallocation of resources from rural and primary healthcare to specialized services which cater to the affluent few, since they are able to afford the necessary technology.

The potential benefit of the second mechanism (i.e., consumption of healthcare services abroad) is its potential to improve the healthcare system by generating additional resources for investment in healthcare. It may also increase the level of foreign exchange: For example, when individuals travel abroad to consume a health service, they contribute to the local economy and bring in foreign currency. The potential cost is similar to that noted above for the first mechanism: It may create a dual market structure with higher quality care going to the affluent, and much lower quality care going to the poor. A related concern is the crowding out of the local population from the higher standard centers at the expense of the public healthcare system.

The potential benefit of the third mechanism (i.e., foreign commercial ventures) is that it helps generate additional investment in the health sector, upgrade health care infrastructure, facilitate employment generation, and provide expensive and specialized medical services. Again, the potential cost may be growing inequality to access and a two-tiered health care system. This two-tiered system results from an internal "brain drain," as the foreign commercial ventures encourage health professionals to move from the public to the private sector.

The potential benefit of the fourth mechanism (i.e., movement of healthcare professionals) is that it may promote the exchange of clinical knowledge among professionals and therefore upgrade the skills and standards in the two countries. The potential costs may be its detrimental effects on equity, quality, and availability of health care services if the health care professionals move on a permanent basis, thereby leading to a shortage of highly trained personnel.

The above description of both potential benefits and costs suggests that the countries involved must take affirmative steps if they are to maximize the net benefits of involvement in GATS. Indeed, the outcome of GATS involvement will largely depend on the nature of the nation's health care system, regulatory environment, and government policies.

Through negotiations,<sup>16</sup> Nepal has committed itself to the trade of a number of health services, mainly using the first three mechanisms of

<sup>16.</sup> WORLD TRADE ORG., UNDERSTANDING, supra note 4, at 106.

trade.<sup>17</sup> As a result, it is unlikely that Nepal will restrict its trade in the near future. Thus, it is important to ask the following question: What will be the short-term and long-term impact of these commitments?<sup>18</sup> The long term impact will likely be positive with more competition for allocation of scarce health resources, resulting in a more effective and productive health care service. The short-term effect, however, is not so clear. One thing is certain, however: The conceptual long-term is made of innumerable short-terms which must be survived to reap the long-term benefits. It is for this reason that this Case Study focuses on the short-term issues for Nepal.

### II. NEPAL'S HEALTH CARE SYSTEM

Until recently, Nepal's health care system has largely been the domain of the public sector with the private sector entrants limiting themselves to the urban areas. Presently, the domestic public healthcare system is quite extensive. In many cases, only public health institutions are present in the rural areas, and these institutions are attempting to cover the whole country in line with Nepal's 1991 National Health Policy.<sup>19</sup> The spread of health services in the country is consistent with the national health policy's objective of "extend[ing] the primary health care system to the rural population so that they benefit from modern medical facilities and trained health care providers."<sup>20</sup> The healthcare system is based on referrals from the lower tiers to the upper tiers. The first points of contact are the "subhealth posts," which number approximately 2589 and strive to be in each Village Development Committee (VDC) in the country; by contrast, there are approximately 764 "later health posts," and they are each supposed to represent five VDCs in the country. In addition, hospitals and primary care centers are spread across the country.<sup>21</sup> Despite this extensive network, institutional weakness and ineffective program management, in part

17. WORLD TRADE ORG., DOC. WT/ACC/NPL/16/Add.2, REPORT OF THE WORKING PARTY ON THE ACCESSION OF THE KINGDOM OF NEPAL TO THE WORLD TRADE ORGANIZATION—

- ADDENDUM 2: SCHEDULE OF SPECIFIC COMMITMENTS IN SERVICES, available at
- http://www.moics.gov.np/wto\_&\_nepal/documents/Schedule%20of%20Commitments%2 0in%20Services1.doc (last visited Apr. 29, 2004).
- 18. Short-term refers to less than one year, while long-term refers to more than five years.

19. National Health Policy, 1991, Nepal Ministry of Health, at

http://www.moh.gov.np/plans\_policies/policy\_plans.htm (last visited Apr. 29, 2004). 20. Id.

21. Chhatra Amatya, The Health Services in Nepal and the World Bank Assistance, in NEPAL RASTRA BANK, WORLD BANK GROUP AND NEPAL 53-65 (2003).

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resulting from the poor regulatory environment, have contributed to poor public service delivery.<sup>22</sup> The former is reflected by the fact that the Ministry of Health used only twenty to forty percent of its development budget during the period from fiscal year 1980/81 to 1997/98.<sup>23</sup> It is also reflected in the trend of decreasing expenditures on primary health care<sup>24</sup> and in the poor allocation of health resources.<sup>25</sup> On the other hand, the absence of a significant correlation between government expenditures on health and various mortality and morbidity rates during the period from fiscal year 1989/1990 to 1999/2000 is evidence of the latter.<sup>26</sup> Furthermore, out-of-pocket spending on health care is estimated to be approximately three-quarters of total health care expenditure,<sup>27</sup> suggesting that healthcare financing can have equity implications.

The poor performance of the public healthcare system is reflected, in part, by certain healthcare measures on which Nepal performs below average for the South Asian region and performs even more dismally by international standards.<sup>28</sup> This poor performance of the public healthcare system has been a motivating force for its decentralization. Proponents of decentralization feel that if health institutions are owned and managed by

23. *Id.* at 24. Nepal's fiscal year begins in mid-July of one year and ends in mid-July of the following year. The exact dates are determined by the Nepalese lunar-based calendar. The current fiscal year, mid-July 2003 through mid-July 2004, corresponds to the Nepali year from Srawan 2060 through Asar 2061.

24. WORLD BANK, supra note 22, at 24.

25. One prime example is that healthcare personnel were often inappropriately placed. JUDITH JUSTICE, POLICIES, PLANS, & PEOPLE: FOREIGN AID AND HEALTH DEVELOPMENT (1989).

26. Shiva Raj Adhikari & Nephil Matangi Maskay, Health Sector Policy in the First Decade of Nepal's Multiparty Democracy: Does Clear Enunciation of Health Priorities Matter?, 68 HEALTH POL'Y 103, 103 (2004).

27. Badri Raj Pande et al., Health Insurance Models in Nepal: Some Discussions on the Status of Social Health Insurance (2004) (unpublished manuscript, on file with The Yale Journal of Health Policy, Law, & Ethics).

28. NEPAL MINISTRY OF FINANCE, *supra* note 7. For example, the child mortality rate per thousand births was 81 for males, 87 for females in 2002; the overall healthy life expectancy at birth was 51.8 years. Nepal, World Health Org., *at* http://www.who.int/country/en/ (based on *The World Health Report 2003*). During the same period in the United States, the child mortality rate per thousand births was 9 for males, 7 for females; the overall healthy life expectancy at birth was 69.3 years. United States of America, World Health Org., *at* http://www3.who.int/whosis/country/indicators.cfm?country=usa. The statistics in other countries in the region, such as Bangladesh, are superior to Nepal. See the World Health Organization's website, http://www.who.int/country/en/, for country-based statistics.

<sup>22.</sup> WORLD BANK, REPORT NO. 19613, NEPAL OPERATIONAL ISSUES AND PRIORITIZATION OF RESOURCES IN THE HEALTH SECTOR (2000).

the local community, there will be greater monitoring and supervision of healthcare services, thereby ensuring their more efficient and effective provision. In this regard, one of the primary goals in the Nepal Health Sector Implementation Plan 2003-2007 is decentralization of the public health care system.<sup>29</sup> This process of decentralization is based on existing laws,<sup>30</sup> and a number of public healthcare institutions have already been handed over to local bodies.<sup>31</sup> However, the move to decentralization does entail transitional costs that may result in inequality to access. The absence of local bodies in some areas, and the inability of some existing local bodies to handle their new responsibilities, may significantly impair the provision of local health services, resulting in the poor having less access to, and a lower quality of, health services. Indeed, the process of decentralization seems to many to be moving blindly ahead without a full consideration of the interaction between decentralization and trade in associated with of the transitional costs health services and decentralization.

# III. HEALTH CARE DECENTRALIZATION AND ITS INTERACTION WITH TRADE IN HEALTH SERVICES

As I argued above, decentralization of public healthcare will lead to greater inequality in the short-term. The trade in health services will magnify this transition cost and lead to greater inequality of access to healthcare services because affluent individuals facing the short-term transitional cost of decentralization will now have the opportunity to access quality health services through the mechanisms of trade discussed earlier. Affluent individuals may use telemedicine; travel to foreign countries for consumption of health services; and move to urban areas to access private

http://www.mof.gov.np/publication/budget/pdf/bspeech2003.pdf (For FY 2003-04, the so-called "Budget Speech" has been published and distributed as the *Public Statement on Income and Expenditure.*); NEPAL MINISTRY OF FINANCE, PUBLIC STATEMENT ON INCOME AND EXPENDITURE OF THE FISCAL YEAR 2002-2003 (2002), *available at* 

http://www.mof.gov.np/publication/statements/2059/index.php# (Nepali version, translated by the author). The Budget Speech for 2002-2003 is available at http://www.mof.gov.np/publication/budget/pdf/bspeech2002.pdf.

<sup>29.</sup> NEPAL MINISTRY OF HEALTH, NEPAL HEALTH SECTOR IMPLEMENTATION PLAN 2003-2007 (2003).

<sup>30.</sup> NEPAL MINISTRY OF LAW JUSTICE AND PARLIAMENTARY AFFAIRS, LOCAL SELF GOVERNANCE ACT 1999 (1999).

<sup>31.</sup> NEPAL MINISTRY OF FINANCE, PUBLIC STATEMENT ON INCOME AND EXPENDITURE OF THE FISCAL YEAR 2003-2004 (2003), available at

healthcare services providers, such as nursing homes, private hospitals and colleges. Thus, liberal trade in services will *exacerbate* the inequality of healthcare access resulting from decentralization.

These short-term effects on the equality of access can already be seen in the growth of private healthcare institutions, such as nursing homes, private hospitals, and colleges, in urban areas and the consequent expansion of health personnel in these areas. Nonetheless, these shortterm effects may give way to long-term benefits because the greater number of health service providers will result in increased competition which will likely benefit society as a whole. Yet the realization of these longterm results may be made more difficult by the present domestic security system in which over 10,000 people have fallen victim to the armed conflict commenced by the Maoist insurgency in February 1996.<sup>32</sup> As a result, there is an absence of local representative bodies, and this situation has resulted in the weakening of the provision of healthcare, especially in the remote, rural areas of the country.<sup>33</sup> This raises an important question: As decentralization proceeds, to whom should responsibility be transferred? Since a central objective of decentralization is to transfer responsibility and a feeling of ownership to the locally elected bodies to enhance their sustainability and facilitate economic development, this is an important question.

### **IV. THREE ISSUES FOR THE PROCESSES OF DECENTRALIZATION**

The interaction of trade in health and decentralization in the present domestic situation is potentially volatile and could result in some unfortunate consequences. Given the significance of these consequences, some suggest that reassessment of these processes is appropriate. However, it is important to remember that many of Nepal's trade commitments are part of WTO membership and cannot be changed without reopening negotiations with affected countries.<sup>34</sup> Thus, it makes more sense to focus reform efforts on decentralization. This Case Study argues that there are three key issues related to decentralization which warrant reassessment: timing, sequencing (i.e., preparedness of local bodies), and pace.

<sup>32.</sup> The armed conflict of the Communist Party of Nepal (Maoist) started over eight years ago from the poor governance and heightened inequality related problems prevalent in the 1990s. For a concise history, see DEEPAK THAPA & BANDITA SIJAPATI, A KINGDOM UNDER SIEGE: NEPAL'S MAOIST INSURGENCY, 1996 TO 2003 (2003).

<sup>33.</sup> See, e.g., Health Workers Caught Between Ongoing Conflict, KATHMANDU POST, Mar. 29, 2004, at 2, available at http://www.kantipuronline.com/kolnews.php?&nid=9685.

<sup>34.</sup> WORLD TRADE ORG., UNDERSTANDING, supra note 4.
#### A. Timing

The move toward decentralization will increase inequality of access to healthcare in the short-term. As mentioned earlier, liberalization of trade in health will magnify the transitional cost of decentralization and the resulting inequality of access for health care. This is doubly dangerous as the country is presently facing political turbulence and a domestic security situation where there is an absence of elected local bodies to ensure sustainability of the process. All these characteristics tend to suggest that moving ahead with decentralization for the sake of moving ahead may not be sensible and may result in high short-term costs, if not failure. It would thus make sense for the decentralization process to be postponed until the domestic situation improves.<sup>35</sup>

#### B. Sequencing

Since the process of decentralization in Nepal will necessarily interact with trade policy, the sequencing of changes in this area should be considered carefully. Decentralization should proceed in parallel with the development of local capacity to bear greater responsibility for the provision of health services. In addition, there should be strengthened monitoring and supervision from the relevant ministries in His Majesty's Government of Nepal to ensure accountability. Moreover, the potential benefits of trade in health services should be harnessed to facilitate the process of decentralization and to provide equitable access to health services. For example, greater trade in health services could help absorb temporary shortfalls in public health services. To facilitate this end, a road map should be developed which takes into consideration administrative, financial, and managerial perspectives on these issues.<sup>36</sup> This would ensure stability and confidence in the local health system.

# C. Pace

The pace of decentralization should be determined by the domestic situation. The two extremes may be the "big bang" type of approach, such

<sup>35.</sup> Nephil Matangi Maskay, Resource Allocation in Health: Targeting Poverty Alleviation through Decentralized Planning and Program Implementation - A Commentary for the Nepalese Perspective, 1 J. NEPAL HEALTH RES. COUNCIL 61-63 (2003).

<sup>36.</sup> NEPAL HEALTH ECON. ASS'N, HEALTH CARE FINANCING AND FINANCIAL MANAGEMENT IN NEPAL: REVIEW, ASSESSMENT AND SUGGESTIONS OF PRESENT AND FUTURE PUBLIC HEALTH CARE FINANCING AND FINANCIAL MANAGEMENT IN NEPAL (2002).

as that which occurred in Russia, and the gradual approach, such as that which is occurring in China. In Nepal, where there is, as of yet, limited culture for independent, regional reforms, decentralization should not be pursued hastily simply for the sake of reaching some predetermined numerical target. Rather, a gradual pace would be more appropriate. As with sequencing, attention to the pace of changes should help ensure the sustainability and success of the process.

#### CONCLUSION

The prior discussion suggests that the transitional cost of decentralization may be magnified if pursued concurrently with the trade commitments that WTO membership brings. This is particularly true in the present context where the political situation is fluid and there is an absence of local representation. This situation suggests that this process may not be sustainable and may, if forced, be prone to failure. As a result, this Case Study suggests three areas in which the decentralization process should be reassessed: timing, sequencing, and pace. Further, it is important to point out that any reassessment has to move away from abstract conceptualizations about the values of decentralization and focus instead on the practical challenges of implementation if it is to produce desired results.<sup>37</sup>

To reach the long-term benefits of increased trade, survival of the short-term transitional costs is essential. This Case Study suggests a general approach aimed at surviving these transitional costs. The Case Study is not advocating a revision in trade policy, as Nepal has already made binding trade commitments. Rather, it is pointing out that Nepal's healthcare system should focus on taking full advantage of the opportunities made possible by the increased trade in health services and should modify its existing approach to decentralization accordingly. This modification, coupled with appropriate health sector reform, should maximize the probability of sustainability and success which will enhance the country's economic development.

<sup>37.</sup> Adhikari & Maskay, supra note 26.

# Cambodia's Membership in the WTO and the Implications for Public Health

Samnang Chea\* and Hach Sok<sup>†</sup>

#### BACKGROUND

With an estimated per capita income of USD\$280, Cambodia is the poorest and least developed country in East Asia and one of the poorest in the world. At least thirty-six percent of Cambodia's fourteen million people live on less than fifty cents per day. Half of Cambodia's children under age five are malnourished.<sup>1</sup>

Although some improvements have been made in recent years, the health situation in Cambodia may still be the worst in the East Asia region. Figures from the World Health Organization (WHO) show that the infant mortality rate is more than double the regional average rate.<sup>2</sup> Malaria and tuberculosis cause thousands of deaths per year.<sup>3</sup> The incidence of HIV/AIDS infection is growing rapidly and may soon overtake other causes of death.<sup>4</sup> The complex social and economic conditions that are both causes and effects of health crises make health care a critical challenge facing Cambodia. For example, health problems, which decrease individual worker productivity and impact family finances, have been causally linked to much of the landlessness and extreme poverty in rural areas.<sup>5</sup>

2. World Health Org., Country Health Information Profile: Cambodia,

http://www.wpro.who.int/chips/chip02/cam.htm (last visited Apr. 25, 2004).

3. Id.

4. *Id*.

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<sup>1.</sup> USAID, Cambodia: Activity Data Sheet, at

http://www.usaid.gov/pubs/cbj2002/ane/kh/442-002.html (last visited Apr. 25, 2004); *see also* U.N. DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT: MILLENNIUM DEVELOPMENT GOALS 198 (2003), http://hdr.undp.org/reports/global/2003/.

<sup>5.</sup> ROBIN BIDDULPH, OXFAM, INTERIM REPORT ON FINDINGS OF LANDLESSNESS AND DEVELOPMENT INFORMATION TOOL (LADIT) RESEARCH SEPTEMBER 1999 TO APRIL 2000 (2000).

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With incomes so low, Cambodians look to public health care which promises free service and medicine. However, the country's public health budget is extremely under-funded; in 2003, it was just two dollars (U.S.) per citizen.<sup>6</sup> Privatization of some public health services has been largely unsuccessful—private hospitals have catered to higher-income people in urban areas while the poorest people, most of whom live in rural areas, have been left behind. Public hospitals are sadly lacking in supplies and staff and offer a very low quality of healthcare. Prices for legitimate supplies of medicine are high for the average Cambodian, giving rise to the smuggling of cheap, counterfeit medicine that has a negative impact on overall population health.

In September 2003, Cambodia was approved to join the World Trade Organization (WTO).<sup>7</sup> As part of its WTO membership, Cambodia will be required to implement the provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.<sup>8</sup> This Agreement outlines a uniform standard for intellectual property protection and requires that member countries give the same protection to nationals of other member countries. Although there are other international treaties that deal with these rights, to date TRIPS is the most comprehensive multilateral agreement on intellectual property and its protection.

To what extent will this Agreement impact the health sector in Cambodia? This Case Study assesses the current situation of the health sector in Cambodia and discusses how this Agreement, and WTO accession in general, will impact public health care.

## I. THE CURRENT SITUATION OF CAMBODIA'S HEALTH SECTOR

Data compiled by the WHO show Cambodian public health indicators to be among the worst in the world.<sup>9</sup> The mortality rate of children under five was 124 per 1000 live births in the year 2000, an appallingly high figure in relation to the estimated mortality rate in the East Asia region of forty

<sup>6.</sup> MINISTRY OF FINANCE, STATE BUDGET IMPLEMENTATION OF CAMBODIA FOR 2003 (March 2004).

<sup>7.</sup> Press Release, WTO News, Ambition Achieved as Ministers Seal Cambodia Membership Deal (Sept. 11, 2003).

<sup>8.</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27.1, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement], available at

http://www.wto.org/english/tratop\_e/trips\_e/t\_agm0\_e.htm.

<sup>9.</sup> See World Health Org., supra note 2.

per 1000 live births.<sup>10</sup> In the past three years, the figures have gotten even worse: The 2003 United Nations Development Programme (UNDP) statistics placed the mortality rate for children under five at 138 per 1000 live births.<sup>11</sup> The main causes of death for the general population are malaria, acute respiratory infection, tuberculosis, diarrhea, and dengue fever. Gaining fast on those causes is the human immunodeficiency virus (HIV), which has been spreading rapidly in the kingdom. HIV is becoming a factor in the low life expectancy numbers in Cambodia.<sup>12</sup> Life expectancy at birth is estimated at only fifty-four years, about fifteen years less than life expectancy in the region.<sup>13</sup>

These poor health statistics are the result of the myriad problems that Cambodians face. Low levels of income and education are exacerbated by the woeful condition of the country's public health system, particularly in rural areas. The Ministry of Finance's statistics reveal the severe shortages of resources that have afflicted the public health system; for example, in 2003, actual expenditures on health were only about half that of the budgeted level.<sup>14</sup> Correspondingly, up to eighty percent of total health expenditures fell upon individual Cambodians.<sup>15</sup>

Access to health services is also limited by the paucity of human resources: The physician-to-population and physician assistant-to-population ratios in Cambodia are lower than those observed in neighboring countries.<sup>16</sup> Additionally, the health infrastructure is minimal.

13. World Bank, Cambodia at a Glance,

http://www.worldbank.org/data/countrydata/aag/khm\_aag.pdf (last modified Aug. 20, 2003); *see also* World Health Org., Select Health Indications 2001,

http://www.who.int/country/khm/en/ (last visited Apr. 25, 2004).

14. MINISTRY OF FINANCE, supra note 6.

15. See World Health Org., supra note 13; WORLD BANK, CAMBODIA: PUBLIC EXPENDITURE REVIEW, ENHANCING THE EFFECTIVENESS OF PUBLIC EXPENDITURE (Jan. 1999). Most of these health expenditure take place in the private sector, where wealthier Cambodians are able to pay for visits to private doctors and hospitals. Private pharmacists are the first point of call for most non-emergency cases. For emergency cases, people tend to go directly to state facilities. See MINISTRY OF HEALTH, STORY OF THE POTENTIAL ROLE OF THE INFORMAL DRUG PROVIDERS (Apr. 2002).

16. As of 2001, WHO statistics showed that there were about 18,000 employees under the Ministry of Health. Of that, 2000 were doctors, 200 dentists, 600 pharmacists, 8000 nurses, and 3000 midwives. World Health Org., *supra* note 13. Even where personnel exist, the services available may be limited; the low wages of public health workers, for example,

<sup>10.</sup> Id.

<sup>11.</sup> U.N. DEV. PROGRAMME, supra note 1, at 208.

<sup>12.</sup> World Health Org., supra note 2.

For example, there are fewer than 7700 hospital beds within the public health facilities.<sup>17</sup> Overall, these factors contribute to very low utilization of public health services.

The concept of health insurance was introduced in 1991, but it has not been widely adopted, likely due to its relatively high cost and perceived low quality.<sup>18</sup> Most Cambodians remain unaware of the existence of insurance, while others do not trust this new system. Individuals, even the higherincome urban dwellers, have not been buying health insurance—they are prone to feel that the quality of the current health system is too weak, and they prefer to pay the higher prices for superior health care in neighboring countries, such as Vietnam, Thailand and Singapore. Law and regulation will play crucial roles in making health insurance more readily available and attractive to Cambodian workers. In particular, encouraging companies to provide insurance as a workers' benefit, particularly in emerging industries such as the garment sector, could provide a much needed boost in health care options.

The current weaknesses in both the public and private health care systems mean that seeking health care, particularly for a serious medical condition, can quickly push a middle class family into poverty and a poor family into utter destitution. Low income families and individuals are deterred from using the public sector, even if that is their only option, because the public facilities are plagued with a lack of equipment and medicines and are staffed by underpaid and demoralized employees. This understandable distrust of the public sector has led to a downward spiral of severe underutilization and mounting inefficiency in public health care facilities. The private sector offers more responsive service and allows customers to purchase drugs and treatment on credit, but private practitioners are often heavily dependent upon drug sales to earn their income and therefore over-prescribe.

For people in Cambodia, like those in many developing countries with a large rural population, drugs are often the first and only access to modern medicine. Given that most health dollars are spent out of people's own pockets,<sup>19</sup> access to drug supplies occurs primarily via private practitioners and not through public health institutions. Unfortunately,

typically result in low levels of job commitment and high rates of absenteeism.

<sup>17.</sup> World Health Org., supra note 2.

<sup>18.</sup> To the extent that health insurance is purchased, it is generally only bought by foreign companies, nongovernmental organizations (NGOs), and international organizations.

<sup>19.</sup> See supra note 15 and accompanying text.

the private sector is poorly regulated, so even this minimum access to medicines is fraught with problems. It is estimated that there are a large number of illegal drug sellers—over seventy percent of all drug shops are unlicensed, and managed by non-pharmacists. The Cambodian government has often pledged to crack down on the illegal drug sellers, but little has been accomplished because of weak enforcement institutions.

#### II. TRADE LIBERALIZATION'S IMPACT ON POPULATION HEALTH CARE

During the past ten years, Cambodia has taken many steps to open its economic policies and to foster growth and development. In 1994, a medium-term adjustment and reform program aiming to restore macroeconomic stability was launched, and a process of institutional strengthening supported by the international community was undertaken. Private sector growth has been promoted and efforts have been made at longer-term structural reforms that would allow sustainable economic growth and poverty alleviation. A liberal investment law was promulgated and trade was liberalized.<sup>20</sup>

As a result, foreign investment flowed into Cambodia during the first years of those reforms; these investments, in turn, allowed rapid development of some emerging industries, such as the garment industry and tourism. External trade significantly expanded and became the main source of economic growth and job creation.<sup>21</sup>

However, income distribution has been uneven. According to estimates by the Economic Institute of Cambodia (EIC), income disparity between rich and poor is growing, and income disparity is also growing among various provinces.<sup>22</sup> Globalization is primarily benefiting higher-income people in urban areas, whereas traditionally poorer people in rural areas are not only seeing fewer benefits but are in a larger sense being left behind as globalization continues.

The fear is that Cambodia's WTO membership will result in even wider income distribution inequalities unless there are clear economic and institutional reforms. According to a recent EIC study on the impact of foreign investment on human development, the poor will likely be unable

<sup>20.</sup> See HACH SOK, CAMBODIA DEV. RESOURCE INST., THE ECONOMIC DEVELOPMENT AND REFORM POLICY IN CAMBODIA: CHALLENGES AND PROSPECTS IN THE INTEGRATION PROCESS (2001).

<sup>21.</sup> Id. at 15.

<sup>22.</sup> See Phalla Kim, Cambodia's Economy in the Election Year 2003, EIC ECON. REV., Sept. 2003, at 13-15, available at http://www.eicambodia.org/publications/publication.htm.

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to seize the opportunities provided by liberalized trade without government support in implementing strict rules and regulations.<sup>23</sup> This inability is because the poor are often uneducated, and trade liberalization can serve to further expand their vulnerability to exploitation. Furthermore, globalization and economic liberalization have huge impacts on the health sector both in the private and public sector. The EIC study clearly shows that these processes positively contribute to economic growth and promote private sector development. But if private sector development occurs in a vacuum, without concurrent attention to the government's provision of good quality public sector services, poor people will be increasingly worse off as measured by growing income inequality.<sup>24</sup>

The current lack of funding and physical equipment for the public health sector has meant that health professionals from the public sector have been siphoned off to private health institutions. Quite simply, government-determined wages of public sector health professionals at about USD\$25 per month are not enough when the minimum cost of living is estimated to be at least three times higher.<sup>25</sup> Consequently, the public sector health professionals spend only the bare minimum of time in their official positions and do the bulk of their work in private clinics. In addition to the wage issues, public sector health institutions suffer from outdated equipment and government neglect. As a result of low wages and a crumbling health infrastructure, the quality of public health service decreases. To reverse this trend, the Cambodian government must make solid commitments to social and health spending, and it must adequately

25. EIC has undertaken a study to assess the poverty line and income distribution in Cambodia. The first estimation drawn from this study showed that the minimum cost of living (including basic education for children and health care) of a Cambodian household—composed of husband, wife, and three children—is about USD\$150 per month in the rural areas and USD\$300 in the urban areas. Therefore, the minimum monthly salary or income of both husband and wife should be at least USD\$75 each in the rural areas and USD\$150 eech in the urban areas. It is noted that, actually, the Cambodian poverty line definition is fifty cents per day per person, while the World Bank definition is twice as high (still only about USD\$30 per person per month). Critics say that fifty cents per day per person is an extreme poverty line existence—that amount might buy a minimum to eat and to clothe oneself, but would not be sufficient for sending children to school or paying for health care when needed.

<sup>23.</sup> HACH SOK, CAMBODIA: INVESTMENT POLICIES AND HUMAN DEVELOPMENT 7-11 (U.N. Dev. Programme Trade Initiative Project, Feb. 2004).

<sup>24.</sup> Hack Sok, Addressing Social Justice for Economic Development and Democracy, EIC ECON. REV., Dec. 2003, at 12-15, available at

http://www.eicambodia.org/publications/publication.htm.

regulate public health staff to promote efficiency and dependability. The government has consistently made pledges to increase substantially the public health budget, but in fact, disbursement has been extremely irregular. Indeed, the government routinely spends less than half the public health budget it allocates for a fiscal year and during extraordinary periods, such as an election year, some public health expenditures can drop to as low as twenty percent of budgeted amounts.<sup>26</sup> The ministries and public institutions responsible for public health do not have the political clout to wrest consistently its budget from a system of internal government financing that is ruled by patronage and kickbacks.

# III. THE IMPACT OF TRIPS ON CAMBODIA'S PHARMACEUTICAL INDUSTRY

The Cambodian drug market is very small, likely due to the public's lack of income necessary to purchase drugs. According to the Ministry of Health figures, drug consumption in Cambodia reached only about USD\$35 million in 2001 (less than USD\$3 per capita). Of that total, forty-three percent was provided free of charge by the government and donors; the remaining fifty-seven percent was paid for by private consumers.<sup>27</sup> On the supply side, Cambodia's pharmaceutical industry consists of four small manufacturers. One of those manufacturers produces drugs for HIV/AIDS. All four Cambodian manufacturers produce drugs without any patent. Drugs produced in Cambodian factories are much cheaper than foreign products, yet many Cambodians cannot even afford drugs produced locally. Wealthier Cambodians often prefer more expensive imported drugs for reason of confidence in quality.

Studies are currently underway regarding the possibility of exporting Cambodian drugs to foreign markets. In June 2002, the WTO council responsible for intellectual property approved a decision to extend until 2016 the transition period during which least developed countries (LDCs) do not have to provide patent protection for pharmaceuticals. In the international arena, the discussions leading to this decision have focused on the need to balance intellectual property protection with the need to tackle serious public health problems of developing countries, especially health crises resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. As an LDC, Cambodia could take advantage of the flexibility of

<sup>26.</sup> Information from the Ministry of Finance (State Budget Implementation of Cambodia for 1998 to 2003) compiled by the authors and on file with *Yale Journal of Health Policy, Law, and Ethics.* 

<sup>27.</sup> MINISTRY OF HEALTH, supra note 15.

the TRIPS Agreement and special treatment for LDCs and encourage the growth of its small drug-producing industry.

Even after the 2016 deadline, there are still flexibilities in TRIPS that will allow LDCs, like Cambodia, to implement the Agreement's provisions related to pharmaceuticals in ways that will continue to benefit their own original pharmaceutical industries. Under the TRIPS emerging Agreement, products made under compulsory licensing, which allows the LDCs to produce generic versions of the medicines under license, must be "predominantly for the supply of the domestic market."28 However, in August 2003, WTO member governments reached a new agreement over intellectual property protection and public health that allows producers under compulsory license to export the pharmaceutical products to foreign markets under certain conditions aimed at safeguarding the legitimate interests of the patent holder.<sup>29</sup> Questions to be answered include the cost of obtaining this license and whether Cambodian producers could comply with safeguard clauses imposed by the patent holder.

Beginning in 2016 Cambodia will be expected to enforce the intellectual property requirements mandated by TRIPS. The first major implication of the patent system will be increased costs for drug production and sale. Cambodia has few pharmaceutical enterprises and a low capacity of production. To take the particular example of HIV drugs produced here now, Cambodia can currently manufacture these drugs without patents until 2016. The population has reasonable access to these locally-produced lower-priced drugs, although even these lower-priced drugs are out of the reach of many poor Cambodians. If Cambodia implements the TRIPS Agreement and must purchase a patent license, the first immediate shock will be the increase in the price of the drugs. Very few persons will have reasonable access to these much-needed drugs. Hence, the implementation of the patent system will adversely affect the health sector. Cambodia's government must find ways to maintain a supply of less expensive pharmaceutical products that give at least some possibility

<sup>28.</sup> TRIPS Agreement, supra note 8, at art. 31(f).

<sup>29.</sup> World Trade Org., General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Sept. 1, 2003), available at http://www.wto.org/english/tratop\_e/trips\_e/implem\_para6\_e.htm. Technically all WTO member countries are eligible to import under this decision, but twenty-three developed countries are listed in the decision as announcing voluntarily that they will not use the system to import. See Press Release, WTO News, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003).

for the poor to access needed medicines. The precipitous increase in the price of medicine that would follow patent licensing will only encourage the smuggling of cheap or counterfeit products.

Second, there are strong doubts that Cambodia has or will have the resources to stay abreast of new technology and invention. Even after the WTO's transitional period, Cambodia will likely lag behind in the areas of pharmaceutical enterprise and pharmaceutical research and development. Therefore, the implementation of the patent system will not only increase the price of drugs, but also limit the supply of drugs in the country because Cambodia may not have access to the technological means to develop or manufacture newer drugs.

It may benefit Cambodia's government, in conjunction with other less developed WTO members, to strengthen the *Doha Declaration* related to TRIPS and public health for the LDCs, and even seek future concessions to ensure cheap access to new medicines.<sup>30</sup> As practical steps to achieve this goal, Cambodia should advocate, in concert with other developing countries, extending the transition period far after 2016 and should seek special licensing prices for least developed members. In the meantime, the Cambodian government must promote national research and development institutions, especially in the area of pharmaceuticals, with the assistance of developed countries.

#### CONCLUSION

The Cambodian pharmaceutical industry remains nascent, and its growth will largely depend on long-term domestic structural reforms. Most of its drug consumption will thus continue to be imported. Cambodia should thus advocate for international agreements that facilitate cheap import drug prices. In the *Doha Declaration* of November 2001, the WTO ministers stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health—by promoting both access to existing medicines and the creation of new medicines. They also issued a declaration on how to help poorer countries that are unable to make medicines domestically to access cheaper generics made under compulsory licensing.<sup>31</sup> Cambodia should thus seek the enhancement of this declaration.

<sup>30.</sup> World Trade Org., Doha WTO Ministerial 2001, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at

http://www.wto.org/english/thewto\_e/minist\_e/min01\_e/mindecl\_trips\_e.htm.

<sup>31.</sup> Id.

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On the domestic supply side, Cambodia has a lot of potential for development since it is situated in the heart of a fast-growing region of Southeast Asia. As a least developed country member, Cambodia could, depending on the laws of the importing country, export most of its products, including drugs, tariff-free to other WTO members. But these opportunities will only turn into benefits if Cambodian industry is competitive and can meet international demands on price and quality. Under the WTO membership agreements, Cambodia must implement a large number of reforms to strengthen its institutions, particularly legal reforms. Specifically, the WTO requires Cambodia to create national intellectual property laws that would conform to the TRIPS Agreement. If these new laws are implemented properly, Cambodia's government could create a new environment that is conducive to trade, while still respecting intellectual property. Particularly for the health sector, if these new laws can be enforced efficiently, the benefits in better health care would be tangible. For example, a reduction in the amount of counterfeit medicine on the local market would have a strongly positive effect on public health.

New TRIPS provisions could also facilitate a technology transfer that might attract more investment to the Cambodian pharmaceutical industry. An increase in the supply capacity could further reduce the price of drugs—making them more affordable for poorer consumers, while also making Cambodia more competitive in the export market. To achieve this transfer, however, Cambodia must work to develop its R&D capabilities in high-technology, medicine, and biotechnology. Only if these efforts are made will Cambodia fully benefit from the TRIPS Agreement.

# Barrier to Trade or Barrier to Profit? Why Australia's Pharmaceutical Benefits Scheme Worries U.S. Drug Companies

# Clive Hamilton, D.Phil.\* Buddhima Lokuge, M.P.H.<sup>†</sup> and Richard Denniss\*\*\*

#### INTRODUCTION

Much of the rhetoric that underpins arguments for "free trade" relies on the assertion that free trade agreements between nations are "win–win" arrangements. That is, it focuses on the textbook conclusion that by reducing trade barriers the total volume of goods and services available for consumption will increase and that, as a result, people in participating countries will likely benefit. In reality, free trade agreements are about winners and losers. Individual industries use their political influence to fight for or to defend their domestic or international profitability. For example, in the recently concluded negotiations of a free trade agreement between the United States and Australia, U.S. sugar farmers succeeded in convincing U.S. negotiators to defend them against increased import competition.<sup>1</sup> The "win–win" rhetoric was further challenged during those same negotiations when U.S. pharmaceutical companies convinced U.S. negotiators to press hard for changes to Australian drug pricing policies that limit pharmaceutical profits.

For more than a year prior to the completion of the United States-Australia Free Trade Agreement (FTA), the U.S. pharmaceutical industry lobby group, PhRMA,<sup>2</sup> and its Australian counterpart, Medicines Australia,<sup>3</sup>

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<sup>1.</sup> See, e.g., Michael Schroeder, Sugar Growers Hold Up Push For Free Trade, WALL ST. J., Feb. 3, 2004, at A13.

<sup>2.</sup> PhRMA refers to the Pharmaceutical Research and Manufacturers of America. See Who We Are, PhRMA, at http://www.phrma.org/whoweare/ (last visited Mar. 30, 2004).

mounted a campaign to convince both the Australian public and the U.S. negotiators that the Australian Pharmaceutical Benefits Scheme (PBS) is a barrier to trade. PhRMA and Medicines Australia argued that reform was necessary in order to deliver the "win-win" benefits of free trade to both Australian consumers and U.S. pharmaceutical manufacturers.

However, the changes to the PBS desired by U.S. manufacturers would result in the transfer of between \$1.0 and \$2.4 billion Australian dollars (AUD) per year in the form of higher medicine prices and profits.<sup>4</sup> Moreover, Australia does not have *any* trade barriers that restrict the sale of pharmaceuticals. Like all developed countries, Australia has requirements to ensure that all pharmaceuticals sold to the public are safe,<sup>5</sup> but these requirements apply equally to drugs developed in Australia or the United States. Australia imposes neither tariffs nor quotas on the importation of pharmaceuticals.

Since the final text of the FTA has not yet been released, we can not fully evaluate the outcome of the pharmaceutical industry's campaign.<sup>6</sup> It appears, however, that Australia has promised to make some changes to the PBS.<sup>7</sup> At the very least, the attack on the PBS provides a compelling example of the way in which free trade arguments are enlisted to undermine social policies that act not as barriers to trade, but to excess profit.

3. Medicines Australia, *at* http://www.medicinesaustralia.com (last visited May 17, 2004).

4. K. LOKUGE & RICHARD DENNISS, TRADING IN OUR HEALTH SYSTEM? THE IMPACT OF THE AUSTRALIA-US FREE TRADE AGREEMENT ON THE PHARMACEUTICAL BENEFITS SCHEME vii-ix (The Austl. Inst., Discussion Paper, No. 55, 2003), *available at* 

http://www.tai.org.au/Publications\_Files/DP\_Files/DP55suma.pdf. At the time of publication,

1 AUD = U.S.\$0.76. This value was determined using The Universal Currency Converter, *at* http://www.xe.com/ucc/. Therefore, the changes sought by U.S. pharmaceutical companies would cost Australians between \$765,000,000 and \$1,835,000,000.

5. See AUSTL.DEP'T OF HEALTH & AGEING, 1995 GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY ON PREPARATION OF SUBMISSIONS TO THE PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE, http://www.health.gov.au/pbs/general/pubs/pharmpac/gusubpac.htm (last visited Mar. 30, 2004).

6. Editor's Note: Since the writing of this Case Study, the agreement was signed (on May 18, 2004) and subsequently the final text was released; it is available at http://www.dfat.gov.au/trade/negotiations/us\_fta/final-text/index.html (last visited July 1, 2004).

7. See infra text accompanying note 34.

#### THE AUSTRALIAN PBS SYSTEM

The Australian PBS is recognized internationally as a superior pharmaceutical pricing scheme. Professor Richard Laing of Boston University's School of Public Health has stated that "Australia... is the one country which seems to have got it right, that what you want to do in controlling costs is to pay what the drugs are therapeutically worth. And the Pharmaceutical Benefits Scheme does that."<sup>8</sup>

Australia's PBS scheme was established in 1948 in response to concerns that not all Australians could afford vital new medicines such as penicillin.<sup>9</sup> Since then, the scheme has developed as a multibillion dollar subsidy to health consumers—consumers are required to pay a maximum co-payment of AUD\$23.10, or AUD\$3.70 for low income earners, and the federal government funds any difference between the maximum co-payment and the full price paid to the pharmaceutical company.<sup>10</sup>

Because the Australian federal government is responsible for the difference between the price of the drug paid to the pharmaceutical company and the co-payment made by citizens, it is in the Australian government's interest to minimize the prices paid for medicines. It is the effect of the PBS on prices that is of greatest concern to American drug companies. However, seeking approval for listing on the PBS is only necessary if drug companies, domestic or foreign, wish to avail themselves of the benefits of the Australian subsidy scheme.<sup>11</sup>

For a new drug to be listed on the PBS, approval for its sale must first be obtained from the Therapeutic Goods Administration (TGA), roughly the equivalent of the United States' Food and Drug Administration. In assessing a request for the approval of a new drug the TGA is required to consider, among other things, the product's quality, safety and efficacy. If the TGA approves the drug for sale within Australia, the supplier may then apply to have the new drug listed for subsidization on the PBS. It is important to point out that a new drug that has been approved for sale by the TGA can be sold, without subsidy, within Australia. It is only necessary for a pharmaceutical company to seek to have their drug listed on the PBS

<sup>8. 7.30</sup> Report: Australian Benefits Scheme Upsets US Drug Companies (ABC radio broadcast, Feb. 27, 2001), http://www.abc.net.au/7.30/s252447.htm.

<sup>9.</sup> LOKUGE & DENNISS, *supra* note 4, at 5; AUSTL. PARLIAMENTARY LIBRARY, THE PHARMACEUTICAL BENEFITS SCHEME—AN OVERVIEW, *at* 

http://www.aph.gov.au/library/intguide/SP/pbs.htm (last updated Jan. 2, 2003).

<sup>10.</sup> AUSTL. PARLIAMENTARY LIBRARY, supra note 9.

<sup>11.</sup> See id.

if they wish to be eligible for the federal government subsidy.<sup>12</sup>

To ensure that a new drug is eligible for subsidy under the PBS, a supplier must apply to the Pharmaceutical Benefit Advisory Committee (PBAC), a committee of experts whose role it is to assess applications for listing on the PBS against a number of criteria, including: the need for the product; the outcomes and costs of a particular pharmaceutical when weighed against other available therapies; and whether any restrictions should be imposed on new listings, such as limits on the number of items that may be prescribed or restrictions on the indications for which a PBS subsidy is available.<sup>13</sup> The National Health Act [of] 1953 specifies that the PBAC must consider whether a new drug addresses an unmet medical need or provides a significant improvement in efficacy or a reduction in toxicity over drugs already listed, and is of acceptable cost-effectiveness.<sup>14</sup> This provision is important as it aims to ensure that new drugs will be listed only if there is evidence that an improved outcome for patients and the community will be delivered.

Once a new drug has been listed by the PBAC, the Pharmaceutical Benefits Pricing Authority (PBPA) negotiates the price that should be paid to the manufacturer.<sup>15</sup> The PBPA may also stipulate conditions of use, such as restrictions on prescription to specific groups. The Department of Health is then responsible for negotiating a price with the drug supplier. The federal government makes the final decision whether to list the drug at the negotiated price.<sup>16</sup>

# U.S. DRUG COMPANIES' CONCERNS WITH AUSTRALIA'S PBS SYSTEM

Pharmaceutical companies are opposed to Australia's approach to price determination, describing the impact of the PBS on the pricing of pharmaceuticals as "insidious."<sup>17</sup> Drug manufacturers in the United States

<sup>12.</sup> See id.

<sup>13.</sup> Austl. Dep't of Health & Ageing, Pharmaceutical Benefits Advisory Committee, *at* http://www.health.gov.au/pbs/general/listing/committee.htm#pbac (last updated Dec. 16, 2003).

<sup>14.</sup> AUSTL. DEP'T OF HEALTH & AGEING, GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY ON THE PREPARATION OF SUBMISSIONS TO THE PBAC: PART 1 (Feb. 4, 2003), *at* http://www.health.gov.au/pbs/pharm/pubs/guidelines/part1.htm.

<sup>15.</sup> AUSTL. PARLIAMENTARY LIBRARY, *supra* note 9.

<sup>16.</sup> See LOKUGE & DENNISS, supra note 4, at 8-9.

<sup>17.</sup> MEDICINES AUSTL., A PRESCRIPTION FOR THE FUTURE HEALTH OF AUSTRALIA: SUBMISSION TO THE INTER-DEPARTMENTAL COMMITTEE PREPARING A REPORT ON THE EFFECTIVENESS OF THE PBS 25 (2002), http://www.medicinesaustralia.com.au/.

have also expressed concern with the "overriding focus on costeffectiveness" of the PBS and have taken issue with the Australian requirement that "[t]o obtain a premium, the applicant must demonstrate significant clinical advantages over its main comparator and satisfactory cost-effectiveness versus that comparator."<sup>18</sup>

The explicit purpose of Australia's PBS is to ensure that pharmaceuticals are affordable for both individual patients and Australian taxpayers. The use of the government's buying power, combined with expert advice on both efficacy and cost effectiveness, ensures that Australian citizens have access to some of the cheapest prescription drugs in the developed world. Residents of the United States sometimes pay up to ten times as much as Australians for identical pharmaceuticals.<sup>19</sup>

While the PBS is highly effective in lowering the prices paid for pharmaceuticals, it does not, in any way, act as a barrier to trade. As indicated above, the PBS contains no tariff or quota barriers and does not treat domestically designed or manufactured pharmaceuticals any differently from imported substances; moreover, it is not necessary for drugs to be listed on the PBS in order for them to be sold in Australia.<sup>20</sup> It appears that the main concern that pharmaceutical manufacturers have with the Australian PBS scheme is that it is effective in countering both the market power and information asymmetry between customers and suppliers that usually exists within the pharmaceutical industry. Of even greater concern to pharmaceutical companies, it seems, is the possibility that other countries—and even some states within the United States—may implement schemes similar to Australia's.

# THE ECONOMICS OF THE PBS

The pharmaceutical industry is characterized by extensive market failure. That is, in the absence of comprehensive government regulation, the industry does not efficiently design, manufacture and distribute pharmaceutical products. The first major form of market failure is due to

http://www.cptech.org/ip/health/c/australia/phrma-au-2003.html.

<sup>18.</sup> PHRMA, 2003 SUBMISSION TO THE US TRADE REPRESENTATIVE (2003),

<sup>19.</sup> See BUDDHIMA LOKUGE & CLIVE HAMILTON, THE AUSTL. INST., COMPARING DRUG PRICES IN AUSTRALIA AND THE USA: THE IMPLICATIONS OF THE US-AUSTRALIA FREE TRADE AGREEMENT 5 (Jul. 2003), available at

http://www.tai.org.au/Publications\_Files/Papers&Sub\_Files/Drug%20comparisons.pdf.

<sup>20.</sup> It should be noted, however, that the vast majority of prescriptions are covered by the PBS due to the substantial cost advantage that PBS drugs have over non-subsidized medicines.

the "public good" nature of new pharmaceutical substances. Organizations involved in pharmaceutical research and development face substantial private costs associated with developing new products—in the absence of patent protection, pharmaceutical manufacturers could "free ride" on the costly research of an innovator. Thus, without patents, firms would be unwilling to invest sufficient resources in the development of new drugs. In order to create an incentive for the development of new medicines, governments—including the Australian and U.S. governments—provide pharmaceutical companies with the patent right to become a monopoly provider of their new product.

The PBS relies on the monopsony buying power of the Australian government to counter the monopoly selling power possessed by pharmaceutical manufacturers with patent protection. The notion that unregulated market outcomes are efficient, be they within countries or between them, is based on the notion of perfect competition.<sup>21</sup> In a perfectly competitive market, it is assumed that there are large numbers of buyers and sellers and that no buyer or seller has any bargaining power. When a seller has monopoly power, as is the case in the Australian pharmaceutical industry where products are protected from competition by twenty-year patents, providing the buyer with "countervailing bargaining power" will result in a more efficient outcome than if the monopolist is allowed to use its power against a large number of small buyers.<sup>22</sup>

The need to encourage innovation is not the only form of market failure evident in the pharmaceutical industry. Another important form of market failure, one which pharmaceutical companies appear much less concerned about, is the substantial asymmetry that exists between consumers and manufacturers concerning the relative therapeutic worth of alternate forms of treatment. Individuals are simply not best placed to make decisions about which products to purchase: They are unlikely to have either the resources or analytical ability to compare systematically the costs and benefits of a wide range of pharmaceutical and nonpharmaceutical treatments for a given condition. As patents allow pharmaceutical companies to act as monopolists, the profit maximizing strategy for a pharmaceutical company is to take advantage of the lack of information on the part of the consumer and set prices based on "what the market can bear" rather than based on the therapeutic worth of the product or the cost of development. The Australian PBS plays an important role in addressing this information asymmetry.

<sup>21.</sup> See PAUL A. SAMUELSON & WILLIAM D. NORDHAUS, ECONOMICS 46 (12th ed. 1985).

<sup>22.</sup> ROBERT S. PINDYCK & DANIEL L. RUBINFELD, MICROECONOMICS 365-66 (4th ed. 1998).

It is difficult, if not impossible, for average health consumers to collect, evaluate and analyze all the information necessary to compare competing forms of treatment for an illness with which they have been diagnosed. They are therefore unlikely to be able to act like the rational, well-informed consumers described in economics textbooks. Furthermore, while doctors may be sufficiently well informed about the efficacy of alternate courses of treatment, individual physicians are unlikely to be able to comparatively compute their marginal costs and benefits—particularly as the costs are not borne directly by the physician, but rather by either patients or taxpayers; for such a level of reasoned decisionmaking, guidance from a body such as the PBAC is essential. Indeed, the PBS uses a team of experts to make judgments about the relative merits of alternative pharmaceutical substances.<sup>23</sup> Such a system not only ensures that those with the relevant expertise conduct the comparisons, but also ensures that the costs of conducting the analysis are pooled across all health consumers.

Ironically, despite the contention that the PBS reduces the incentives for innovation, the scheme's heavy reliance on comparative cost-benefit analyses actually promises that only innovative products that deliver demonstrable benefits will receive the benefits of subsidies—thereby aiming to discourage the development of "copy cat" (or "me-too") drugs. Drug pricing systems that do not make extensive use of such economic analyses provide an incentive for pharmaceutical companies to invest heavily in advertising (to take advantage of the information asymmetry between manufacturers and consumers) rather than product innovation (which would be rewarded by a cost-benefit analysis if new benefits could be demonstrated).<sup>24</sup> In a typical market where individual buyers are poorly informed, the development of "copy cat" drugs, backed up by substantial advertising expenditures to achieve superficial product differentiation, is likely to be a more profitable strategy than the development of new substances.

Finally, it is necessary to address the contention that policies such as

<sup>23.</sup> Once again, it is important to note that if an individual disagrees with a decision not to list a drug for subsidy on the PBS, he or she is free to purchase that drug, at the price chosen by the pharmaceutical company, as long as it has been deemed safe by the TGA. See *infra* text accompanying note 12.

<sup>24.</sup> Despite the attempts of some in the United States to introduce reforms to the pharmaceutical industry designed to lower consumer prices, the U.S. federal government has actually legislated to prohibit the use of economic evaluations through the Medicare Modernization Improvement Act of 2003. *See, e.g.*, Rosa L. DeLauro, *DeLauro Spearheads Letter to Trade Rep. Zoellick Regarding Rx Drug Reimportation* (Dec. 15, 2003), http://www.house.gov/delauro/press/2003/Zoellick\_letter\_12\_16\_03.html.

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the Australian PBS drive up pharmaceutical prices in other, less regulated, markets. While high rates of profit in the pharmaceutical industry are typically defended as being necessary in order to fund more research and development,<sup>25</sup> it is neither obvious, nor inevitable, that higher pharmaceutical prices in Australia will result in increased research and development or lower pharmaceutical prices in the United States. The only reason that a for-profit company would pass on the benefits of higher prices or lower costs achieved in one market to consumers in another market was if they were under competitive pressure to do so. While it is possible that drug companies could chose to redistribute the gains they make from Australian consumers to U.S. consumers, it is also possible, and more likely, that they would pass any gains made in Australia directly to their U.S. shareholders instead.<sup>26</sup> It is worth noting that, in Australia, U.S. drug companies are continuing to maintain that the United States-Australia FTA will not lead to an increase in the prices paid by Australian consumers.<sup>27</sup> Putting aside the merits of this assertion, it seems inconsistent for the drug companies to simultaneously maintain that there will be no increase in drug prices (and thus, that it is in Australia's interests to sign the FTA), while suggesting that the FTA will result in a fairer worldwide distribution of the costs of pharmaceutical research and development.

#### THE PBS AND THE UNITED STATES-AUSTRALIA FTA

Despite the fact that the PBS does not, in any way, act as a barrier to trade between Australia and the United States, the office of the U.S. Trade

26. If anything, it is competition that ensures that prices fall, not higher profits extracted in other markets. However, competition within the U.S. drug industry has not prevented it from remaining the most profitable industry in the United States over the past ten years. *See* FAMILIES USA, PROFITING FROM PAIN: WHERE PRESCRIPTION DRUG DOLLARS GO (July 2002), http://www.familiesusa.org/site/DocServer/PPreport.pdf?docID=249. It is unlikely that any gains to pharmaceutical companies from Australian consumers would be redirected to the pockets of U.S. consumers.

27. See MEDICINES AUSTL., MEDICINES AUSTRALIA WELCOMES FTA ANNOUNCEMENT (Feb. 9, 2004).

<sup>25.</sup> For example, the industry is fond of citing Joseph DiMasi's estimates of the high cost of drug research and development. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003). For responses to DiMasi's methods and calculations, see ROBERT YOUNG & MICHAEL SURRUSCO, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S "SCARE CARD" (2001) (responding to DiMasi's original study) and Richard G. Frank, Editorial, *New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 325 (2003).

Representative stated in its 2003 National Trade Estimate Report on Foreign Trade Barriers: "Research-based U.S. pharmaceutical firms are disadvantaged by several Australian Government policies. These include a reference pricing system that ties the price of an innovative U.S. medicine to the lowest price medicine in the same therapeutic or chemical group, regardless of patent status of the medicines."<sup>28</sup>

There is no doubt that drug companies are adversely affected by the fact that the Australian government refers to the prices of existing alternatives when deciding how much it is willing to pay for a new drug; that is, after all, the objective of the PBS. But this disadvantage, in the form of lower profits, is not derived from any barrier to trade. It is derived from the implementation, in Australia, of a pharmaceutical pricing scheme designed explicitly to counter the bargaining power of all pharmaceutical companies over their customers.

United States-based pharmaceutical interests also sought to change Australia's intellectual property (IP) laws through the United States-Australia FTA in order to extend the period of time during which drugs were protected from low-cost generic pharmaceuticals.<sup>29</sup> While there was no attempt to extend the actual twenty year patent life of pharmaceuticals, there was an attempt to change IP laws to impede manufacturers of generic pharmaceuticals from getting their products on to the market as soon as the twenty year patent life ended.<sup>30</sup> The practice by generic manufacturers of using the data collected by the patent holder to convince regulators of the safety and efficacy of a substance is known as "springboarding," and is officially recognized by the World Trade Organization (WTO).<sup>31</sup> As the following quotation from the U.S. Trade Representative shows, pharmaceutical companies have convinced U.S. trade negotiators that the ability to use old test data is a barrier to trade: "The Australian Government is considering allowing 'springboarding,' allowing generic pharmaceutical manufacturers to begin trials and production of pharmaceuticals so that these drugs can receive immediate patent approval and can be sold immediately after a patent expires."<sup>32</sup> By

<sup>28.</sup> U.S. TRADE REPRESENTATIVE, 2003 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 12 (2003), http://www.ustr.gov/reports/nte/2003/australia.pdf.

<sup>29.</sup> See id.

<sup>30.</sup> See id.

<sup>31.</sup> The WTO upheld Canada's right to allow a "Regulatory Review Exception" to patent law. World Trade Org., Panel on Canada, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, at 146-48 (Mar. 17, 2000), *available at* http://www.wto.org/english/tratop\_e/dispu\_e/7428d.pdf.

<sup>32.</sup> U.S. TRADE REPRESENTATIVE, *supra* note 28, at 11.

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delaying the launch of generic competition, patent holders can extend the period over which they receive the high prices that patents deliver. It has been estimated that for every extra year that generic drugs can be kept out of the Australian market the profits made by drug companies will increase by one billion Australian dollars.<sup>33</sup>

At the time of writing, the text of the FTA negotiated between Australia and the United States has not been made available for public scrutiny. It is, however, illustrative of the lack of transparency in the process that summaries of the deal released by the Australian and U.S. administrations differ substantially on the issue of negotiated changes to the PBS. The U.S. Trade Representative's website states: "Australia will make a number of improvements in its Pharmaceuticals Benefits Scheme (PBS) procedures that will enhance transparency and accountability in the operation of the PBS, including establishment of an independent process to review determinations of product listings."<sup>34</sup> Yet, the Australian Department of Foreign Affairs and Trade simply states: "The Pharmaceutical Benefits Scheme (PBS), in particular the price and listing arrangements that ensure Australians access to quality, affordable medicines, remains intact."<sup>35</sup>

#### INTERNATIONAL IMPLICATIONS

Australia's PBS is a highly effective and efficient public policy device that provides Australian citizens with some of the lowest pharmaceutical prices in the developed world. However, the effectiveness of the PBS has drawn criticisms from the U.S. pharmaceutical industry and, in turn, from the office of the U.S. Trade Representative that threaten its future.

As highlighted earlier, if Australian citizens paid as much for their pharmaceuticals as their counterparts in the United States the cost of purchasing pharmaceuticals would increase by between AUD\$1 and AUD\$2.4 billion per year;<sup>36</sup> further, if the pharmaceutical companies succeed in achieving changes to IP laws to delay the introduction of generics after the expiry of patents, the cost is likely to exceed AUD\$1

<sup>33.</sup> LOKUGE & DENNISS, *supra* note 4 at 2.

<sup>34.</sup> U.S. TRADE REPRESENTATIVE, FREE TRADE "DOWN UNDER": SUMMARY OF THE U.S.-AUSTRALIA FREE TRADE AGREEMENT (Feb. 8, 2004), *available at* 

http://www.ustr.gov/releases/2004/02/2004-02-08-factsheet-australia.pdf.

<sup>35.</sup> AUSTRADE, FREE TRADE AGREEMENT WITH THE UNITED STATES (Feb. 9, 2004), *available at* http://www.austrade.gov.au/corporate/layout/0,0\_S1-1\_CORPXID0054-2\_-3\_PWB110416012-4\_-5\_-6\_-7\_,00.html.

<sup>36.</sup> LOKUGE & DENNISS, supra note 4, at ix.

billion per year.<sup>37</sup>

While such sums of money are no doubt substantial, they are far more likely to affect public health in Australia than to impact the pharmaceutical industry. These numbers are simply not so large when viewed in terms of the industry's global profits; for example, in 2001 the ten largest U.S. drug companies had a combined revenue of \$U.S.167 billion.<sup>38</sup> However, an increase of this magnitude would represent a highly significant change in the Australian government's expenditure on pharmaceuticals, as at present the cost to the government of pharmaceutical subsidies is on the order of five billion Australian dollars. It has been estimated that the price charged to patients would need to nearly double, or the government would have to exact tax increases.<sup>39</sup> As discussed below, such an increase in the cost of pharmaceuticals to patients is likely to have a serious impact on public health.

The biggest threat to the pharmaceutical industry posed by the PBS is arguably not its minimal impact on global pharmaceutical profits, but it's appeal as an approach and the corresponding threat that other countries may begin to implement similar schemes. While the United States-Australia FTA does not provide a direct mechanism for drug companies to affect the pharmaceutical schemes of other countries, the negotiation process highlights the likely pressures that other countries will face should they seek to limit prices in any way. All countries, including the United States itself,<sup>40</sup> are struggling to reconcile consumers' demand for new medicines (many of which are very expensive) and the need to have equitable access to them, with the desire to keep taxes and public expenditure low. One of

- 37. BUDDHIMA LOKUGE ET AL., A BACKDOOR TO HIGHER MEDICINE PRICES? INTELLECTUAL PROPERTY AND THE AUSTRALIA-US FREE TRADE AGREEMENT (Nov. 2003), *available at* http://www.tai.org.au/WhatsNew\_Files/WhatsNew/Patents.pdf.
  - 38. FAMILIES USA, supra note 26.
  - 39. LOKUGE & DENNISS, supra note 4, at x.

40. Commenting on the problems faced by state governments in the United States, New York Attorney General Eliot Spitzer said recently, "New Yorkers face a health-care crisis – a crisis driven to a large degree by the enormous growth in the cost of prescription drugs. This cost is eroding individual's health care and is a large factor in the massive state deficit." Eric Durr, *GlaxoSmithKline Charged with Inflating Prices*, TRIANGLE BUS. J., Feb. 13, 2003, *available at* http://triangle.bizjournals.com/triangle/stories/2003/02/10/daily37.html. Even President Bush's brother, Florida Governor Jeb Bush, has stated that "[p]rotecting the large profit margins for the multibillion-dollar pharmaceutical companies is not a priority. We are more concerned about making sure our senior citizens have better access to affordable prescription drugs." Jeff Tieman, *A Formulary in Progress, Florida Panel Will Make Regular Changes to Medicaid List of Preferred Drugs*, MOD. HEALTHCARE, Sept. 10, 2001.

the easiest ways to reconcile these competing objectives is to follow Australia's lead and to restrict the price associated with new medicines.

In recent years the United States has shifted much of its international trade focus away from multilateral agreements and towards bilateral agreements.<sup>41</sup> The FTA between Australia and the United States was one of the first bilateral agreements between the United States and a developed country. The willingness of the United States negotiating team to pursue the operation of social policies within Australia, rather than to confine itself to issues of tariffs and quotas, is therefore likely to signal the nature of subsequent FTAs negotiated by the United States. The United States-Australia FTA negotiations were explicitly used as a mechanism for watering down Australia's PBS system.

While the notion that low cost production techniques will spread rapidly between countries engaged in trade with each other is widely accepted, the view that all countries should converge upon uniform modes of social service provision is, perhaps, less widely held. It is therefore important to consider the implications of the inclusion of social policies in FTAs between developed countries as, over time, differences that have developed to meet the differing democratic preferences of counties may be difficult to maintain.

The Australian PBS, with its combination of government subsidy, costbenefit based price control, and low up-front prices for consumers (particularly concession card holders) ensure that drug prices do not create a significant barrier for Australians seeking medical treatment. According to one source, while sixteen percent of elderly residents of the United States spent more than one hundred U.S. dollars per month on prescription drugs, no elderly Australians spent that much despite the proportion of the populations that required them to take prescription medicines being quite similar.<sup>42</sup>

Access to affordable pharmaceuticals provides an important plank on which equity is delivered in Australia and is an essential component of the country's health system. Movement towards a system in which the chronically ill and the elderly are asked to pay higher prices will reduce

<sup>41.</sup> See, e.g., JOHN AUDLEY, CARNEGIE ENDOWMENT FOR INT'L PEACE, BAD BILATERAL TRADE DEALS ARE NO BETTER THAN BAD MULTILATERAL DEALS (Oct. 2003),

http://www.ceip.org/files/pdf/issuebriefoct2003.pdf.

<sup>42.</sup> CATHY SCHOEN ET AL., THE ELDERLY'S EXPERIENCES WITH HEALTH CARE IN FIVE NATIONS: FINDINGS FROM THE COMMONWEALTH FUND 1999 INTERNATIONAL HEALTH POLICY SURVEY 13 (May 2000), *available at* 

http://www.cmwf.org/programs/international/schoen\_5nat\_387.pdf.

public health outcomes, as well as equity, and will increase expenditures in other areas of the health budget, such as hospitals, where the adverse consequences of patients failing to take appropriate medicines will become apparent.

#### CONCLUSION

The PBS is not a barrier to trade; it is a barrier to excessive profits from the sale of pharmaceuticals in Australia. The PBS relies on the intervention of the government, on behalf of health consumers, to counter the monopoly power that patents provide to pharmaceutical manufacturers and to assist with reducing the information asymmetry between individual health consumers or providers and pharmaceutical manufacturers.

The U.S. trade negotiators showed themselves to be more than willing to act on behalf of the pharmaceutical industry in negotiating an FTA with Australia. When the final text of the FTA is released, it will be possible to evaluate more comprehensively the wins that have been achieved and losses that have been suffered. It seems that Australia has granted some concessions, including the establishment of a new appeals body. It does not seem incautious to predict that the changes negotiated as part of the FTA between Australia and the United States will likely result in higher prices for Australian consumers and higher profits for drug companies.

On a broader level, perhaps the most dangerous precedent that has been established in the United States-Australia FTA is that it now appears that even developed countries such as Australia may be susceptible to sacrificing their social policies in pursuit of improved access to the U.S. marketplace. In bilateral trade agreements, the far superior bargaining power of the United States may be too much for foreign governments to resist, especially when the full costs of their concessions will not be felt for some time.

# Australia-United States Free Trade Agreement and the Australian Pharmaceutical Benefits Scheme

Peter Sainsbury, Ph.D.\*

#### INTRODUCTION

This Case Study examines, with particular reference to the Australian Pharmaceutical Benefits Scheme (PBS), the events that occurred during the negotiation of the Australia-United States Free Trade Agreement (FTA) in 2003 and early 2004. The inclusion of the PBS in the FTA was a source of considerable concern in Australia due to its potential impact on health, and was a sticking point in negotiations.

Following brief descriptions of the PBS and the relationship between drug companies and the PBS, I outline in roughly chronological order some of the significant developments in the negotiations from a public health viewpoint. I also analyze the framing of the negotiations by the United States and Australian governments and the lack of transparency and public accountability with which the negotiations took place. I argue that trade negotiations, like the FTA, can have important health consequences; as such, public health advocates must become more active participants in the negotiations process.

This Case Study tells a story of process, not outcomes. In the telling I wish to stimulate consideration of the role public health workers can play in international trade negotiations, an arena in which they have not traditionally been much involved, but one that will assume increasing importance for the health of both individuals and nations.

AUSTRALIAN PHARMACEUTICAL BENEFITS SCHEME (PBS)

The Australian federal government<sup>1</sup> established the PBS in 1948 to

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<sup>1.</sup> Australia-in the bottom left-hand corner of the Pacific, with a population of twenty

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ensure that all Australians would be able to afford the increasingly effective, yet more expensive, therapeutic drugs that were becoming available. Since 1948 the range of drugs included in the PBS has expanded, the cost to the government has increased, and the mechanisms by which drugs are assessed for inclusion in the scheme have changed. Nonetheless, the PBS has retained its basic characteristics over the last six decades. The following is a brief review of the services the PBS now provides:

- A federal government subsidy for approximately 600 prescribed medications—in approximately 2600 different forms, strengths and brands—for all Australians.<sup>2</sup> Nearly eighty percent of all prescription medicines available at pharmacies are included.<sup>3</sup> The total government contribution is uncapped and currently totals around \$4.5 billion Australian dollars (AUD) per year.<sup>4</sup>
- Fixed out-of-pocket expenses for patients. Most members of the public pay up to AUD\$24 per prescription and approved pension cardholders pay AUD\$4 per prescription.<sup>5</sup> Although it varies from drug to drug, overall for every dollar paid by a patient, the PBS contributes five.<sup>6</sup>
- A financial safety net for chronically sick people who require multiple prescriptions. The PBS covers all out-of-pocket expenses in excess of AUD\$200 per year for pensioners and reduces the cost per prescription to AUD\$4 for non-pensioners

2. Austl. Dep't of Health & Ageing, General Public: Pharmaceutical Benefits Scheme, *at* http://www.health.gov.au/pbs (last visited Mar. 1, 2004).

3. Austl. Dep't of Health & Ageing, About the PBS, at

http://www.health.gov.au/pbs/general/aboutus.htm (last modified Dec. 24, 2003).

4. *Id*. At the time of publication, 1 AUD = USD \$0.76. This value was determined using The Universal Currency Converter, *at* http://www.xe.com/ucc/.

6. Id.

million—has a federal-state system of government similar to the United States. Under the Australian Constitution, states have primary responsibility for the provision of health services, but over the years the federal government has acquired many responsibilities by funding nation-wide programs. For further information on shared health programming responsibilities in Australia, see, for example, John McMillan, *The Constitutional Power of the Commonwealth in Public Health, in* PUBLIC HEALTH LAW IN AUSTRALIA – NEW PERSPECTIVES 105-37 (1998), *available at* http://www.health.gov.au/pubhlth/publicat/document/law2.pdf; RICHARD SCOTTON & CHRISTINE R. MACDONALD, THE MAKING OF MEDIBANK (Univ. of N.S.W. School of Health Service Admin. No. 76, 1993).

<sup>5.</sup> Austl. Dep't of Health & Ageing, supra note 3.

once their out-of-pocket expenses exceed AUD\$700 per year.<sup>7</sup>

- Strict government controls over which drugs are included in the scheme, and the medical conditions for which they are approved. All applications for a drug to be included in the PBS are carefully assessed by government appointed committees. New drugs are included only if they demonstrate a therapeutic benefit over existing PBS-listed drugs and an economic benefit for the government (e.g., a generic preparation of an existing PBS-listed patented drug).<sup>8</sup> Not all drugs that fulfill the first criterion are included in the PBS, however. Although there is no explicit threshold, drugs for which the additional cost per life-year gained is less than AUD\$42,000 (1998/99 values) tend to be approved; drugs with an additional cost per life-year gained over AUD\$76,000 tend not to be approved.<sup>9</sup>
- Close management of government payments for drugs included in the PBS. The price the government will pay for a drug is based on therapeutic worth (i.e., its usefulness to the patient compared with other available drugs), not on how much it cost the drug company to develop and produce the drug. If evidence demonstrates that a new drug is no better for patients than an existing drug, the government will pay the producer of the new drug only what it pays the producer of the existing drug.<sup>10</sup> This is a variant on the reference pricing systems utilized by many governments throughout the world. government's bargaining position is, of course, The strengthened by its near monopsony.

The result is that Australia has one of the cheapest drug bills in the developed world: Compared with the United States, the PBS saves Australia about AUD\$1-2.5 billion per year.<sup>11</sup> Yet, Australians still have access to the

<sup>7.</sup> Austl. Dep't of Health & Ageing, Frequently Asked Questions, *at* http://www.health.gov.au/pbs/general/faq.htm#safety2.

<sup>8.</sup> K. LOKUGE & RICHARD DENNISS, THE AUSTL. INST., TRADING IN OUR HEALTH SYSTEM: THE IMPACT OF THE AUSTRALIA-US FREE TRADE AGREEMENT ON THE PHARMACEUTICAL BENEFITS SCHEME vii-viii (The Austl. Inst. Discussion Paper, No. 55, 2003),

http://www.tai.org.au/Publications\_Files/DP\_Files/DP55suma.pdf.

<sup>9.</sup> Bethan George et al., Cost-Effectiveness Analysis and the Consistency of Decision Making: Evidence from Pharmaceutical Reimbursement in Australia (1991 to 1996), 19 PHARMACOECONOMICS 1103, 1103-1109 (2001).

<sup>10.</sup> LOKUGE & DENNISS, supra note 8, at 9, 22.

<sup>11.</sup> See id. Given the exchange rate at the time of publication, Australians save between \$765,000,000 and \$1,835,000,000 annually on drugs costs compared with the United States.

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newest drugs (provided evidence demonstrates that they are safe and effective) in a timely fashion and at a price that most patients and the country as a whole can afford. Advocates of the PBS claim that it delivers high quality health care, good money value, efficiency and equity—a powerful and unusual combination of attributes.<sup>12</sup> Over the last decade the cost of the PBS has increased by approximately fifteen percent per year, the number of prescriptions has increased by five percent per year, and the price per prescription has increased by nine percent per year.<sup>13</sup> By world standards the PBS's performance in controlling drug costs has been very impressive, and it has many international admirers.<sup>14</sup>

# DRUG COMPANIES AND THE PBS

Not surprisingly, drug manufacturers enjoy the stability and reliability offered by government purchasing but do not appreciate the strict governmental controls placed on them by the PBS. Drug companies have three major criticisms. First, they argue that because the PBS uses very strict cost-efficacy data to determine drug availability and pricing, it unfairly restrains trade by limiting companies' freedom to charge whatever the market will pay.<sup>15</sup> Second, drug companies complain that the PBS does not allow them to recoup their immense investments in research and development (R&D), and hence that Australians are freeloading on patients in countries with higher drug prices, such as the United States.<sup>16</sup> Third, they call for consumers, including socially disadvantaged ones, to

http://www.mga.usyd.edu.au/radius/Radius\_Vol%2016%20no%201.pdf.

16. Id.

<sup>12.</sup> See, e.g., PUB. HEALTH ASS'N OF AUSTL., PHARMACEUTICAL BENEFITS SCHEME (PBS) AND THE AUSTRALIA:UNITED STATES OF AMERICA FREE TRADE AGREEMENT (FTA) POLICY, 2003 (adopted 2003), available at http://www.phaa.net.au/policy/freetrade.htm; AUSTRALIAN FAIR TRADE & INVESTMENT NETWORK (AFTINET), TRADING AUSTRALIA AWAY? (2003), http://www.aftinet.org.au/campaigns/USFTALeaflet.May03.pdf; Peter Sainsbury, A Bitter Pill, 16 RADIUS 5 (2003), available at

<sup>13.</sup> LOKUGE & DENNISS, supra note 8.

<sup>14.</sup> PRODUCTIVITY COMM'N, INTERNATIONAL PHARMACEUTICAL PRICE DIFFERENCES (2001); NATIONAL CENTRE FOR EPIDEMIOLOGY AND POPULATION HEALTH, THE EFFECTS OF THE GENERAL AGREEMENT ON TRADE IN SERVICES ON AUSTRALIAN POPULATION HEALTH: SUBMISSION TO THE SENATE INQUIRY INTO THE GENERAL AGREEMENT ON TRADE IN SERVICES (GATS) (2003), http://nceph.anu.edu.au/Publications/pdfs/Senate\_GATS\_inquiry\_submission.pdf.

<sup>15.</sup> MEDICINES AUSTRALIA, A PRESCRIPTION FOR THE FUTURE HEALTH OF AUSTRALIA: SUBMISSION TO THE INTER-DEPARTMENTAL COMMITTEE PREPARING A REPORT ON THE EFFECTIVENESS OF THE PBS (2002).

assume greater responsibility for the costs of medications.<sup>17</sup>

Essentially, drug companies desire greater freedom to sell their products in Australia at whatever price the market will support, preferably while maintaining a government program that guarantees both a market for their drugs and a combination of reliable payers. Perhaps more significantly, drug companies, who are mostly multinational conglomerates with large financial interests in the United States, have a strong interest in political developments there. Efforts to undermine the PBS can also be seen as an attempt to discourage U.S. legislation allowing the Centers for Medicare and Medicaid Services to implement a similar program, with negotiation of large price discounts domestically on behalf of the Centers' forty million beneficiaries.<sup>18</sup> As a result of these dual motivations, drug companies lobbied the Australian government and threatened legal action to undermine the PBS before the FTA negotiations began.<sup>19</sup>

It is worth noting that it is bigger profits—not survival—that the drug companies are fighting for. In the United States the pharmaceutical industry has provided the highest return on investment, among industries, every year for the last ten years<sup>20</sup> and drug companies feature prominently among the largest and the most profitable companies worldwide.<sup>21</sup> Regarding drug companies' R&D costs, both their marketing and advertising expenses (approximately twenty-seven percent of revenue for the nine major U.S. drug companies) and their profits (approximately eighteen percent) exceed what they pay in R&D (approximately eleven percent).<sup>22</sup>

#### NEGOTIATING THE AUSTRALIA-UNITED STATES FREE TRADE AGREEMENT

The free trade agreement between Australia and the United States was finalized in February 2004 following a year of negotiations. Early in 2003 public health observers in Australia, already made wary by discussions about multilateral trade agreements, were alerted by media reports to the

20. See id.

<sup>17.</sup> Id.

<sup>18.</sup> Sheryl Gay Stolberg & Gardiner Harris, *Industry Fights To Put Imprint on Drug Bill*, N.Y. TIMES, Sept. 5, 2003, at A2 (reprinted as *Donate or Else, Drug Companies Told Staff* in the SYDNEY MORNING HERALD, Sept. 9, 2003, *available at* 

http://www.smh.com.au/articles/2003/09/05/1062549020461.html?from=storyrhs).

<sup>19.</sup> LOKUGE & DENNISS, supra note 8.

<sup>21.</sup> Donald L. Barlett & James B. Steele, Why We Pay so Much for Drugs, TIME, Feb. 2, 2004, at 44.

<sup>22.</sup> LOKUGE & DENNISS, supra note 8.

possible inclusion of the PBS in the Australia-United States bilateral FTA. Several elements of these reports provoked concern. First, the U.S. drug industry testified during U.S. public hearings into the FTA about the allegedly low prices paid for new drugs in Australia and identified the PBS as a target for inclusion in the FTA.<sup>23</sup> Second, U.S. negotiators pushed for greater transparency in the evaluation of drugs for inclusion in the PBS; an appeals mechanism for denied applications; and changes to the pricing mechanisms of the PBS (including changes to the reference pricing system and adjustments for inflation).<sup>24</sup> Third, the U.S. drug companies' trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), budgeted at least USD\$150 million per year to lobby U.S. and foreign governments to fight price controls and protect patents.<sup>25</sup>

These revelations prompted opposition political parties and those concerned about public health in Australia to question the government about the inclusion of the PBS in the FTA negotiations.<sup>26</sup> The responses from the Australian government were evasive, failing to confirm or deny whether the PBS would be discussed as part of the negotiations.<sup>27</sup>

It is of particular interest that opposition to inclusion of the PBS in the FTA did not come solely from the Australian side. Several U.S. politicians were unhappy about the attempt by the United States to influence the PBS, and seven wrote to President Bush in October 2003 praising the PBS and urging the President to "indicate to the Australians that the U.S. has no

26. John Garnaut, No Free Trade Without Open Markets: Vaile to US, SYDNEY MORNING HERALD, Mar. 4, 2003, at 4; Matt Wade & John Garnaut, Drug Price Fears Over Trade Deal, SYDNEY MORNING HERALD, Mar. 18, 2003, at 5; Press Release, Craig Emerson & Stephen Smith, Keep PBS Out of US FTA Negotiations (Mar. 19, 2003),

http://craigemersonmp.com/mediatm?id=410&sv=offset=14&0=.

27. Many media outlets documented the government's conflicting statements on this issue. *See, e.g.*, Garnaut, *supra* note 26; Emerson & Smith, *supra* note 26; Press Release, The Austl. Inst., Vaile Attempts To Cover Up US FTA Intentions (May 19, 2003),

http://www.tai.org.au/MediaReleases\_Files/MediaReleases/PRFTAand%20Vaile.pdf; Media Briefing, Stephen Deady & Ralph Ives, Up US FTA Intentions Austl. Dep't of Foreign Affairs & Trade, The First Round (17-21 March) of Free Trade Agreement Negotiations Between Autralia and the United States (Mar. 21, 2003),

http://www.dfat.gov.au/media/transcripts/2003/030321\_fta\_brief.html.

<sup>23.</sup> Tom Allard, US Drug Companies Cry Poor over PBS, SYDNEY MORNING HERALD, Jan. 17, 2003, at 4.

<sup>24.</sup> Morgan Mellish, US Drug Firms Push for Changes to PBS, AUSTRALIAN FIN. REV., Mar. 3, 2003, at 3.

<sup>25.</sup> Robert Pear, Drug Companies Increase Spending on Efforts to Lobby Congress and Governments, N.Y. TIMES, June 1, 2003, at 33.

interest in negotiating any changes to the Australian Pharmaceutical Benefits Scheme that would hamper its ability to conduct and review comparative effectiveness and cost effectiveness studies on pharmaceuticals."<sup>28</sup>

In January 2004, nine senior Democrats in the House of Representatives wrote to President Bush with similar concerns.<sup>29</sup> Anxious to protect the U.S. Veterans Administration, Indian Health Service and Department of Defense drug purchasing arrangements, the Democrats also sought reassurance that the FTA would not change the pricing structure of U.S. government procurement programs for drugs.<sup>30</sup>

As the debate in Australia continued throughout 2003 and January 2004, non-government public health sources provided careful analyses of the possible health effects of the inclusion of the PBS in the FTA;<sup>\$1</sup> made submissions to government entities;<sup>\$2</sup> issued press releases; worked with others to focus political, media and public attention on the FTA negotiations;<sup>\$3</sup> and maintained an active network of concerned individuals and organizations. I personally spoke at several public meetings, some organized by concerned citizens' groups, gave many media interviews and wrote several short articles for newspapers and small-scale publications.<sup>44</sup> With relatively limited resources available, and an uncooperative (and evasive) government, it is difficult to see what else public health workers could have done during this period to protect the PBS.

28. Leigh Sales, *PBS a Stumbling Block in US-Aust Free Trade Talks* (ABC radio broadcast, Jan. 14, 2004), *available at* http://www.abc.net.au/am/content/2004/s1025409.htm; Press Release, Rep.Tom Allen, Statement on Completion of the U.S.-Australia Free Trade Agreement (Feb. 10, 2004), http://tomallen.house.gov/printer.asp?contentID=1224.

29. US Dems Express FTA Drug Fears, SYDNEY MORNING HERALD, Jan. 19, 2004, available at http://www.smh.com.au/articles/2004/01/19/1074360692066.html.

30. Letter from Nancy Pelosi et al., to George W. Bush (Jan. 2004) (on file with author).

31. See, e.g., Lokuge & Denniss, supra note 8; Buddhima Lokuge et al., A Backdoor to Higher Medicine Prices? Intellectual Property and the Australia-US Free Trade Agreement (Nov. 2003), available at

http://www.tai.org.au/WhatsNew\_Files/WhatsNew/Patents.pdf.

32. TRACY SCHRADER, DOCTORS' REFORM SOCIETY, HEALTH IMPLICATIONS OF THE PROPOSED FREE TRADE AGREEMENT BETWEEN AUSTRALIA AND THE UNITED STATES (Jan. 2003), *available at* http://www.drs.org.au/new\_doctor/78/Schrader\_FTA\_78.htm.

33. AUSTRALIAN FAIR TRADE & INVESTMENT NETWORK, supra note 12.

34. Sainsbury, supra note 12; Peter Sainsbury, To Prevent Medicare Hit, Senators Must Not Fall for the Myths, SYDNEY MORNING HERALD, Jul. 23, 2003, at 17; Peter Sainsbury, The Crisis in Health(care), HOSPITAL&HEALTHCARE, May 2003, at 10.

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### SPINNING THE AUSTRALIA-UNITED STATES FREE TRADE AGREEMENT

The FTA was finalized on February 8, 2004, although the full text was not made available until March 4, 2004. In the meantime, both governments placed summaries of the agreement on the websites of their respective trade departments. Not surprisingly, each government sought to put a positive spin on the agreement for their own interest groups and emphasized the concessions they had won and the places where they had stood firm. Comparing what each said about the PBS is interesting. The U.S. government highlighted:<sup>35</sup>

- The shared recognition of the importance of innovative pharmaceuticals in health care, R&D in the pharmaceutical industry and the protection of intellectual property; the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures; and the need to recognize the importance of innovative pharmaceuticals through procedures that objectively value their demonstrated therapeutic significance;
- The improved transparency and accountability in the PBS that will flow from the establishment of an independent process to review determinations of product listings;
- The establishment of a joint Medicines Working Group to promote discussions on emerging health care policy issues;
- The quicker availability of innovative medical products that will arise from collaboration between the U.S. Food and Drug Administration and the Australian Therapeutic Goods Administration;
- The stronger protections for patents and trade secrets that will arise from, for instance, the extension of patent terms to compensate for delays in granting patents and the provision of notice to the patent holder when the validity of a drug patent is to be challenged.

The Australian government meanwhile emphasized:<sup>36</sup>

<sup>35.</sup> Press Release, Office of the U.S. Trade Representative, U.S. and Australia Complete Free Trade Agreement (Feb. 8, 2004),

http://www.ustr.gov/Document\_Library/Press\_Releases/2004/February/U.S.\_Australia\_C omplete\_Free\_Trade\_Agreement.html.

<sup>36.</sup> MARK VAILE, FREE TRADE AGREEMENT WITH THE UNITED STATES (Feb. 8, 2004), http://www.dfat.gov.au/trade/negotiations/us.html.

- Maintaining accessibility to affordable medicines under the PBS and the fulfillment of the government's promise that the price of drugs will not increase as a result of the FTA;
- Improving public understanding of the PBS system and faster access to subsidies for new drugs that will arise from improvements to the transparency and timeliness of PBS processes;
- Increasing opportunities for companies seeking listing of new drugs to have input to the process;
- Reinforcing Australia's existing intellectual property protection framework for drugs, and the benefits that will arise from aligning Australia's intellectual property regime with that of the world's largest intellectual property market.

No one will be surprised that each government promoted aspects and interpretations of the agreement that mollified the groups that each was seeking to please. Nor is it surprising that the two governments publicly presented their own interpretations of the FTA for a month before the actual wording of the agreement was released. The delay and the spin were frustrating for public health advocates, but the ready availability of this information on government websites permitted revealing comparisons to be made and facilitated more rapid critical appraisal of the full text when it became available.

# WHAT THE FTA ACTUALLY MEANS FOR THE PBS

The full text of the FTA<sup>37</sup> was released on March 4, 2004, but it added little detail to what had already been made public. Given the conflicting accounts of the FTA presented by Australia and the United States, and the differing interpretations of the sections covering the PBS, it is clear is that the Australian government is trying to pull the wool over someone's eyes. But, is it the U.S. negotiating team and the pharmaceutical industry, or is it the Australian public? Has the Australian negotiating team managed to conjure up forms of words and agree to bureaucratic changes that will make no substantive difference to the PBS (in some cases because the arrangements already exist) and thus provide no real gains for drug companies? Or are the changes to the mechanisms of the PBS ultimately going to increase drug prices for sick Australians? Will this make it difficult for poorer Australians to afford the medications they need? Will equity in

<sup>37.</sup> OFFICE OF THE U.S. TRADE REPRESENTATIVE, UNITED STATES-AUSTRALIA FREE TRADE AGREEMENT (Mar. 1, 2004), http://www.ustr.gov/new/fta/Australia/text/index.htm.

Australia's health care system be reduced?

Immediately after March 4, support for all these views could be found in the Australian media. Government spokespeople provided reassurances that nothing in the FTA would threaten the structure of the PBS or lead to increased drug prices;<sup>38</sup> political commentators and public health workers predicted dire consequences for the price of drugs in Australia;<sup>39</sup> and drug company representatives expressed delight with the FTA and its implications for prices, profits and investment.<sup>40</sup>

## THE FTA AND THE DEMOCRATIC PROCESS

Ironically, throughout much of the negotiation process, Australian observers were able to obtain more information from American than Australian sources,<sup>41</sup> and in general the U.S. side of the negotiations was more open to public scrutiny. Indeed, it was easy to form the impression in Australia that the government would have been happier if people had found the proposed FTA and the negotiation process too difficult and complex to comprehend and had simply left it to the government to sort out. Additionally, there is no requirement in Australia for the whole FTA to be placed before the Australian parliament for debate and ratification, although some of the specific tariff barrier changes do need parliamentary approval.

During 2003 and early 2004, the efforts of individuals and groups who were concerned about possible harmful effects of the FTA in Australia did, however, ensure that the Australian government was aware that the wording of the agreement would be closely scrutinized. Also, in January 2004 the federal opposition announced that it would refer the FTA, once finalized, to a Senate Select Committee for a public inquiry and "thorough examination."<sup>42</sup> In an unsuccessful attempt to forestall this parliamentary delaying tactic, which ran the risk of producing much adverse publicity

40. Allen, supra note 39; Davis, supra note 36.

41. American sources that were both informative and readily available to the Australian public included newspapers, the PhRMA website, U.S. negotiators' media conferences, and U.S. government hearings. *See, e.g.*, Barlett & Steele, supra note 21.

42. Press Release, Mark Latham & Stephen Conroy, Labor To Refer Australia-US FTA to Senate Committee (Jan. 27, 2004) (on file with author).

<sup>38.</sup> Mark Metherill et al., Drug Scheme at the Forefront of Trade Scrutiny, SYDNEY MORNING HERALD, Mar. 5, 2004, at 6; Mark Davis, PBS Appeals, Cosmetic or Not?, AUSTRALIAN FIN. REV., Mar. 5, 2004, at 6.

<sup>39.</sup> Alan Ramsey, *Howard's Labours Are Slipping Away*, SYDNEY MORNING HERALD, Mar. 6, 2004, at 37; Lisa Allen, *Drugs Appeal To Be Burden*, AUSTRALIAN FIN. REV., Mar. 5, 2004, at 7.
about the FTA, in March 2004 Minister Vaile referred the agreement to the government-controlled Joint Standing Committee on Treaties for a public inquiry and report to Parliament.<sup>43</sup> Thus, at the time of publication, Australia has two parliamentary inquiries into the FTA and I do not think many people will be surprised if they reach markedly different conclusions. The democratic process and the FTA (not to mention the public purse) might all have benefited more from just one public enquiry twelve to eighteen months earlier.

One might ask why the Australian government, which itself considers the PBS to be one of the best systems of its kind in the world,<sup>44</sup> was so willing to allow the scheme to be placed on the negotiating table. One can only speculate, but the current Australian (conservative) government has consistently promoted increased private provision of and increased user payments for health services, rolling back the public sector and decreasing government intervention in industry generally. Those of a Machiavellian disposition might conclude that the government is hoping PBS costs will blow out to such an extent that they can argue that the PBS is no longer financially sustainable and that the only responsible response is to restrict access to it and turn it from a universal program to a welfare based safety net for the poor. Alternatively, or perhaps additionally, the government may have initially hoped that if it made some major concessions on the PBS it would be able to negotiate a better deal on agricultural exports to the United States. Or perhaps the government hoped that a less evidencebased PBS decision-making process would lead to higher drug prices and higher drug company profits and that this would tempt drug companies to increase their investment and production capacity in Australia.

It is also worth noting that several senior advisers to the current Australian government have moved on to senior positions in drug companies.<sup>45</sup> These links between the government and the industry, and the consequent conflicts of interest, were not made public by either of these groups and are an example of how poor transparency in government processes can create, perhaps unjustified, suspicions about the underlying motivations for government policies.

In yet another twist, despite the FTA as a whole not needing

<sup>43.</sup> Press Release, Andrew Southcott, Public Inquiry into the Australia-US Free Trade Agreement (Mar. 10, 2004) (on file with author).

<sup>44.</sup> Austl. Dep't of Health and Ageing, supra note 3.

<sup>45.</sup> Press Release, Pub. Health Ass'n of Austl., Howard Government Plays Mean and Tricky on the PBS in the Australia/US Free Trade Agreement (Mar. 4, 2004), *available at* http://www.phaa.net.au/Advocacy\_Issues/howardgovfta.htm.

parliamentary approval, it is possible that the opposition parties in the Senate will reject the specific tariff barrier changes that do need parliamentary approval and that these relatively few issues will scupper the whole agreement.

#### LESSONS FOR PUBLIC HEALTH

It is regrettable that in a supposedly democratic nation negotiations which have the potential to (1) increase the price of medications for Australia as a whole and for individual patients, (2) limit the access of many poorer people to essential medications, and (3) damage public health and the broader social infrastructure, have been conducted with such a lack of transparency and public and parliamentary debate.<sup>46</sup> Governments would, in my opinion, do well to remember that universal suffrage and the opportunity to participate in regular secret ballots are not the only hallmarks of a democratic society. The manner in which even legitimately elected governments conduct the business of government between elections is also an important aspect of democracy. Public health workers have a significant and legitimate part to play in promoting this wider concept of democracy. To do so, however, will require an expansion of public health's traditional role.

With reference to the FTA, this expansion has principally involved:

- Continually monitoring, comparing, analyzing and questioning the information available in, for instance, the media, websites, government publications, press statements and reports of parliamentary proceedings and committees about the content and progress of negotiations;
- Researching and reporting the possible effects on public health of the issues being negotiated. Valid empirical evidence is invaluable in ensuring that politicians, the media and the public are aware of, and care about, the likely health impacts of trade agreements;
- Working with others, inside and outside the health sector, to lobby politicians, mobilize public opinion and keep the matter in the public arena, often over extended periods. For instance, during the FTA negotiations Australian public health workers joined with actors, environmentalists, trades unions and

<sup>46.</sup> Press Release, Pub. Health Ass'n of Austl., Howard Should Come Clean on the Pharmaceutical Benefits Scheme (Dec. 3, 2003), available at

http://www.phaa.net.au/Advocacy\_Issues/howardpharmaceutical.htm.

welfare groups, all of who were concerned about the effects of the FTA on their interests, to prepare analyses, organize public meetings and issue press releases;

• Ensuring that politicians knew that the negotiations were being closely monitored, and that the outcomes would produce benefits and harms, winners and losers, and possibly electoral consequences.

It may be years before the effects of the FTA on the PBS and the Australian drug industry become clear, as indeed it may be years before any conclusions can be reached about whether the FTA has been beneficial for Australia overall. It is also unclear whether the efforts of consumer groups, public health activists, health professionals, opposition political parties, trades unions and public interest groups throughout 2003 to keep the PBS in the spotlight and try to prevent the government trading away the PBS had any effect. And it remains uncertain whether, as a tactic to make the deal unacceptable to the United States, the opposition parties in the Senate will reject those aspects of the FTA that need parliamentary approval.

Three things are clear, however. First, that the drug industry in the United States and Australia saw the FTA as an opportunity to undermine the evidence-based, strict and effective procedures underpinning the PBS. Second, that national and international democratic processes are intimately connected to public health. Third, that public health workers cannot limit their attention to epidemiological method, social theory and academic publication. Those who are concerned about public health (the health of the public, I mean here, not the discipline of study) must also maintain a vigilant eye on the whole of society, glean information from all sorts of sources, cherish values as much as evidence, develop a keen understanding of international affairs, become skilled observers of bureaucratic processes, be prepared to involve themselves in political lobbying and develop methods to monitor the effects of instruments of government such as the FTA. And whatever the gross effects of any policy or action, public health workers must always ask, "Who are the winners, and who are the losers?"

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## Trade Agreements, Intellectual Property, and the Role of the World Bank in Improving Access to Medicines in Developing Countries

Juan Rovira, Ph.D.\*

#### INTRODUCTION

The price of medicines is one of the main barriers to treatment access for many poor people in developing countries due to their low purchasing power and the limited availability of public or private insurance in poor countries. It has been estimated that between fifty percent and ninety percent of pharmaceutical expenditures in developing countries are paid for out-of-pocket.<sup>1</sup> In developed countries, on the other hand, over seventy percent of such expenditures are funded through insurance or other reimbursement schemes.<sup>2</sup>

Patents and other mechanisms of market exclusivity facilitate the acutely problematic pricing of new drugs: Intellectual property rights (IPR) and regulatory protections grant a temporary monopoly to a right-holder, thereby allowing prices to be set well above marginal and direct manufacturing costs.<sup>3</sup> Although the majority of essential drugs—as defined by the World Health Organization's essential drug list<sup>4</sup>—are off-patent,

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<sup>1.</sup> Jonathan Quick et al., Twenty-five Years of Essential Medicines, 80 BULL. WORLD HEALTH ORG. 913, 914 (2002), available at

http://www.who.int/medicines/organization/par/cd\_25th\_anniversary/whobull.pdf. 2. *Id.* 

<sup>3.</sup> This correspondingly encourages private investment in pharmaceutical research and development (R&D).

<sup>4.</sup> WORLD HEALTH ORG., 13TH WHO MODEL LIST OF ESSENTIAL MEDICINES (2003), *available at* http://mednet3.who.int/eml (last visited Apr. 29, 2004).

there are some important and even life-saving drugs (such as those for HIV/AIDS and cancer) and vaccines that are patent-protected.

In recent years, research intensive industries and the developed countries in which they are located have made a strong push for international IPR harmonization. Harmonization of IPR amounts to pressures for developing countries to raise their IPR protection to developed-country levels. This trend has taken place in the last decade in the multilateral context of the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. In recent years, developed countries have also pushed to increase patent protection beyond the levels required by TRIPS—known as "TRIPS-plus" provisions—when negotiating bilateral free trade agreements (FTAs).<sup>5</sup>

This Case Study offers an insider's analysis of the role played by the World Bank in affecting the affordability and accessibility of drugs in developing countries in the current IPR environment. After exploring the relationship between current trade agreements, international IPR, and access to medicines, the Case Study describes the lending activities of the Bank in the pharmaceutical area and argues that the type and amount of funding that developing countries obtain from the Bank is unlikely to significantly address problems of inadequate financing for pharmaceutical purchases. However, the conditions set by the Bank for countries to procure pharmaceuticals using the Bank's funds might have positive effects on competition that could extend beyond Bank-funded purchases and increase, in the long run, the efficiency of pharmaceutical expenditures.<sup>6</sup>

This Case Study analyzes the position recently adopted by the Bank regarding IPR and the procurement of AIDS pharmaceuticals and other medical goods; the Bank seeks to encourage countries to use the flexibilities within the TRIPS Agreement and in their own legislation to

<sup>5.</sup> See, e.g., DAVID VIVAS-EUGUI, QUAKER UNITED NATIONS OFFICE, REGIONAL AND BILATERAL AGREEMENTS AND A TRIPS-PLUS WORLD: THE FREE TRADE AREA OF THE AMERICAS (2003), available at

http://www.geneva.quno.info/pdf/FTAA%20(A4).pdf?PHPSESSID=47e04ef374bf9b6ceecf e7d421a6d28c.

<sup>6.</sup> Note, however, that while the problems posed by high drug prices can often be mediated by pro-competitive interventions, this approach may not suffice to make drugs affordable to the poorest populations under all circumstances. *See, e.g.*, MOHGA K. SMITH, GENERIC COMPETITION, PRICE AND ACCESS TO MEDICINES: THE CASE OF ANTIRETROVIRALS IN UGANDA 6 (Oxfam Briefing Paper No. 26, July 10, 2002), *available at* 

http://www.oxfam.org/eng/pdfs/pp020710\_no26\_generic\_competition\_briefing\_paper.p df.

obtain the best available prices for products of guaranteed quality.

## I. ACCESS TO MEDICINES: TRIPS AND BEYOND

Many proponents of free trade agreements have claimed that the liberalization of trade improves the well-being of the participating countries by removing trade barriers, enlarging potential markets and, ultimately, allowing countries to increase their exports of goods for which they have a comparative advantage. Under this argument, both developed and developing countries benefit from increased trade.<sup>7</sup> Throughout the 1990s, intellectual property provisions were progressively included in trade agreements under this logic. The supporters of strong property rights claimed that strong IPR would not only benefit developed countries and the innovative pharmaceutical industry, which is highly concentrated in a handful of developed countries, but would also have a favorable impact on developing countries. Strong IPR, it was argued, makes new products quickly available, generates foreign investment in developing countries, and provides incentives for R&D into new therapies.<sup>8</sup>

Negotiated during the 1986-1994 Uruguay Round of the WTO and signed in 1994, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has been the primary focus of attention in the debate over IPR and access to medicines. However, IPR issues are also relevant to other multilateral and bilateral trade agreements. Overall, TRIPS and the IPR provisions of FTAs have received tremendous support from developed countries as a result of pressure from their industries, but have received mixed responses from developing country ministers.<sup>9</sup>

The debate over the effects of IPR in general and on pharmaceuticals in particular is far from closed. But there is certainly much concern among developing countries and activists about the negative effects that IPR might have on prices and, correspondingly, the affordability and accessibility of drugs.<sup>10</sup> While the World Bank has expressed its concerns about the effects

<sup>7.</sup> See, e.g., Robert B. Zoellick, Trade Helps Africans Help Themselves, WALL ST. J., May 23, 2001, at A26.

<sup>8.</sup> See, e.g., Roger Bate, The Worst Pandemic Looks To Get Worse, TECH. CENTRAL STATION, Feb. 20, 2004, at http://www.aei.org/news/newsID.1994,filter./news\_detail.asp.

<sup>9.</sup> See Peter Drahos & Ruth Mayne, Global Intellectual Property Rights: Knowledge, Access and Development (2002).

<sup>10.</sup> See, e.g., Access to Essential Medicines Campaign, Testimony of Doctors Without Borders/Médecins Sans Frontierès (MSF) at the Public Hearing Concerning Market

of IPRs on medicine pricing, there is little literature from the Bank on FTAs and practically no comment on the effects of IPR clauses included in FTAs.<sup>11</sup>

A potential balance between the demands of industry in the developed world and the interests of developing countries seemed to arrive with the 2001 signing of the *Doha Declaration on TRIPS and Public Health*, which has been discussed extensively elsewhere.<sup>12</sup> The *Declaration* was unanimously signed by WTO delegates and stated "that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."<sup>13</sup> But some developed countries, especially the United States, seemed to consider the *Doha Declaration* an unsatisfactory solution for their own interests; as a result, they have attempted to move the cause of strong IPR to other fora, such as bilateral and regional FTAs.<sup>14</sup> Advocates for developing countries state that developing country trade ministers should refrain from signing trade agreements with "TRIPS-plus" provisions.<sup>15</sup>

One could argue that developing countries are not obliged to sign trade agreements unless they expect the benefits to outweigh the corresponding costs. But the impact of any given trade agreement is far from predictable. Whatever the specific outcomes, benefits are also likely to accrue for relatively wealthy population groups, while costs such as those associated with a lower accessibility to drugs are likely to affect the most vulnerable population groups.<sup>16</sup>

An estimation of the cost of various clauses of an FTA is not an easy task. Estimating the static effects alone requires a large amount of

11. See Mamphela Ramphele & Nicholas Stern, Generic Drugs Can Make the Money Last, N.Y. TIMES, Mar. 1, 2003, at A19.

12. See, e.g., Fred M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO, 5 J. INT'L ECON. L. 469, 469-505 (2002).

13. World Trade Org., Doha WTO Ministerial 2001, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at

http://www.wto.org/english/thewto\_e/minist\_e/min01\_e/mindecl\_trips\_e.htm.

14. See generally ACCESS TO ESSENTIAL MEDICINES CAMPAIGN, DOHA DERAILED: A PROGRESS REPORT ON TRIPS AND ACCESS TO MEDICINES 4 (2003), available at http://www.accessmed-msf.org/documents/cancunbriefing.pdf.

15. See, e.g., JENNIFER BRANT, ROBBING THE POOR TO PAY THE RICH? HOW THE UNITED STATES KEEPS MEDICINES FROM THE WORLD'S POOREST 31 (Oxfam Briefing Paper No. 56, Nov. 2003), available at http://www.oxfam.org/eng/pdfs/pp031201\_robbing\_medicines\_US.pdf.

16. See JIM KIM ET AL., DYING FOR GROWTH: GLOBAL INEQUALITY AND THE HEALTH OF THE POOR (2000).

ACCESS IN THE FREE TRADE AREA OF THE AMERICAS NEGOTIATIONS OF THE OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (Sept. 9, 2002).

information concerning demand elasticities, defining a counterfactual, and making risky assumptions on the evolution of the market conditions. Moreover, it is far from clear that welfare economics provides the appropriate tools for assessing the social cost and benefits of patent protection and the resulting variations in drug prices and consumption. For instance, the consumer surplus, a conventional measure of benefit in welfare economics, might not be an acceptable measure of the value of a lifesaving drug for an indigent person. It is probably safe to conclude that it would be quite difficult to agree on any scientific or objective procedure that allows us to measure the effects of an IPR regime in a conclusive way.

While it is clear that it will be difficult for developing countries to estimate the costs to their domestic welfare, developed countries must confront an ethical issue: To what extent should a developed country take advantage of the economic and political needs and weaknesses of developing countries in order to obtain some trade advantages likely to result in reduced survival and increased distress for poor countries populations? Even assuming a purely selfish approach, one might wonder whether the intangible negative effects of signing such agreements—such as anger and resentment toward developed countries—will ultimately outweigh the economic advantages attained.

A more probing question concerns the long-term evolution of access to drugs and pharmaceutical innovation-whether the present system of pharmaceutical R&D and innovation is an acceptable and efficient one, satisfying the needs and demands of both developed and developing countries. The system is currently based on patents and other exclusive marketing rights as the key incentive for private investment in drug development. Private firms are expected to make an investment that they expect later to recover in the form of extraordinary, monopoly profits. The possible negative effects of such a system are significant: reduced accessibility to the drugs among poor countries and population groups, obstacles to research by other parties in areas protected by patents, and the like. The key problem probably derives from the fact that the patent system leads R&D toward profitable diseases and conditions, rather than toward diseases that cause the most morbidity and mortality.<sup>17</sup> This explains the obstacles to creating drugs for neglected diseases, as well as the (probably excessive) research on highly-profitable "me-too" drugs that make a small

<sup>17.</sup> Press Release, Drugs for Neglected Diseases Initiative: Teaming Up To Address Neglect (Mar. 12, 2003), http://www.accessmed-

msf.org/prod/publications.asp?scntid=12320031354463&contenttype=PARA&.

or negligible contribution to therapeutic innovation.<sup>18</sup>

The options proposed as alternatives to the patent system are manifold. They are mostly based on the separation of R&D and the innovation market from drug manufacturing processes.<sup>19</sup> The funding of drug development in this manner would require public funding and private donations. Taking into account the global public good that most therapeutic innovation promotes, the issue should probably be addressed at a multilateral level, perhaps through an international treaty establishing how member countries should pay for the R&D and then have access to the innovation.

Under this hypothetical scheme, once the priorities for R&D are established by the members of the treaty, the funding should be allocated in some competitive way among potential research organizations. The funding could take the form of grants, allocated before the R&D activity is carried out, or prizes awarded to the innovations *a posteriori*. Under any scenario, the manufacturing sector would work under generic competition. Any manufacturer would be allowed to produce the final products free of any charge or for a fixed compensation.<sup>20</sup>

Such a scheme might sound utopian, and it would indeed be unwise to assume that the present patent system could be radically changed in the near future. The likely opposition of the research industry to such changes and the difficulties in raising the funds for an alternative system are formidable. But various proposals might well be tested as pilot experiences for specific drugs. Essential drugs for neglected diseases seem a clear category to start with: They are not adequately researched, anyway; therefore, a failed experience would not have a negative impact on drug availability.

## II. THE WORLD BANK'S FINANCING OF MEDICINE PURCHASES

Within the context established in the previous Part, this Case Study

<sup>18.</sup> See ROBERT YOUNG & MICHAEL SURRUSCO, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" 13 (2001), available at

http://www.citizen.org/congress/campaign/special\_interest/articles.cfm?ID=6538. 19. See JAMES LOVE, FROM TRIPS TO RIPS: A BETTER TRADE FRAMEWORK TO SUPPORT

<sup>INNOVATION IN MEDICAL TECHNOLOGIES (May 2003) (unpublished manuscript),</sup> http://www.cptech.org/slides/trips2rips.doc (last visited Apr. 29, 2004); see also JEAN
LANJOUW, A PATENT POLICY PROPOSAL FOR GLOBAL DISEASES (Brookings Policy Brief No. 84, June 2001), available at http://www.brookings.edu/views/papers/lanjouw/20010611.pdf. 20. Id.

aims to demonstrate the World Bank's effect on various factors relating IPRs to medicine access. The World Bank has been lending funds for the purchase of medicines through its Health, Nutrition and Population (HNP) sector since the late 1970s. The World Bank's first project to include pharmaceutical financing was called the Peru Health project and was granted in 1983. Between 1983 and 1999, 116 Bank projects incorporated a pharmaceutical component.<sup>21</sup> Four types of pharmaceutical purchases were provided with funding: (1) those for HNP projects that financed drug procurement for specific diseases; (2) those for pharmaceutical stand-alone projects; (3) those employing pharmaceutical components as part of broader health reform projects; and (4) those linked to non-health-specific activities such as structural adjustment, critical investment, and private sector investment loans. The conclusion of a study on these lending practices indicated that a major portion of the World Bank pharmaceutical planned lending (eighty-two percent) was directed toward pharmaceutical procurement.<sup>22</sup> The remaining eighteen percent of Bank-planned lending in pharmaceutical projects included financing civil works and equipment, training of professionals, and technical assistance.

The World Bank has historically been reluctant to finance recurring expenditures.<sup>23</sup> This position has been expressed most clearly in the case of pharmaceutical lending, as the Bank has restricted the financing of pharmaceutical procurement to the following situations: (1) as a method to control specific diseases; (2) as an integral part of a national drug policy; or (3) as part of a cost recovery or other drug financing program.<sup>24</sup> The apparent contradiction between the Bank position and the results found in the above-mentioned study might be explained by the insufficiency of health care budgets, the demanding requirements of all-too-frequent humanitarian emergencies, and the preference of borrowers to spend money on tangible goods rather than in hiring consultants to provide policy advice.

A more recent study found that the total amount of procurement for pharmaceuticals and medical products (PMP) from fiscal years 1999 to

<sup>21.</sup> EDUARDO SABATE ET. AL., FINANCIAL AND POLICY AUDIT OF THE WORLD BANK'S PHARMACEUTICALS LENDING: BACKGROUND STUDY FOR WORLD BANK PHARMACEUTICALS DISCUSSION PAPER 1 (World Bank Human Development Network, Sept. 2000).

<sup>22.</sup> RAMESH GOVINDARAJ ET. AL., WORLD BANK PHARMACEUTICALS PAPER 6 (2000).

<sup>23.</sup> See Denis Broun, Procurement of Pharmaceuticals in World Bank Projects 4

<sup>(</sup>HRO Working Papers Report No. 13525, 1994).

<sup>24.</sup> Id at 4-10.

2002 under Bank loans was \$401 million (approximately \$133 million per year, on average).<sup>25</sup> According to rough estimates, pharmaceutical sales for Latin America, Asia and Pacific, Middle East, and Africa amounted to thirty-nine billion dollars in 2001.<sup>26</sup> The relative magnitude of the purchases funded from Bank loans (0.3%) is unlikely to have a substantial impact on the performance of the markets. Furthermore, if non-pharmaceutical PMP could be excluded from the computed figures, the share of pharmaceuticals might come down substantially.

For the Bank as a whole, procurement of PMP amounts to 4.3% of the procurement of all goods and to 1.4% of all procurement categories. Restricting our analysis to the HNP sector, the share of PMP procurement of all procurement categories rises to 17.7%.<sup>27</sup>

#### The Effects of World Bank Lending on Competition in Pharmaceutical Markets

The World Bank is not directly involved in the production, procurement or purchasing of pharmaceuticals, nor does it have any regulatory capacity. It can nevertheless influence market behavior and pricing in an indirect way. The Bank requires national procurement agencies to apply competitive procurement procedures, such as international competitive bidding (ICB), when using loan proceeds.<sup>28</sup> The Bank thus promotes a process—akin to generic competition—that should lead to lower, more competitive prices.<sup>29</sup> While this approach is powerless

27. RODRIGUEZ-MONGUIO & ROVIRA, *supra* note 25, at 13. Note that sixty-six percent of the total procurement of PMP corresponds to the South Asian region. *Id.* 

28. See infra Annex 1; THE WORLD BANK, HIV/AIDS MEDICINES AND RELATED SUPPLIES: CONTEMPORARY CONTEXT AND PROCUREMENT (2004), available at http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-Procure-HIV-AIDS-Meds.pdf.

29. See Patricia M. Danzon & Michael F. Furukava, Prices and Availability of Pharmaceuticals: Evidence from Nine Countries, W3 HEALTH AFF. 521 (2003) (comparing average price levels for drugs in eight countries); see also ANNA COOK, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (Congressional Budget Office 1998) (examining the impact of generic drug competition on drug prices since the passage of the 1984 Hatch-Waxman Act).

<sup>25.</sup> ROSA RODRIGUEZ-MONGUIO & JUAN ROVIRA, AN ANALYSIS OF PHARMACEUTICAL LENDING BY THE WORLD BANK 11-13 (HNP Discussion Paper 2004), *available at* 

 $http://www1.worldbank.org/hnp/hsd/documents/AnAnalysis of Pharmaceutical Lending.p\ df.$ 

<sup>26.</sup> GLAXOSMITHKLINE, ANNUAL REPORT 45 (2002).

when products are patent-protected or enjoy other legal forms of market exclusivity, as is often the case with pharmaceuticals,<sup>30</sup> it is expected to facilitate competition in the presence of product differentiation, moral hazard, and other market failures and imperfections.

However, a recent study cast some doubts on the extent to which the Bank's procurement requirements-even when unobstructed by legal hurdles-effectively promote international competition. The study found that a large share of the Bank's lending for PMP during the period of FY 1999 to FY 2002 financed either the domestic pharmaceutical industry of the borrower countries or the procurement of supplies from international organizations. Nearly twenty-nine percent of the total value of loans supplied by the Bank went toward PMP provided by suppliers from the same country that had received the Bank's loan.<sup>sī</sup> ICB was the procurement method for ninety percent of the contracts with the same supplier and borrower country. In the cases of Bosnia-Herzegovina, Cameroon, China, Indonesia, Macedonia, and Nicaragua, all PMP purchased were supplied by a national supplier irrespective of the procurement method used.<sup>32</sup> From a total of fifty Bank borrower countries, twenty-two suppliers accounted for ninety-nine percent of the total PMP purchased from FY 1999 to FY 2002.33 International organizations such as UNICEF and the Pan American Health Organization were also key

To respond to concerns raised with regard to the quality of the medicines subject to open-bidding procedures, the Bank requires procurement agencies to assess the quality of the manufacturers and products using prequalification of suppliers and other strategies. In the case of ARV and other HIV-AIDS drugs, the World Bank supports the initiative on prequalification of manufacturers and products led by the World Health Organization. *See, e.g.*, Helen Frankish, *WHO Steps Up Campaign on Counterfeit Drugs*, 362 THE LANCET 1730 (2003).

30. In those cases where the TRIPS Agreement offers countries some safeguards, parallel importation, the issuance of compulsory licenses, or the implementation of government use of a patent might be considered.

33. The Indian pharmaceutical industry was the main foreign supplier of pharmaceuticals and medical products: The Indian industry supplies 15.7% and 14.3% of the total PMP purchased by the twenty-two main Bank borrowers and by all fifty borrower countries, respectively. In spite of this apparently strong exporting capacity, Indian pharmaceutical products went mainly for domestic consumption, accounting for 89.1% of the country's total PMP. *Id.* 

<sup>31.</sup> RODRIGUEZ-MONGUIO & ROVIRA, supra note 25, at 12.

<sup>32.</sup> Other countries also have a large percentage of the total procurement of PMP supplied by domestic manufacturers: Burundi (63.5%), Egypt (87%), Mexico (86.3%), Morocco (67.7%), Philippines (59.5%), and Kenya (75.9%). *Id.* 

suppliers, jointly accounting for 44.8% of the total supply.<sup>34</sup>

## III. A NEW WORLD BANK POSITION ON GENERICS AND IPR

Bank lending for pharmaceuticals was traditionally used for the procurement of essential drugs and vaccines that are mostly off-patent. Since Bank projects have usually targeted basic health needs of poor populations, the Bank argued that these could be addressed with relatively old, well-established medicines. Since 1993, when the first Standard Bidding Procedures (SBP) for pharmaceuticals were issued, requirements were set to use international non-proprietary names (INN) for product specification. In recent years, and especially in the context of the "scalingup" of HIV/AIDS treatment programs in developing countries, purchasers of drugs have been faced with the high cost of using some on-patent drugs, especially antiretrovirals (ARVs), which have had dramatic impacts on the survival and quality of life of people living with HIV/AIDS. Many countries could not afford the high prices of on-patent drugs. The entry into the market of generic versions of ARVs, mainly produced by Indian manufacturers, opened the opportunity for countries to dramatically reduce the costs of AIDS treatment, in turn making it possible for countries to treat a much larger number of individuals with their available budgets.<sup>35</sup>

In the early 2000s, the Bank did not have an explicit and consistent practice with regard to the procurement of generic versions of ARVs that were on-patent in most developed countries. Uncertainties on the part of both the Bank and country ministers regarding the implications of TRIPS for developing countries sometimes resulted in countries choosing originator products aimed at ensuring conformity with a country's domestic legislation and with international agreements.<sup>36</sup>

Two recent documents have clarified the Bank position on this matter. In March 2003, two top World Bank managers published an op-ed in *The New York Times* openly endorsing the option of developing countries

<sup>34.</sup> Id.

<sup>35.</sup> SMITH, supra note 6, at 6.

<sup>36.</sup> See, e.g., THE WORLD BANK, PROJECT APPRAISAL DOCUMENT FOR PROPOSED LOANS IN THE AMOUNT OF US\$25.0 MILLION TO THE DOMINICAN REPUBLIC AND US \$15.15 MILLION TO BARBADOS IN SUPPORT OF THE FIRST PHASE OF THE US\$155.0 MILLION MULTI-COUNTRY HIV/AIDS PREVENTION AND CONTROL ADAPTABLE PROGRAM LENDING (APL) FOR THE CARIBBEAN REGION, 13 (Paper No. 22184-LAC 2001).

buying generic drugs whenever possible.<sup>37</sup> More recently, the World Bank published a Technical Guide to offer guidance to improve the performance of the agencies involved in the procurement of HIV/AIDS products.<sup>38</sup> In the Guide's chapter on IPRs, the Bank offers explicit guidance to developing countries on how to use the flexibilities of the TRIPS and of their own legislation in order to obtain the lowest possible prices while ensuring a standard quality of the supply of pharmaceuticals and other medical products. The publication of the Technical Guide was welcomed by some NGOs and activist organizations.<sup>39</sup>

The impact of the Bank's position on the global market appears limited by the relatively modest amount of its own pharmaceutical lending. However, it might have a strong demonstration effect on countries and on other institutions, such as the Global Fund for AIDS, TB and Malaria, based on the prestige and leverage that the Bank has on economic and policy issues in the international arena. The strategies and procedures initially applied in the field of HIV/AIDS products may be extended later to other therapeutic areas, where IPR-related high prices may constrain the affordability of essential drugs, especially among the poor in developing countries.

<sup>37.</sup> Ramphele & Stern, *supra* note 11, at A19.

<sup>38.</sup> THE WORLD BANK, supra note 28.

<sup>39.</sup> See, e.g., Posting of Brook Baker, B.Baker@neu.edu, to IP-Health@cptech.org (Feb. 26, 2004), http://lists.essential.org/pipermail/ip-health/2004-February/005987.html; Posting of Michael Palmedo, mpalmedo@cptech.org, to IP-Health@cptech.org (Feb. 24, 2004), http://lists.essential.org/pipermail/ip-health/2004-February/005982.html.

## ANNEX 1: PROCUREMENT METHODS RECOMMENDED BY THE WORLD BANK

According to the World Bank's procurement guidelines,<sup>40</sup> it is one of the Bank's roles to review the procurement process and to ensure that it is performed in accordance with the procedures established in these guidelines.

In each particular case, the procurement method and the category of goods are agreed upon by the Bank and the borrower and are specified in the loan agreement.

The procurement guidelines offer the following methods:

- 1. International competitive bidding (ICB) is generally required for all individual procurements valued at US\$200,000 or more. This value is different from region to region and even within regions there are differences among countries "although exceptions can be made in appropriate circumstances."<sup>41</sup>
- 2. National competitive bidding (NCB) is applicable in those cases where there is not enough foreign competition. National Competitive Bidding (NCB) is the competitive bidding procedure normally used for public procurement in the country of the borrower. NCB may be the preferred method of procurement where foreign bidders are not expected to be interested because: (a) the contract values are small, (b) works are scattered geographically or spread over time, (c) works are labor intensive or (d) the goods or works are available locally at prices below the international market.<sup>42</sup>
- 3. Limited international bidding (LIB), which is essentially an ICB conducted by invitation to the suppliers or contractors to participate, is to be applied when there is only a limited number of potential suppliers. Limited International Bidding (LIB) is essentially ICB by direct invitation without open advertisement. It may be an appropriate method of procurement when (a) the contract values are small, (b) there are only a limited number of suppliers, or (c) other exceptional reasons may justify departure

<sup>40.</sup> See THE WORLD BANK, STANDARD BIDDING DOCUMENT PROCUREMENT OF HEALTH SECTOR GOODS (2000).

<sup>41.</sup> Id. at 106.

<sup>42.</sup> Id. at iv.

from full ICB procedures.48

- 4. Shopping (International, ISH or National, NSH) is a procurement method based on comparing price quotations obtained from several suppliers, usually not less than three, and is an appropriate method for procuring readily available off the shelf goods or standard specification commodities that have a small value.<sup>44</sup>
  - a. International shopping (ISH) generally implies soliciting bids from at least three suppliers in at least two different countries and is usually restricted to procuring small volumes of goods.
  - b. National shopping (NSH) from local supplier may be used where the desired goods are ordinarily available from more than one source in the country of the borrower at competitive prices.
- 5. Direct contracting (DIR) can be utilized when goods can be obtained just from one supplier. DIR without competition may be an appropriate procurement method when (a) an existing contract for goods or works may be extended for additional goods or works of a similar nature, (b) standardization of equipment or spare parts, to be compatible with existing equipment, may justify additional purchases from the original supplier, (c) the required equipment is proprietary and obtainable only from one source, (d) the contractor responsible for a process design requires the purchase of critical items from a particular supplier as a condition of a performance guarantee, or (e) in exceptional cases such as in response to natural disasters.<sup>45</sup>
- Procurement may be made from United Nations's sources or other agencies, applicable for a total amount of procurement up to USD\$5 million for U.N. agencies and USD\$ 250,000 for NGOs.<sup>46</sup>

<sup>43.</sup> Id. at 23.

<sup>44.</sup> Id. at 21.

<sup>45.</sup> Id. at iv.

<sup>46.</sup> Id. at vi.

## **BOOK REVIEWS**

## Justice in Times of Crisis

Michael Boylan, Ph.D.\*

## In the Wake of Terror: Medicine and Morality in a Time of Crisis. Edited by Jonathan D. Moreno. Cambridge, MA: M.I.T. Press, 2003. Pp. 229.

In the United States, we are currently consumed by the threat of future terrorism. Our barometer of danger vacillates between different colored assessments of how likely it is that some catastrophic event is about to occur.<sup>1</sup> Is this merely hype, or do we face an imminent threat? To some degree, the answer to that question is irrelevant. Guided by the precautionary principle,<sup>2</sup> most would argue that the nation must prepare itself for the worst case scenario.

Most of the current literature on our response to terrorism examines policy initiatives that purportedly seek to protect the public good.<sup>3</sup> These policy initiatives aim to strike the proper balance between achieving the directives of the general will and sufficiently protecting individual liberties.<sup>4</sup> To date, most scholars and public thinkers have been primarily

3. This Book Review will focus its discussion specifically on civil security measures.

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<sup>1.</sup> See Press Release, White House Office of the Press Sec'y, Homeland Security Presidential Directive-3 (Mar. 2002),

http://www.whitehouse.gov/news/releases/2002/03/20020312-5.html (discussing the color-coded Homeland Security Advisory System).

<sup>2.</sup> A good discussion of the principle of precautionary reason can be found in Deryck Beyleveld & Shaun Pattinson, *Precautionary Reason as a Link to Moral Action, in* MEDICAL ETHICS 39 (Michael Boylan ed., 2000).

<sup>4.</sup> See, e.g., DAVID COLE, ENEMY ALIENS: DOUBLE STANDARDS AND CONSTITUTIONAL

concerned with assessing the best way to strike this difficult balance.

As important as such works are, a crucial component of our national preparation against terrorism has not yet been adequately addressed: namely, the involvement of the medical community. The medical community must be viewed as an essential part of this effort since they are among the first responders in times of emergency. Yet, this has not been a particularly fruitful area of scholarship, perhaps because many assume that plans already in existence for natural disasters will be sufficient to address any incident of terrorism. Such logic is mistaken. Terrorist incidents and the preparation for such incidents constitute new challenges for the national health care system. For this reason, the threat of terrorism should prompt us to reconsider some of the ethical questions posed by health care delivery in times of crisis.

In the Wake of Terror is a fine introduction to the questions we must address and the issues we must consider as we prepare ourselves for any future terrorist attacks.<sup>5</sup> Through a series of original essays, the book discusses many of the public health, medical, and policy questions that the nation faced in the aftermath of 9/11 and that the nation will face again in the event of future terrorist attacks. In the Wake of Terror does not insist upon a particular answer or approach, but rather sketches the broad penumbra of approaches from which policy specifications will be chosen. While its presentation of these different options is valuable, In the Wake of Terror does not offer clear guidance on which option is best because it does not provide an ethical framework for evaluating these different policy options. This Book Review briefly describes the essays in this book and then examines how two salient issues involving public health and medical awareness (i.e., the protection of individual rights and the allocation of resources to the ill and injured) might be evaluated within the context of a rights-based theory of justice.

FREEDOMS IN THE WAR ON TERRORISM (2004); DAVID DAGE, CASUALTY OF WAR: THE BUSH ADMINISTRATION'S ASSAULT ON A FREE PRESS (2004); NAT HENTOFF, THE WAR ON THE BILL OF RIGHTS—AND THE GATHERING RESISTANCE (2003); PHILIP B. HEYMANN, TERRORISM, FREEDOM, AND SECURITY: WINNING WITHOUT WAR (2003); LOST LIBERTIES: ASHCROFT AND THE ASSAULT ON PERSONAL FREEDOM (Cynthia Brown ed., 2003); CHRISTIAN PARENTI, THE SOFT CAGE: SURVEILLANCE IN AMERICA FROM SLAVERY TO THE WAR ON TERROR (2003); JEFFREY ROSEN, THE NAKED CROWD: RECLAIMING SECURITY AND FREEDOM IN AN ANXIOUS AGE (2004); THE WAR ON OUR FREEDOMS: CIVIL LIBERTIES IN AN AGE OF TERRORISM (Richard C. Leone & Greg Anrig, Jr. eds., 2003).

5. IN THE WAKE OF TERROR (Jonathan D. Moreno ed., 2003).

### I. THE ESSAYS

The first section of the book, "Public Health," begins with an introductory essay by Paul A. Lombardo. The essay offers a historical perspective on the possibility of research abuses in times of national crisis and sets a cautionary tone for the present.<sup>6</sup> Lombardo argues that the balance between biomedical progress and a protectionist ethic is often skewed by wartime's unwitting recruits for science: Concerns about vulnerable populations and protections for research subjects have often given way to the needs of defense. However, as Lombardo argues, it is not always clear that protecting the public safety required these trade-offs to be made.

The second essay,<sup>7</sup> written by current policy-makers James G. Hodge, Jr. and Lawrence O. Gostin, begins, "Perhaps no duty is more fundamental to American government than protecting the public's health."<sup>8</sup> Indeed, the imperative to protect the public's health establishes a utilitarian justification for the government's exercise of very strong powers in the name of the general will; these powers include involuntarily inoculating and quarantining individuals, thereby sacrificing people's personal liberties in the name of protecting the many. Hodge and Gostin argue that the exercise of some of these powers can be permissible, so long as they do not go too far: "The rights of individuals may be balanced with societal interests provided the balance does not support restraints that are excessive, arbitrary, or egregious (e.g., based upon racial or ethnic grounds)."9 The question, of course, is where to draw the line. Gostin was instrumental in working on the Model State Emergency Health Powers Act (MSEHPA)<sup>10</sup>—one attempt to strike such a balance for the public's good. This model legislation creates wide-ranging powers that permit state governments to engage in testing, mandatory vaccination, and involuntary quarantine. These practices would be permitted at the discretion of each

http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf.

<sup>6.</sup> Paul A. Lombardo, "Of Utmost National Urgency": The Lynchburg Colony Hepatitis Study, 1942, in IN THE WAKE OF TERROR, supra note 5, at 3.

<sup>7.</sup> James G. Hodge, Jr. & Lawrence O. Gostin, Protecting the Public's Health in an Era of Bioterrorism: The Model State Emergency Health Powers Act, in IN THE WAKE OF TERROR, supra note 5, at 17.

<sup>8.</sup> Id.

<sup>9.</sup> Id. at 19.

<sup>10.</sup> THE CTR. FOR LAW & THE PUBLIC'S HEALTH AT GEORGETOWN AND JOHNS HOPKINS UNIVS., THE MODEL STATE EMERGENCY HEALTH POWERS ACT (2001),

state governor.<sup>11</sup> While governments may want these powers, it remains important to ask: Does the MSEHPA strike the proper balance? Gostin and Hodge do not help us to answer this question, and it is unsurprising that they do not. The only way to answer such a question is by reference to a comprehensive moral/social theory that *In the Wake of Terror* unfortunately lacks.<sup>12</sup>

In the Wake of Terror's lack of theoretical grounding does not mean that none of the essays attempt to answer this difficult question. In the third essay of this section, George J. Annas argues that the MSEHPA does not strike the proper balance.<sup>13</sup> Annas believes that we must take human rights seriously even in war—and especially in a quasi-war, like the war on terrorism.<sup>14</sup> Thus, Annas criticizes the Bush-Rumsfeld decision to ignore the requirements of the Geneva Conventions in determining what rights to provide to alleged members of Al Qaeda and the Taliban held at Guantanamo Bay,<sup>15</sup> as well as the Centers for Disease Control's proposal to force medical treatment upon Americans in the event of biological attack.<sup>16</sup> Finally, he questions the handling of the anthrax crisis; he is particularly critical of the administration of experimental vaccines to many individuals who were only *potentially* exposed.<sup>17</sup> Yet, while Annas offers reasons for his opposition to these specific policies, he does not offer a comprehensive ethical framework for evaluating these and other policies.

The fourth essay, by Ronald Bayer and James Colgrove, steps back and places the previous essays' debate about how to balance the need to recognize individual liberties and to maintain the public good into a critical historical context.<sup>18</sup> The results of this tug of competing interests

14. Though Annas does not explain his argument for why the current "war on terrorism," is only a "quasi-war," one must assume that Annas holds to the standard "just war" doctrine, *see* Alex Moseley, *Just War Theory*, The Internet Encyclopedia of Philosophy, http://www.iep.utm.edu/j/justwar.htm (last visited Apr. 10, 2004), and believes that wars can only be fought between states. Since the 9/11 terrorists are not a country and do not aspire to be one, there can be no war against them.

15. George J. Annas, *Terrorism and Human Rights, in* IN THE WAKE OF TERROR, *supra* note 5, at 37 (citing Katherine Q. Seelye, *A P.O.W. Tangle: What the Law Says*, N.Y. Times, Jan. 29, 2002, at A14).

17. Id. at 43.

<sup>11.</sup> Id. at 42.

<sup>12.</sup> For discussion of a comprehensive moral/social theory, see infra Part II.

<sup>13.</sup> George J. Annas, *Terrorism and Human Rights, in* IN THE WAKE OF TERROR, *supra* note 5, at 33.

<sup>16.</sup> Id.

<sup>18.</sup> Ronald Bayer & James Colgrove, Rights and Dangers: Bioterrorism and the Ideologies of

have not always been admirable. As Bayer and Colgrove note, the MSEHPA law may be viewed as a modern equivalent to the quarantine laws passed in previous times of crisis because both MSEHPA and the quarantine laws rest upon a utilitarian justification to aid the public.<sup>19</sup> The authors argue that, to a large extent, such an approach received support in the United States because of fears about Iraq and the lethal nerve gas attack perpetrated by a Japanese cult.<sup>20</sup> While such approaches may work and may also receive some public support, there is also much public resistance. This resistance results from the recognition that we may be able to achieve the same results without sacrificing as many individual civil liberties as the MSEHPA would.<sup>21</sup> Any future policy must take this possibility into account. However, Bayer and Colgrove do not go far enough in suggesting a model for assessing the trade-offs.<sup>22</sup>

Part two, "Resource Allocation," represents the strongest section of the book because it comes closest to providing an ethical framework for the book's policy discussions. The section begins with an essay by James F. Childress.<sup>23</sup> Childress is a utilitarian and argues that triage (i.e., the allocation of scarce resources according to a formula that treats each individual identically according to a distributional calculus) is a just way of allocating resources. Like all classical utilitarians, Childress emphasizes that each person should count only as one: The rich industrialist and the common farmer are to be treated identically, and resources should be allocated to each of them so as to maximize medical utility.<sup>24</sup> While

22. For some preliminary suggestions in this regard, see infra Part II.

23. James F. Childress, *Triage in Response to a Bioterrorist Attack, in* IN THE WAKE OF TERROR, *supra* note 5, at 77. Childress is co-author of a widely respected textbook on bioethics. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (5th ed. 1994).

24. Maximizing medical utility requires taking actions that will secure "the greatest good for the greatest number" among those with medical needs. Childress, *supra* note 23, at 80. Obviously, calculations of how to do this can take a number of forms. For a discussion of how these calculations are to be made, see MICHAEL BOYLAN, BASIC ETHICS 76-79 (2000).

Public Health, in IN THE WAKE OF TERROR, supra note 5, at 51.

<sup>19.</sup> See id. at 52-53. Bayes and Colgrove note that "[t]he courts almost always deferred to public health authorities who deprived individuals of their liberty in the name of public health." *Id.* (citing Jacobson v. Mass., 197 U.S. 11 (1905); *In re* Halko, 54 Cal. Rptr. 661 (1966); and Wendy Parmet, *AIDS and Quarantine: The Revival of an Archaic Doctrine*, 14 HOFSTRA L. REV. 53, 61 (1985)).

<sup>20.</sup> Id. at 55.

<sup>21.</sup> Id. at 61.

supporters of egalitarian justice might favor a lottery,<sup>25</sup> Childress argues that attempting to maximize medical utility is a better way to allocate resources.<sup>26</sup>

The second essay of this section, written by Kenneth Kipnis, contains the strongest analysis in the book<sup>27</sup> because Kipnis recognizes that there is not just one form of triage. Kipnis begins the essay by describing various allocation strategies<sup>28</sup> and then tri-furcating triage into: (a) clinical triage in which the basis of need dictates the priority of care,<sup>29</sup> (b) battlefield triage in which those with minor injuries are treated first so that they can go out and fight another day,<sup>30</sup> and (c) disaster triage in which one creates a horizontal line beginning with the walking wounded; followed by those who are seriously injured, but can be treated with relatively simple procedures; and then those who are seriously injured and will require complicated and risky solutions for their medical needs. Disaster triage argues that the middle group should be treated first.<sup>31</sup> Since terrorism creates scenarios that are most like the scenario presented by disaster triage, Kipnis argues that this middle group should receive care first, and he provides suggestions of policy initiatives that would implement what he deems to be this ideal allocation strategy.<sup>32</sup>

The third part of the book, "Health Care Workers," turns from questions of resource allocation to the roles of those who will be doing the allocating. Lisa A. Eckenwiler examines the task of emergency management as a complicated systems problem.<sup>33</sup> This view is necessary because many agencies already have some jurisdiction over health care delivery in times of crisis.<sup>34</sup> For these agencies to work together effectively,

25. Egalitarianism is a theory of distributive justice in which all goods are distributed equally without regard to merit or need. This theory is predicated on the existence of a 'supporting moral theory which sanctions the grounds of the claimed right. For one version of this theory, see MICHAEL A. BOYLAN, A JUST SOCIETY 137-98 (2000).

30. Battlefield triage is the opposite of clinical triage.

31. Kipnis, supra note 27, at 99-100.

32. Id. at 105-06.

34. These agencies include EMS teams, public health officials, epidemiologists,

<sup>26.</sup> Childress, supra note 23, at 79-84.

<sup>27.</sup> Kenneth Kipnis, Overwhelming Casualties: Medical Ethics in a Time of Terror, in IN THE WAKE OF TERROR, supra note 5, at 95.

<sup>28.</sup> Id. at 96-100.

<sup>29.</sup> This form is used in emergency rooms in hospitals that are able, for the most part, to match patient need with therapeutic support.

<sup>33.</sup> Lisa A. Eckenwiler, *Emergency Health Professionals and the Ethics of Crisis, in* IN THE WAKE OF TERROR, *supra* note 5, at 111.

it is necessary to integrate their services with a systems approach. However, such a complicated operation can also raise ethical problems that require policy decisions.<sup>35</sup> Dr. Eckenwiler identifies key questions faced by health care workers in times of crisis: When should health care workers mobilize, and how should they intervene once they have made that decision?<sup>36</sup> She provides a preliminary framework for answering these questions and also identifies key challenges faced by health care workers. She notes that the possibility that health care workers might be made agents of the law is a particularly significant problem and one that is a "source of significant moral distress for many health professionals";<sup>37</sup> this is a problem that Bayer and Colgrove also mention.<sup>38</sup>

In the next essay, Griffin Trotter discusses connections between health care reform and terrorism and recognizes the idealistic nature of many past reforms.<sup>39</sup> Trotter points out that when market forces are used to allocate resources, concerns about "equality" do not factor into the allocation; as a result, the current medical system in the United States is not friendly to the poor and the uninsured.<sup>40</sup> For example, one significant problem that occurs in the present system is the transfer of patients. These transfers can take the form of diverting ambulances to other hospitals, thus increasing the time before the patient can be seen by any medical personnel, or transferring patients who have been seen but not treated, thereby delaying treatment because of the need for additional paperwork to be completed.<sup>41</sup> Obviously, such transfers are not in the best interests of patients who need emergency care. Uninsured patients, usually the indigent, are at greater risk for being subject to patient transfers.<sup>42</sup> Since many emergency room doctors act as primary care physicians for the poor, many needy individuals could be denied basic health care in the event of a national emergency if emergency room doctors are called to aid those affected by the national disaster. The author suggests that if we had universal healthcare, we would be better prepared for a terrorist

39. Griffin Trotter, Emergency Medicine, Terrorism, and Universal Access to Health Care: A Potent Mixture for Erstwhile Knights-Errant, in IN THE WAKE OF TERROR, supra note 5, at 134.

laboratory staff, and clinicians called by local authorities, state and federal agencies, and the Center for Disease Control. Eckenwiler, *supra* note 33, at 112-13.

<sup>35.</sup> Id. at 111, 113-18.

<sup>36.</sup> Id. at 114-21.

<sup>37.</sup> Id. at 125.

<sup>38.</sup> See Bayer & Colgrove, supra note 18, at 52.

<sup>40.</sup> Id. at 134.

<sup>41.</sup> Id. at 136-37.

<sup>42.</sup> Id. at 138.

emergency.<sup>43</sup> Under this view, universal healthcare could be considered a part of our national defense.<sup>44</sup>

Part Four, "Industry Obligations," is a particularly valuable section of the book because it begins to explain how industry may help to ameliorate the problems set out in the previous parts. In her essay, Evan G. DeRenzo begins by questioning whether a market-based approach to terrorism will be sufficient.<sup>45</sup> This concern derives from the fact that the generally espoused motive of business is to make a profit.<sup>46</sup> However, DeRenzo suggests that businesses can also see achieving the public good as their comotive for being.<sup>47</sup> Indeed, the ethical goal of business, in this case the pharmaceutical industry, must include more than simply making a profit or else every company would be engaged in illegal and lucrative ventures. The fact that businesses do not go that far in pursuit of the profit motive provides support for DeRenzo's point. Like the founder of the Bank of America,<sup>48</sup> DeRenzo cites support of the public good as a legitimate goal, since a strong public can aid policy makers when they face future crises.

In the final essay in this part, Ann E. Mills and Patricia H. Werhane, one of the premier philosophers of business ethics in the United States, address the issue of organizational ethics.<sup>49</sup> They implicitly respond to the question raised by the previous essay: How should we ask businesses to contribute? Any discussion of that question must first acknowledge that the mission of the healthcare industry changes in times of terrorism.<sup>50</sup> Traditionally, the health care industry has been forced to balance concerns about cost versus concerns about quality of care. Recently, the industry has begun to use vertical integration as a cost-cutting strategy, as "[t]he dominant logic of the for-profit health care industry changed from providing care to providing quarterly profits."<sup>51</sup> However, in the event of

50. Id. at 168.

51. *Id.* at 170. Vertical integration, like vertical monopolies, combine control over the various phases of rendering a service or producing a product. Some form of vertical strategy

<sup>43.</sup> Id. at 142-45.

<sup>44.</sup> Id. at 143.

<sup>45.</sup> Evan G. DeRenzo, The Rightful Goals of a Corporation and the Obligations of the Pharmaceutical Industry in a World with Bioterrorism, in IN THE WAKE OF TERROR, supra note 5, at 149.

<sup>46.</sup> Id. at 150.

<sup>47.</sup> Id. at 152.

<sup>48.</sup> Id. at 156-57.

<sup>49.</sup> Ann E. Mills & Patricia H. Werhane, *After the Terror: Health Care Organizations, the Health Care System, and the Future of Organization Ethics, in* IN THE WAKE OF TERROR, *supra* note 5, at 167.

crisis, the healthcare industry will have to emphasize concerns about quality of care over concerns about cost. In fact, in the case of a crisis, there will likely be a large influx of patients; some estimates suggest that it will cost hospitals \$11.3 billion to prepare for such an influx.<sup>52</sup> Hospitals will not be able to prepare sufficiently under the current system. Rather, they must shift to a community service model that incorporates public health goals. This shift can be achieved by developing systems, or "networks of relationships between individuals, between individuals and organizations, among organizations, and among individuals, organizations, institutions, agencies, and government."<sup>53</sup> These systems begin from the bottom-up, are adaptive to change, and are designed to integrate the resources of all stakeholders.<sup>54</sup> The element of the stakeholder gives accountability to the whole process.<sup>50</sup>

In the first essay of the last section of the book, "Research and Genetics," Alan R. Fleischman and Emily B. Wood argue for research standards for the use of human subjects.<sup>56</sup> They make points that should be salient to researchers and those who supervise their research. They argue that research on humans should ensure respect for persons (via informed consent), beneficence (via an effective cost-benefit calculus), and justice (via fairness and equitability).<sup>57</sup> They remind us that in research we must never forget vulnerable populations.

By using a history lesson to identify challenges for the future, Eric M. Meslin ends the book where it began.<sup>58</sup> Meslin observes that while times

is necessary for any large operation. But if a company can control or obtain *ownership* in these phases, then that company's power to control prices greatly increases. The mechanics of this are discussed in Pamela Jones Harbour, Vertical Restraints: Federal and State Enforcement of Vertical Issues (2004) (unpublished written materials),

http://www.ftc.gov/speeches/harbour/0403vertical.pdf. Because it is also possible that such an entity can fix prices to the detriment of the consumer, we have passed laws against vertical monopolies such as the Sherman Anti-Trust Act, 15 U.S.C. § 1 (2000).

<sup>52.</sup> Ann E. Mills & Patricia H. Werhane, *After the Terror: Health Care Organizations, the Health Care System, and the Future of Organization Ethics, in* IN THE WAKE OF TERROR, *supra* note 5, at 173.

<sup>53.</sup> Id. at 175.

<sup>54.</sup> Id.

<sup>55.</sup> Id. at 177.

<sup>56.</sup> Alan R. Fleischman & Emily B. Wood, Research Involving Victims of Terror—Ethical Considerations, in IN THE WAKE OF TERROR, supra note 5, at 185.

<sup>57.</sup> Id. at 188-89.

<sup>58.</sup> Eric M. Meslin, Genetics and Bioterrorism: Challenges for Science, Society, and Bioethics, in IN THE WAKE OF TERROR, supra note 5, at 199.

change and new agendas emerge, we are plagued by classic problems such as the balancing of secrecy and freedom, research aims and human subject autonomy. These tensions inevitably complicate any new policy. However, Meslin urges us to evaluate new policies and practices according to timetested criteria for addressing such problems, and he reminds us not to ignore input from the scientific community. As he notes, disruption in one area of our health delivery system will inevitably affect other parts.<sup>59</sup> Finally, Meslin addresses the issue of secrecy versus scientific freedom. As he notes, science does best in the sunlight, while national security seeks the shadows.<sup>60</sup> These are all traditional concerns; they are simply resurfacing in slightly modified forms in light of the new problems at hand. While the situations may change, the criteria for evaluating them are timeless. But as all of the essays in In the Wake of Terror suggest, sometimes the various criteria for evaluating these policies are in tension with each other. This tension suggests the need to establish an ethical framework against which to assess these policy considerations.

## **II. THE NEED FOR AN ETHICAL FRAMEWORK**

While In the Wake of Terror introduces and facilitates important discussions about preparations for a terrorist disaster within the national medical and public health community, it fails to present the ethical framework that is necessary for the development of sound policy. In particular, the collection of essays raises two compelling themes that merit further discussion as we make these preparations: the protection of individual rights and the principles of allocation. Though various essays in the book touch on these issues, there is a conspicuous lack of grounding in ethical theory.<sup>61</sup> This omission is unfortunate because this sort of grounding is essential if the reader is to be able to assess and recommend medical and public health policy responses in the wake of a terrorist attack. In this Part, I suggest a possible ethical framework against which such policy considerations could be assessed and illustrate how the choice of framework can affect one's policy decisions.

Protection of individual rights. During a terrorist onslaught, ordinary rules that emphasize the need to protect individual rights are often replaced by emergency codes and protective strategies that are less sensitive to such needs. As Bayer and Colgrove discuss, the MSEHPA is just

<sup>59.</sup> Id. at 208.

<sup>60.</sup> Id. at 208-10.

<sup>61.</sup> The sole exceptions are Childress's and Kipnis's discussions of utilitarianism.

one in a long series of examples. If we assume that society's legal framework follows from accepted moral principles, then the protective strategies of the society during crises should also flow from those same ethical principles.<sup>62</sup> Thus, it is important to identify the moral theory and corresponding principles that will drive public policy.

Many would argue that utilitarianism, a theory that aims to please the greatest number by maximizing their utility,<sup>63</sup> is the appropriate foundational theory since it coheres nicely with the values that support free markets and democracy. In this sense, this theory seems to be both very American and quite consonant with the theoretic underpinnings of public health. Certainly, it is important to work at defending our country via reasonable means, such as searches of airline passengers and their baggage, sea shipping containers, and other means of foreign entry, as well as domestic protections such as screening mail. All of these implementation strategies seem to make sense when seen in the light of precautionary reason.<sup>64</sup>

However, it is important to heed the cautions of George J. Annas: Minority populations and vulnerable groups often fare poorly under zealous utilitarian-based policies.<sup>65</sup> Indeed, practices such as profiling are particularly problematic.<sup>66</sup> Despite the concerns about profiling, it has made a strong comeback in the aftermath of 9/11,<sup>67</sup> with increased

65. IN THE WAKE OF TERROR, *supra* note 5; Annas, *supra* note 13, at 37-40, 43-47; *cf.* Bayer & Colgrove, *supra* note 18, at 58-64; Eckenwiler, *supra* note 33, at 122-24; Fleischman & Wood, *supra* note 56, at 191-93; Lombardo, *supra* note 6, at 4-6, 9-11; Meslin, *supra* note 58, at 212.

66. For discussions of the existence of, and concerns about, racial profiling, see generally MILTON HEUMANN & LANCE CASSAK, GOOD COP, BAD COP: RACIAL PROFILING AND COMPETING VIEWS OF JUSTICE (2003); Richard J. Lundman & Robert L. Kaufman, Driving While Black: Effects of Race, Ethnicity, and Gender on Citizen Self-Reports of Traffic Stops and Police Actions, 41 CRIMINOLOGY 195 (2003).

67. Irene Jung Fiala, Anything New? The Racial Profiling of Terrorists, 16 CRIM. JUST. STUD.

<sup>62.</sup> Every serious moral system creates a decision-making procedure that will provide an answer for every eventuality. The question is why we accept one procedure over aother.

<sup>63.</sup> See generally BOYLAN, supra note 24, at 66-87.

<sup>64.</sup> In contrast to the policies that I describe as "racial profiling," these practices are not—or at least need not be—targeted toward specific groups of people. Of course, even the reasonableness of these non-targeted policies can be subject to dispute. See, e.g., Expert Believes Airport Screening Must Be Fixed Before It's Changed, ORLANDO SENTINEL TRIB., June 2, 2003, at CFB3 (noting the criticism of one aviation consultant that the "government's plan to use extensive background checks on passengers is troubling from a privacy standpoint"). A full defense of their reasonableness is beyond the scope of this Review.

detentions and arrests of people of Arabic or Middle Eastern descents.<sup>68</sup> Are these actions legally justified? It is hard to know since so much is still cloaked in secrecy.<sup>69</sup> Even if we knew more, the legal and ethical propriety of racial profiling would likely remain the subject of contentious debate.

Among the many problems that profiling presents,<sup>70</sup> it has the potential to negatively affect the practice of medicine and public health: Profiling risks marginalizing minority groups such that communication between members of those minority groups and the medical community is hampered.<sup>71</sup> As a result of this hampered communication, medical professionals often know little about the values and lifestyles of these groups, and misunderstandings often result from different uses of language, different understandings of the meanings of facts, and different value determinations. For example, if a physician is unaware of one Muslim view on male physicians examining females, he would not understand the patient's reluctance to seek medical care. This could lead to a serious condition going untreated. Alternatively, a physician might be aware of this worldview, but dismiss it as primitive or parochial or simply fail to understand it. Whatever its cause, this lack of communication impairs the clinical processes of diagnosis, prognosis, and treatment, resulting in differential medical care.<sup>72</sup>

If such difficulties can impair diagnosis and treatment in normal settings, the possibility for detrimental effects on medical care are only greater when the physician-patient interaction occurs in settings emotionally charged by the threat of an imminent terrorist incident. Concerns of this kind have always been present with immigrant

53 (2003).

70. There is an extensive literature evaluating the legality of racial profiling, but those issues are beyond the scope of this Book Review. *See, e.g.*, Albert W. Alschuler, *Racial Profiling and the Constitution*, 2002 U. CHI. LEGAL F. 163. For a discussion of the problem from the point of view of classes and mathematical logic, see BOYLAN, *supra* note 25, at 93-112.

71. See Michael A. Boylan, Culture and Medical Intervention, J. CLINICAL ETHICS (forthcoming 2004).

72. Id.

<sup>68.</sup> Salah D. Hassan, *Enemy Arabs*, 17 SOCIALISM & DEMOCRACY 175 (2003); Liam Braber, Comment, Korematsu's *Ghost: A Post September 11th Analysis of Race and National Security*, 47 VILLANOVA L. REV. 451, 452-53 (2002).

<sup>69.</sup> See Michael Welch, Ironies of Social Control and the Criminalization of Immigrants, 39 CRIME, LAW & SOCIAL CHANGE 319, 323-25 (2003) (discussing the use of secret evidence in immigration cases); cf. Ayse Ceyhan, Terrorism, Immigration and Patriotism under Surveillance, 44 CULTURES ET CONFLICTS 117 (2001).

populations,<sup>78</sup> but if profiling creates stigmatized populations among nonimmigrants, these sub-populations may suffer from the same harms that have historically been inflicted on immigrant populations. This is particularly troubling when the groups affected are small because then it becomes more difficult for those group to become self-sufficient in areas such as health care delivery. In the public health setting, utilitarian calculations may underestimate the effect that practices such as racial profiling have on marginalized populations because the mainstream population can tend to ignore, or devalue, considerations relevant to those populations.

One way to protect those without a resonant public voice is to introduce a rights-based approach into the public dialogue. Many proponents of rights-based moral theories<sup>74</sup> have challenged some of the premises that underlie classic utilitatarianism.<sup>75</sup> Under this view, there should be procedures that ensure that the least advantaged should not be called upon to forfeit their individual liberties except in the most extreme scenarios. Such procedures are necessary under a rights-oriented moral theory, which requires the establishment of both base-line protections for individuals' needs and the correlative duties of society that protection of those needs entail.<sup>76</sup> This argument assumes that human beings' primary aim is to act. Therefore, certain fundamental rights are protected because of their critical role in facilitating action.<sup>77</sup> Under this view, racial profiling would not be justified because it interferes with an individual's ability to act freely in society as an individual, rather than as a member of a stereotyped group Thus, while profiling might be justified under a utilitarian approach, it would not be justified under a rights-based theoretical orientation. Clearly, then, our choice of theoretical ethical approach can play a critical role in determining what protective law enforcement strategies are justified in times of emergency.

Indeed, police strategies should be of concern to the medical and public health communities—especially since, as Eckenwiler notes, many of

<sup>73.</sup> Id.

<sup>74.</sup> John Rawls, Alan Gewirth, and I are all proponents of such a theory.

<sup>75.</sup> See generally BOYLAN, supra note 25, at 53-58; ALAN GEWIRTH, REASON AND MORALITY 312-22 (1978); JOHN RAWLS, A THEORY OF JUSTICE 4 (1971) ("[Justice] does not allow that the sacrifices imposed on a few are outweighed by the larger sum of advantages enjoyed by many."). Each of these writers develops a different argument for why a deontological, rights-based theory of ethics is superior to a utilitarian-based theory. These arguments are beyond the scope of this Book Review.

<sup>76.</sup> See Wesley N. HOHFELD, FUNDAMENTAL LEGAL CONCEPTIONS 41 (1919).

<sup>77.</sup> For discussion of this argument, see BOYLAN, supra note 25, at 53-69.

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the scenarios being discussed in the public health sphere include a *de facto* enrollment of the medical community into policing of our population.<sup>78</sup> Certainly, the medical community could be an efficient addition to law enforcement organizations' activities. But is that the proper role of our health care workers?

I would suggest that it is not. On the one hand, it is essential to integrate the various components of our society in our fight against terrorism. On the other hand, this effort should not require individuals to do jobs unnatural to them. Curing the sick while doing no harm<sup>79</sup> is natural to medicine, but becoming law enforcers would put physicians in a different position—one that they are unprepared to fill. It is not hard to imagine situations in which the health care worker qua policeman might be forced to act contrary to the medical needs of the patient, thereby abnegating her professional duties as a physician.<sup>80</sup> Surely, it works to no one's benefit for such an important societal profession to compromise itself. It weakens the profession just at the time when we all count upon its strength.

The principles of allocation. As with protection of individual rights, principles of allocation will also be colored by the ethical system that we choose. Childress argues for a utilitarian system.<sup>81</sup> This might make sense since such a system would be closely aligned with the cost-benefit analysis that seems to drive the prominent triage formulae. Moreover, it is true that the rights-based theories are principally designed to work under normal circumstances and have an "ought implies can" caveat.<sup>82</sup> In other words,

80. For example, what if an attending physician suspected that a patient had material information that could aid in an investigation, but also believed that a comprehensive debriefing of the patient would put the patient's life in danger. In this situation, the physician qua healer would have a responsibility to attend to the medical needs of the patient. However, physician qua agent of the law should interrogate the patient to prevent the potential harm to many others. Thus, the individual physician simultaneously has a duty to interrogate and not interrogate the patient.

81. James F. Childress, *Triage in Response to a Bioterrorist Attack, in* IN THE WAKE OF TERROR, *supra* note 5, at 77, 79ff.

82. Obviously, a lot rides on "reasonably." The policy dimensions of this are discussed

<sup>78.</sup> Eckenwiler, supra note 33, at 125.

<sup>79.</sup> This is a paraphrase of the Hippocratic Oath. For a discussion of the Hippocratic Oath in the context of professional ethics, see MICHAEL BOYLAN & KEVIN E. BROWN, GENETIC ENGINEERING: SCIENCE AND ETHICS ON THE NEW FRONTIER 12-25 (2002). For a discussion of the oath in the context of the Hippocratic corpus, see Michael Boylan, *Hippocrates (c. 450 BCE to 380 BCE.)*, The Internet Encyclopedia of Philosophy, *at* http://www.iep.utm.edu (last visited Apr. 9, 2004).

under this view, no duty can be ascribed to any agent or group that cannot, given the circumstances, *reasonably* fulfill it. Thus, when the "can" is called into question—as it would be in the case of an act of terrorism—the "ought" becomes weakened.

Yet this does not mean that rights-based theories cannot provide guidance in allocating resources. As Kipnis notes in his essay, there is not just one way to allocate resources; rather, there are at least three forms of triage.<sup>83</sup> Which is most appropriate for instances of terrorism? Under a rights-based theory, care should be allocated on the basis, at least in part, of need. Therefore, the battlefield triage approach would contradict a rights-based theory because medical attention is meted out in the opposite order of need in order to clear the hospitals of people as quickly as possible.

But what about the other two options? Our choice depends upon which factor we wish to emphasize: numbers of people being treated and discharged or the satisfaction of those most in need. One possibility would be to employ clinical triage within parameters: A small unit that would take the most extreme cases under a lottery system would treat as many of those requiring over x percentage of medical resources (as measured by time and materials expended) as possible, while the majority of the medical care would be devoted to treating everyone else. The order in which members of this latter group would be treated would be determined solely on the basis of need. The advantage of a lottery system that is employed for the very ill and injured is that everyone can understand that such extraordinary times will not allow for everyone to be treated. Since all people's lives are of equal importance, random measures will be taken to attend to these individuals. While the losers in this class will surely die at a very high rate, they are being attended to in a way that does not make any utility calculations regarding whom should be saved.

This sort of triage arrangement is an amalgam of Kipnis's clinical and disaster triage, but because it is based on a rights-oriented moral theory, it has a slightly different outcome measurement. Arguably such an allocation formula is ultimately fairer to all because it recognizes all people's right to medical care, while also admitting that the extraordinary circumstances of the terrorist attack has made rationing of some sort a practical necessity. However, what is driving this sort of rationing is not an attempt to achieve the greatest good for the greatest number, but rather an attempt to create a system that, to the greatest extent possible, respects the fundamental

by BOYLAN, supra note 25, at 143-44, 162, 174-75, 202, 213, 240.

<sup>83.</sup> Kipnis, supra note 27, at 97-100.

rights of all people equally according to the strength of their need.

Obviously, this is an important question that should be engaged in the public sphere. So, too, are all of the other questions raised and policy issues discussed in In the Wake of Terror. Thus, In the Wake of Terror provides an excellent introduction to the connections between the threat of bioterrorism and public health because it identifies all of the issues salient to this discussion. Unfortunately, In the Wake of Terror can serve only as an introduction to this discussion because while it identifies the important issues, it does not tell the reader how to evaluate them. In this Review, I have not set out to provide definitive answers to any of the questions In the Wake of Terror raises; rather, I have hoped to show that the ethical framework one chooses can significantly alter the policy outcomes one reaches. While I have used only two examples-the protection of individual rights and the allocation of resources-to illustrate this point, it is equally true of all of the issues discussed in In the Wake of Terror. As we continue to live in a world in which a terrorist threat seems imminent, the questions raised in In the Wake of Terror will continue to be of paramount importance. But identifying the important questions is obviously not enough. Identifying an appropriate ethical framework is a critical next step as we try to determine how best to answer those questions.

# The Market Matters: Reforming the U.S. Health Care System

## Vincent E. Kerr, M.D.\*

Epidemic of Care: A Call for Safer, Better, and More Accountable Health Care. By George C. Halvorson & George J. Isham. San Francisco: Jossey-Bass, 2003. Pp. 271.

Imagine a world where few can afford necessary and life-saving treatments, where hospitals and physicians can no longer provide uncompensated care, where government and employers can pay for only the barest safety net, and where health care facilities are so understaffed that they are dangerous. That world may be closer than you think.

This nightmare scenario is suggested by recent trends cited in *Epidemic* of Care: A Call for Safer, Better, and More Accountable Health Care.<sup>1</sup> This book, written by George Halvorson and George Isham, is a wonderful primer on why health care in this country is as flawed and as expensive as it is, and it presents information about which everyone should be concerned. Medicare recipients, retired workers, active workers, the poor, the unemployed, and children are all adversely affected by the poor quality of care too often provided by today's health care system. No economic class will go untouched if the disturbing picture *Epidemic of Care* paints of the future of health care becomes a reality. But, perhaps more importantly, *Epidemic of Care* is also a call to action.

*Epidemic of Care* begins with an extensive review of the twin crises of escalating cost and questionable quality facing the American health care system. This overview describes not only the present situation, but also forecasts the likely economic implications of the current trajectory of American health care.<sup>2</sup> Halvorson and Isham both identify the problems and, toward the end of the book, forward a "national health strategy" with

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<sup>1.</sup> See GEORGE C. HALVORSON & GEORGE J. ISHAM, EPIDEMIC OF CARE: A CALL FOR SAFER, BETTER, AND MORE ACCOUNTABLE HEALTH CARE (2003).

<sup>2.</sup> See id. at 35-45.

clear initiatives to streamline and improve the current system.<sup>3</sup> They admit that certain problems, such as the nursing shortage in this country and the anticipated shortfall of other health care professionals in the near future, do not seem to have easy answers.<sup>4</sup> But they do suggest proposals—seven broad, national initiatives—that adequately address other, perhaps more pandemic problems, including the poor quality of health care delivery today and the apparent paradox in the medical community's overprovision of care despite being in the midst of a resource shortage.

Specifically, Epidemic of Care insists that before change can come, the problems detailed in the first half of the book-specifically, the problems with the cost and quality of care-must be recognized on a national level. Only that national recognition will produce the resolve necessary to pursue the seven broad initiatives that the authors argue will cure the woes of the current system. The last seven chapters provide an analysis of the proposals: (1) provide safer care; (2) create savings accounts for health care to improve market dynamics for buying and selling health care; (3) improve prevention efforts; (4) prevent provider monopolies and anticompetitive behaviors; (5) fund programs for the uninsured; (6) continue to fund training, education, and research; and perhaps most importantly, (7) create an "automated medical record that will give the doctor and patient in the exam room all of the information needed to provide best care efficiently and consistently."<sup>5</sup> The authors persuasively argue that this last initiative is a prerequisite for successful implementation of the other six.

Certainly, adoption of these recommendations would do much to improve the delivery of care. Unfortunately, their seven initiatives alone will not fully address the problems the authors so elegantly point out in the first half of *Epidemic of Care*. Because the authors have paid insufficient attention to issues of feasibility and implementation and the importance of the market place, their proposals will not end the irrational financial incentives and the vast clinical gray zone (i.e., the ever expanding number of treatment choices and the imprecision and variability of arriving at correct diagnoses) that exist in much of medicine. The authors have suggested an intriguing, but ultimately only partial cure for what ails the American health care system. The missing ingredients in this prescription are a more thoughtful consideration of how their proposals might be implemented and a more robust use of the power of market forces to

<sup>3.</sup> Id. at 155.

<sup>4.</sup> Id. at 234-35.

<sup>5.</sup> Id. at 157.
achieve that end.

# I. THE AUTHORS' BACKGROUNDS

To fully appreciate the perspective that Halvorson and Isham advance in *Epidemic of Care*, a brief understanding of their backgrounds is critical. Their proposed solutions are based, in part, on their experiences managing regional health plans with large, closely affiliated physician practice groups and hospitals. Halvorson is the chairman and CEO of Kaiser Permanente, the nation's largest integrated, non-profit health care delivery system.<sup>6</sup> As a fully-integrated provider, Kaiser Permanente offers multi-specialty insurance, hospital, and pharmacy services to its members. Prior to Kaiser, Halvorson worked in Minnesota at HealthPartners,<sup>7</sup> where George Isham still serves as chief health officer and medical director.<sup>8</sup> HealthPartners offers an integrated package of health coverage, insurance, and services.<sup>9</sup> Both authors have been leaders in improving clinical processes and measurement, in part through their adoption of electronic tools and support processes for physicians.

The authors contend that the example of improvements cultivated in tightly controlled physician organizations similar to the ones with which they have experience has relevance in a larger, more fragmented system (i.e., the U.S. health care system). This is possible, they believe, if government funding can be expanded to support technological improvements such as automated electronic medical records, additional training and education, and more research.<sup>10</sup> However, neither author has had the opportunity to apply these same solutions on a truly national scale to an unorganized delivery system, which is what any solution must do if it is to be applied to the entire U.S. health care system. Indeed, the financial structure of systems like Kaiser Permanente and HealthPartners of Minnesota provides incentives to rationalize, without necessarily rationing, medical care.<sup>11</sup> Such organized delivery systems, though imperfect, are capable of fostering wide adoption of clinical practice standards rarely seen

<sup>6.</sup> Id. at xxix.

<sup>7.</sup> Id.

<sup>8.</sup> *Id.* at xxx.

<sup>9.</sup> *Id*.

<sup>10.</sup> Id. at 180, 235.

<sup>11.</sup> Rational care makes trade-offs and judgments about efficacy within the context of evidence-based medicine, but still provides the highest quality care. For example, using an expensive anti-inflammatory when aspirin might be equally safe and efficacious would not be condoned in a rational system.

in the broader physician population. A different solution, however, may be required for widespread implementation across the nation's health care system.

### **II. THE HEALTH CARE CRISIS**

In making their case that there are serious problems ailing the current health care system, the authors point to several facts that have already been widely publicized. They note that health care expenditures have risen for the past five years at an alarming pace that is several times the rate of inflation. However, while health care expenditures consume an increasing percentage of the gross domestic product (GDP), the care received is often unsafe, highly variable, and frequently falls far short of known clinical standards in a way that few other industries would tolerate. The authors draw the link between poor quality and higher cost, but do not stop there. They also examine the role of private insurance as a funding mechanism for health care and as an arbiter of societal mandates, the role of market forces in the cost equation, and the mistakes of managed care over the past decade.

Indeed, cost is unquestionably a significant issue. Affordability and access to health care perennially rank high among the concerns of Americans in Kaiser Family Foundation annual surveys.<sup>12</sup> The popular press echoes this sentiment. Over the past three years, health care issues, particularly cost, have been the topic of innumerable, often front page, stories in the national press.<sup>13</sup>

This past year, the Medicare reform bill that included a Medicare prescription drug benefit appeared to be one of the most closely watched and hotly debated issues in Congress.<sup>14</sup> At the core of this issue was affordability for the nation—who should receive the benefit and who should not, what would be covered, what the true projected cost of providing such a benefit would be, who should pay and how much, and how pharmaceutical manufacturers would be affected if the government

<sup>12.</sup> KAISER FAMILY FOUND., HEALTH CARE PRIORITIES (JAN./FEB. 2004), AT HTTP://WWW.KFF.ORG/HEALTHPOLLREPORT/CURRENTEDITION/CARE/INDEX.CFM (LAST VISITED MAY 8, 2004).

<sup>13.</sup> See, e.g., Chad Terhune, Fast Growing Health Plan has a Catch, WALL ST. J., May 14, 2003, at A1; Milt Freudenheim, Employees Paying Bigger Share for Healthcare, N.Y. TIMES, Sept. 10, 2003, at A1.

<sup>14.</sup> For information on the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003, see http://www.cms.hhs.gov/medicarereform (last visited May 8, 2004).

entered the prescription business for Medicare recipients. In this way, the Medicare reform bill debates were similar to previous national discussions on health care: Cost played a central role in every argument. The General Accounting Office (GAO) estimates that, if the current rate of increases in health care spending continue and if certain other assumptions are met, the growth in percent of GDP consumed by health care could materially affect our nation's ability to borrow from other nations within ten years. This impact on the United States's ability to borrow could, at worst, precipitate a call for repayment of existing debt.<sup>15</sup> If this scenario were to play out, it could cause a national financial crisis. Indeed, one could argue that were it not for cost, much of the discussion about quality would not take place and many of the discussants, particularly purchasers, would not be as engaged.

If cost is central to the debate, who or what are the culprits? In Epidemic of Care, the authors suggest many of the possible causes of spiraling costs: health plans, providers, purchasers, patients, and medical technology firms. They rightfully identify the changing payment mechanism-from traditional indemnity insurance to HMOs to a more relaxed managed care—as an additional cause.<sup>16</sup> The loss of defined fee schedules and a reversion to a more conventional fee-for-service model to cover procedures and services fundamentally changed the contract with the insured and altered the dialogue between patients and insurers. During the economic boom of the late 1990s, consumers resisted the restrictions of traditional HMOs, and employers, eager to retain employees during a tight labor market, paid for broader access to providers. Because profits were high, they could afford these increased costs. This led to a relaxation of tight managed care controls, resulting in diminished control by the health plans over processes and costs.<sup>17</sup> Meanwhile, medical malpractice claims escalated, spawning medical necessity determinations. Medical necessity led to increasing denials of care, which led to consumer backlash. The backlash created loose or no controls and further escalation of costs.<sup>18</sup>

Halvorson and Isham tend to view these changes as unique to the health care industry, but one could argue that they are more directly linked to economic factors external to the health care system. Arguably,

<sup>15.</sup> U.S. Gen. Accounting Office, *Health Care System Crisis: Growing Challenges Point to Need for Fundamental Reform*, http://www.gao.gov/cghome/healthcare (Jan. 13, 2004).

<sup>16.</sup> HALVORSON & ISHAM, supra note 1, at 117-26.

<sup>17.</sup> Id. at 142.

<sup>18.</sup> Id. at 134-36.

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almost all cost developments—the demand for plans to leverage volume to get price discounts; the Balanced Budget Act, which is curiously not mentioned in the book but appeared to be responsible for a huge shift in hospital pricing dynamics;<sup>19</sup> and even the backlash against managed care—were lagging indicators directly linked to the overall state of the economy. In fact, there have been cyclical expansions and contractions in health care expenditure increases for the past forty years, roughly related to economic cycles.<sup>20</sup>

Yet even while recognizing that the health care system does not exist in a vacuum, it is also important to recognize that some of these cost developments do result from factors unique to the health care system. Indeed, the authors draw the inevitable link between poor quality and cost. Five years ago a firestorm was unleashed when the national press, in headline stories,<sup>21</sup> seized upon an as yet unreleased report by the Institute of Medicine which declared that the health care received in America's hospitals is fundamentally unsafe and cited avoidable medical errors in hospitals as one of the leading causes of death in this country.<sup>22</sup> The story is echoed in reports of high profile medical error cases such as that of Jessica Santillan, the young woman whose death was due to an error in matching blood types.<sup>23</sup>

Safety in the health care system is a pervasive and sentinel quality issue, and this concern extends beyond the hospital safety concerns cited in the original IOM report to the omissions of care in the ambulatory care setting. As Beth McGlynn and others have reported, these omissions occur at an alarmingly high rate,<sup>24</sup> and the consequences of these omissions are many: additional procedures, suffering, and years of life lost. Six sigma, a

http://www.cms.hhs.gov/charts/healthcaresystem/all.asp (last modified Oct. 27, 2003).

<sup>19.</sup> The Balanced Budget Act of 1997 contained provisions on payment to physicians. See, e.g., Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 298. Hospitals, often with forty percent or more of their revenue coming from Medicare, saw revenues fall, which created pricing pressure on the private insurance market.

<sup>20.</sup> See, e.g., CTRS. FOR MEDICARE & MEDICAID SERVS., AN OVERVIEW OF THE US HEALTHCARE SYSTEM: TWO DECADES OF CHANGE 1980-2000,

<sup>21.</sup> See, e.g., Bob Davis & Julie Appleby, Medical Mistakes  $\delta^{\wedge}$  Top Killer, USA TODAY, Nov. 30, 1999, at A1.

<sup>22.</sup> For a copy of the report, see INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (2000), http://www.nap.edu/openbook/0309068371/html.

<sup>23.</sup> See, e.g., Dan Vergano, Teen Has 2<sup>nd</sup> Chance After Mismatch Forces 2<sup>nd</sup> Transplant, USA TODAY, Feb. 21, 2003, at A1.

<sup>24.</sup> See Elizabeth A. McGlynn et al., The Quality of Healthcare Delivered to Adults in the United States, 348 New Eng. J. MED. 2635 (2003).

statistically driven approach to process control used by many manufacturers, teaches us that defects or mistakes represent waste, and waste is costly.<sup>25</sup> Manufacturers focus on controlling process to reduce the number of defects and thus the amount of waste in producing a higher yield of reliable goods. Almost by definition, this results in a cost benefit as long as the price of achieving process control is less than the cost of the waste being eliminated.

Another major problem that the authors address is the threat that the uninsured pose to the current system. As employers, particularly small businesses, scale back or even cancel health benefits, the number of uninsured will rise, and, as a voting bloc, they will wield significant political power.<sup>26</sup> Additionally, this will cause an increase in the amount of uncompensated care, the cost of which is currently being shouldered by others who use the system, including employers, payers, and hospitals. Ironically, on a percent of charges basis, the greatest burden is shouldered by those who fully pay their own bills since they do not enjoy the discounts of group purchasers.

Thus, Halvorson and Isham persuasively argue that there are serious problems in the United States health care system as it currently operates. Yet because Halvorson and Isham fail to fully appreciate how these problems influence—and are influenced by—market forces, their solutions are necessarily limited. While they offer the beginnings of needed reform, their recommendations by themselves do not go far enough to cure what ails the U.S. health care system.

#### III. EPIDEMIC'S RECOMMENDATIONS

Solving these problems will undoubtedly require a political solution.<sup>27</sup>

27. The problem of the uninsured presents just one example. Employers have long been too inactive in this arena, but a sizable group of employers, under the auspices of the Human Resources Policy Association (HRPA), have identified this issue as their number one concern and are seeking to tackle it through a collaborative process. For more

<sup>25.</sup> For additional information about six sigma, see http://www.6-sigma.com (last visited May 8, 2004).

<sup>26.</sup> While the uninsured today may be less likely to vote or contribute to political campaigns, it is reasonable to assume that if their number increases and their demographic profile shifts, the issue of coverage may become politicized. For example, if more active, white collar workers lose health benefits and pay for an increasing share of their health care costs, or as retirees find their private or federal health benefits shrinking, they will be more likely to voice their concerns. For further discussion, see HALVORSON & ISHAM, *supra* note 1, at xx-xxvii.

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As they transition toward their discussion of solutions, Halvorson and Isham are correct in dismissing a single payer national health care system solution. Even with age and other demographic adjusters, the United States is an outlier on medical per capital expenses.<sup>28</sup> Beside the vested interests of many incumbent stakeholders, the costs of centrally funding benefits for all Americans would likely prove prohibitive given current expense levels. The ability to control costs would hinge on politically painful decisions such as rationing care. The authors cite the lack of a Medicare drug benefit as proof of the government's willingness to ration care, but the recent passage of the Medicare drug bill may have altered their views.<sup>29</sup> The core of the Medicare drug debate centered around funding, and the design of the final plan was largely crafted to make it affordable and its passage possible. The Medicare drug bill is a study in the political challenges a single payer system would face. Even Senator Hillary Clinton now acknowledges the failures of the Clinton Administration proposal and is instead proposing precisely what the authors suggest in their seventh-and fundamental-initiative: the creation of an electronic medical information infrastructure.<sup>30</sup>

Although Halvorson and Isham list their recommendation to provide electronic medical records (EMR) and aids last, it is actually the most important as it is the critical underpinning of their other six ideas. Improving quality care, their first initiative, as well as ensuring productivity and consistency in the health care system, will be aided by an automated medical record tool that enables access to legible, organized, historical health information at multiple points of care. Additionally, this tool, as envisioned by the authors, will support evidence-based clinical decision processes, provide reminders, and generate data on performance. This data will make it possible to evaluate process, thus providing another opportunity for improvement in the quality of care.<sup>31</sup>

29. HALVORSON & ISHAM, supra note 1, at 145.

30. Senator Clinton made this remark during her keynote address at the World Health Congress in Washington, D.C. on January 25, 2004. For more information about the World Health Congress, see http://www.worldcongress.com (last visited May 8, 2004). For a review of her speech, see Erik Goldman, *Online Claims Processing: Sen. Clinton Eyes EMRs as New Key to Reform*, OB/GYN NEWS, Apr. 1, 2004, at 26.

31. HALVORSON & ISHAM, supra note 1, at 27.

information on the HRPA, see http://www.hrpolicy.org (last visited May 12, 2004).

<sup>28.</sup> For more information, see Org. for Econ. Co-operation & Dev., *Health at a Glance* 2003 - OECD Countries Struggle with Rising Demand for Health Spending, at http://www.oecd.org/document/38/0,2340,en\_2649\_201185\_16560422\_1\_1\_1\_0.html (last visited May 12, 2004).

While an effective EMR tool would be a welcome improvement if available to the broader population, it still falls far short of the goal of aiding the logical clinical decision-making process. Here, Epidemic of Care does not recognize the relevance of market dynamics and making use of those dynamics to ensure the implementation of a more robust use of EMR. Indeed, a truly complete EMR tool will tap into narrative records with their wealth of clinical data; of course, the problems presented by varying nomenclature, as well as the sensitivity and accuracy of observed findings during physical examinations, will need to be solved. Technology is rapidly reaching a point where it can support these aims. However, these tools are not currently widely adopted because there is no compelling incentive for health care providers to create that system for the key stakeholders-whether doctors, patients, hospital administrators, health plans, or employers. Market adoption will depend on creating those incentives and disincentives. Although the authors suggest that additional training or government funding will provide a stimulus to invest in change,<sup>32</sup> there are other factors that are far more likely to create that effect. In particular, a broad and consistent demand for performance measurement, the sharing of comparative information, and differentiating providers and systems based on performance through information, movement of patients, or financial reward are all powerful market tools purchasers and payers have barely begun to use.

EMR and Isham's most important While is Halvorson recommendation, their other six recommendations are also worthy of brief discussion. Halvorson and Isham's first is to improve safety.<sup>33</sup> Given that it intuitively makes sense that improved quality will lower costs, it is unsurprising that this is their first recommendation. While reducing the number of harmful errors and the overuse of procedures would clearly have this effect, Halverson and Isham fail to recognize that since the goal of health care is better outcomes in total for the patient and her family, better quality may mean higher expenditures in some cases.<sup>34</sup> A more

34. For example, a forty-five year old male at risk for a heart attack may reduce his risk by using pharmaco-therapeutic agents and making lifestyle changes. Since his risk of an acute event is not absolute, and the certainty of his fate cannot be determined in advance on an individual basis, he may use the drugs for a lifetime for an event he may never have had, eliminating any return on his investment. Ignoring the impact on mortality and morbidity for a moment, even if he knew with certainty his ultimate fate, the cost of medication and treatment could exceed the cost of treating the acute event and, in the end, is not guaranteed to absolutely avoid it. Prevalence, length of use, cost, adherence to

<sup>32.</sup> Id. at 239.

<sup>33.</sup> Id. at 156.

expensive procedure may be less invasive, mean less disfigurement, or offer greater diagnostic certainty. Patients may define this as better quality, even if the outcome is unchanged. The cost of lifetime medication to prevent a fatal event in a population at risk may exceed the cost of caring for the minority who would suffer an event. While some economists argue that these improvements lead to increased longevity and productivity that exceed the medical expense by a factor of three or more,<sup>35</sup> this is a difficult analysis to prove and requires many unknown assumptions.<sup>36</sup> Additionally, because the recipient of health benefits is often not the one who pays for those benefits, conventional cost-benefit analyses no longer hold, and our notions of supply and demand curves must account for a system with three (and sometimes even more) stakeholders. Nothing in the cost/quality equation is helpful in dealing with the added expense of new, highly effective, but expensive technology. While the authors identify this as an issue,<sup>37</sup> they do not adequately address it in their recommendations.

Halvorson and Isham's second proposal to ameliorate the current crisis—turn the patient into a consumer<sup>38</sup>—is also not fully grounded in the dynamics of the market. They cite the proliferation of the Internet and the high hit rate of medical information sites as proof that patients are interested in being better informed and becoming actively engaged in medical decision making on issues such as choice of health plans, providers, and therapies.<sup>39</sup> This is likely true, but given the wealth of information available, its adoption and use by consumers seems underwhelming.<sup>40</sup> Part of the problem may be that the historical lack of

indications for use, the predictive capability of screening measures, and the efficacy of an intervention including its unintended consequences or adverse side effects all determine if an intervention is in fact cost effective.

<sup>35.</sup> See, e.g., David M. Cutler, The Real Medicare Conundrum, Presentation to the Medical Technology Leadership Forum (Feb. 2004), at

http://www.mtlf.org/events/pdf/cutler\_Presentation.pdf (last visited May 8, 2004).

<sup>36.</sup> For example, Cutler's analysis relies on a set of assumptions about death and disability rates and potential earning power and an ideal application of therapeutic interventions. If these assumptions were to change, so would the return on investment he estimates.

<sup>37.</sup> HALVORSON & ISHAM, supra note 1, at 40.

<sup>38.</sup> Id. at 99.

<sup>39.</sup> For a discussion of the role of the Internet in medical care, see HALVORSON & ISHAM, *supra* note 1, at 99-108.

<sup>40.</sup> Internet site visit rates or "hits" should not be taken as proof that consumers are factoring what they read on those sites into their decision making in a substantive way. In addition unless we track reasons for usage, we do not know the reasons they visit these sites:

relevancy of consumer information about health care has stymied adoption.

More importantly, consumer health care decisions are emotive as well as cognitive; not all individuals approach decision making in the same way, and under different circumstances the same individual may place different weights on what they value. For example, what one is willing to do for a terminally ill child may differ from what one would be willing to do for oneself in the same condition. The difference in risk between one health care choice versus another may seem small in the eyes of a consumer. But in a heavily personalized transaction it may well be that people value trust and the personal relationship highly. The argument for providing as much relevant and timely information as is feasible to consumers is strong. Some will use it and benefit from it; others will not, but will at least have had the opportunity to do so. If the goal is to influence patient decision making, we may need tools that go well beyond the cognitive in order to reach patients and address their more fundamental needs. To not anticipate this is to be disappointed by the results. The drug makers who are successful in their direct advertising appeal to consumers do this well, albeit to improve sales, as do the makers of soap, coffee, and many other consumer commodities.

The third initiative, improving population health, is addressed through the development of local community prevention goals.<sup>41</sup> Setting prevention targets for health plans is a bold and laudable move especially for primary prevention efforts. The authors should also recognize the need for public accountability in this regard and the benefit of community-wide actions. The authors cite the obesity epidemic as an opportunity for prevention efforts,<sup>42</sup> but do not fully incorporate the way we work and play, the food choices most widely promoted, and the relevant community resources and social factors, all of which are tied into the obesity problem. In addition, the authors have omitted the few relevant examples where market-based forces have changed individual behavior. Johnson and Johnson pioneered research in providing individuals with financial and other incentives to adopt healthier lifestyles with some reported success.<sup>43</sup>

We do not know if they use them to research personal questions, questions for family members, or if they are simply looking for general information.

<sup>41.</sup> HALVORSON & ISHAM, supra note 1, at 199.

<sup>42.</sup> Id. at 195.

<sup>43.</sup> Ronald Ozminkowski et al., Long-term Impact of Johnson & Johnson's Health & Wellness Program on Health Care Utilization and Expenditures, J. OCCUPATIONAL & ENVTL. MED, Jan. 2002, at 21.

is a schedule of rewards, very much like frequent flyer points, which can be earned for certain behaviors and then redeemed for tangible items.<sup>44</sup> Such designs are still novel and their effectiveness is not yet proven, but they are intriguing in the context of creating new benefit designs with market incentives (beyond the goal of improved health) for the patient.

As the authors point out in their explanation of the fourth initiative, consolidation was a predictable response to market forces.<sup>45</sup> As payers became larger and began to demand deeper discounts, providers responded through a series of mergers and acquisitions to protect their slim margins. Unfortunately for Halvorson and Isham, it may be too late for antitrust efforts to remedy the problem in many markets. The government is partly culpable not only because of the judiciary's unwillingness to enforce antitrust law,<sup>46</sup> but also because of its role as a purchaser who sets the price in the marketplace. In the future, the government must behave responsibly and use its leverage to further performance reporting and create performance-based rewards. For example, CMS could provide direct payments to any providers that improve outcomes in a pre-determined set of clinical performance measures. Other purchasers then need to follow suit and push for reporting at the facility and provider level.

As mentioned above, the issue of the uninsured—initiative five—is incredibly complex, and Halvorson and Isham have proposed a piecemeal approach that would alleviate, but not solve, the problem.<sup>47</sup> Their ideas are based on the fact that all uninsured are not equal. In particular, the chronically uninsured account for about half of the national number. To prevent corporations from dropping or drastically reducing coverage for some employees, Halvorson and Isham suggest a "pay or play" model that would require all employers to make a contribution toward health coverage for each employee.<sup>48</sup> However, this sort of mandated change is likely to be vigorously resisted by small employers.<sup>49</sup> Similarly, it may be

http://www.ncqa.org/Programs/bridgestoexcellence/index.htm (last visited May 8, 2004).

<sup>44.</sup> Bridges to Excellence (BTE) is an employer sponsored initiative which aims to reward physicians and patients for adhering to a set of evidence-based clinical practices in managing chronic conditions such as diabetes and cardiovascular disease. Rewards for physicians are based on qualification under the NCQA/DPRP program. For more information, see Bridges to Excellence, *at* 

<sup>45.</sup> HALVORSON & ISHAM, supra note 1, at 81.

<sup>46.</sup> Id. at 80.

<sup>47.</sup> Id. at 219-21.

<sup>48.</sup> Id. at 229.

<sup>49.</sup> This opinion is based on the reasonable assumption that small employers are less

politically untenable to publicly fund even a minimum set of benefits for the working poor. Such an action removes much of the motivation from the employers who currently fund such programs for low wage earners. Vouchers which would capitalize on private markets for supplying insurance or care and which would limit the financial liability of the government might have more political traction.<sup>50</sup> In today's political climate, one that seems ill-suited to addressing the needs of the uninsured, the system of utilizing and expanding community-based clinics is likely to be the most practical, although limited in its impact given current resource allocation.<sup>51</sup> However, the initiation of change in any of these policies will require both broad purchaser support and organized lobbying by the medical community. Unfortunately, there is no ready prescription for getting this to happen. Hospitals will likely continue to watch their payer mix and devise strategies to avoid being swallowed by the cost, and the current system will continue providing care until it becomes untenable.

The sixth initiative is aimed primarily at reducing the impending shortages in many health care fields and calls for government to fund training. More importantly it calls for research and support for the "reengineering" of health care.<sup>52</sup> Most industries that embark on this kind of change do so because there is a critical business imperative.<sup>53</sup> That does not exist in health care—yet. The good news is that there is precedent for this kind of government funding. Taxpayer dollars have been used, not always prudently, to support key industries and maintain a technical advantage both in defense and in health research.<sup>54</sup> Such a mechanism could be used

51. Capitalizing on an existing structure of publicly funded clinics may prove more practical, since new funding may not be required if these clinics have unused capacity or could inexpensively be offered as an option to those meeting income requirements.

52. HALVORSON & ISHAM, supra note 1, at 233-40.

53. For example, U.S. automotive manufacturers responded to the competitive threat of imported makes with higher levels of quality by changing quality control, design engineering, and manufacturing processes and ultimately improving the quality and reliability of American manufactured automobiles.

54. Examples include the National Institute of Health (NIH), the space program, weapons development, the formation of the RAND corporation in the 1940s in response to

equipped to absorb additional costs relating to health care since many currently do not offer or subsidize health insurance to their employees. For more information about small business owners and health care coverage, see Kaiser Family Found., *National Survey of Small Businesses, at* http://www.kff.org/insurance/20020402a-index.cfm (2002).

<sup>50.</sup> This statement is based on the historical lack of political action to support the uninsured working poor and the current environment that exhibits reluctance to fund new or additional entitlements for the poor.

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here, but as a nation we seem divided over how to view our health care delivery infrastructure. Is it a public resource or a private industry? The recent bio-terrorist threats certainly exposed fault lines in our thinking about public health resources. Will market forces provide adequate incentives and coherent direction to produce meaningful change? We know we need hospitals and physicians, like fire stations, to be available and prepared to respond in a crisis; but unlike most fire stations, we have not yet decided how to fund them or make them completely adequate to the task. Most care processes have not been engineered for efficiency. As hospitals nurse thin margins and competitive forces siphon off profitable procedures, a new urgency and focus on process efficiency may evolve. Another catalyst may be the growing demand for comparative efficiency measures.<sup>55</sup> The ultimate marriage of reliable effectiveness and efficiency measures will provide a powerful vehicle for channeling patients and rewards and creating a strong market incentive for improvement.

### **IV. CONCLUDING THOUGHTS**

Not only does *Epidemic of Care* fail to incorporate the realities of market dynamics in its proposed solutions, but it also fails to mention several promising market-based efforts to promote better care. For example, the Bridges to Excellence program sponsored by GE, Ford, UPS, Verizon, and other large employers in concert with health plans such as Humana, United Healthcare, and others focuses on improved diabetic care in three markets and supports the adoption of automated clinical office tools to improve care.<sup>56</sup> It relies on the American Diabetes Association/National Committee for Quality Assurance (ADA/NCQA) physician recognition program to achieve better outcomes and uses both benefit design and patient incentives to achieve results. In fact, the authors cite the ADA/NCQA program favorably.<sup>57</sup> It is one of a handful of programs that pays physicians in the form of an annual per patient bonus based on clinical performance.

the need for technological superiority in war, and, more recently, the support of the airline industry following 9/11.

<sup>55.</sup> Examples of this growing demand include employer initiatives such as the Leapfrog Group, which plans to look at efficiency measures in addition to quality outcomes. For more information, see The Leapfrog Group, *at* http://www.leapfroggroup.org (last visited May 13, 2004)

<sup>56.</sup> See Bridges to Excellence, Overview, at

http://www.bridgestoexcellence.org/bte/bte\_overview.htm (last visited May 13, 2004).

<sup>57.</sup> HALVORSON & ISHAM, supra note 1, at 22.

In addition, there is a wealth of activity in the marketplace focused on the broad provider community. The National Quality Forum created under the Clinton Administration has worked to endorse valid quality and safety measures for the industry.<sup>58</sup> Some large national plans, such as United Healthcare, are adopting these measure sets and actively encouraging their collection and dissemination.<sup>59</sup> CMS has been active in piloting quality performance demonstration projects and voluntary hospital measure collections and in paying for performance initiatives.<sup>60</sup>

Other efforts driven largely by national self-insured employers are pushing for provider level quality and efficiency measures. One of the most notable is the Leapfrog Group, a consortium of over 150 large employers who banded together initially to promote hospital safety through public reporting about three important "leaps." Responding to the Institute of Medicine report, To Err Is Human, which attributed between 44,000 and 100,000 deaths in hospitals to avoidable medical errors, <sup>61</sup> the Leapfrog Group adopted three initial "leaps" correlated with lower incidences of avoidable medical errors.<sup>62</sup> They asked hospitals to report on intensivist staffing and rounding in intensive care units, adoption of computerized order entry to reduce the number of drug errors, and the number of a select group of surgical procedures performed in each hospital annually. Each leap is measurable, attainable, and capable of producing safety and outcome improvements immediately. It is curious that the authors, who must have been familiar with this national effort, chose not to explore this market based initiative in their discussion of safety. It is arguable that many of the quality initiatives that followed, such as the partnership on voluntary reporting of hospital performance measures sponsored by CMS, JCAHO, and the AMA may have been directly influenced by the pressure of Leapfrog.<sup>63</sup>

<sup>58.</sup> See Nat'l Quality Forum, About the National Quality Forum, at http://www.qualityforum.org/about/home.htm (last visited May 13, 2004).

<sup>59.</sup> For general information on UnitedHealth Group, see

http://www.unitedhealthgroup.com/ (last visited May 22, 2004).

<sup>60.</sup> See, e.g., Ctrs. for Medicare & Medicaid Servs., Premier Hospital Quality Incentive Demonstration, at http://www.cms.hhs.gov/researchers/demos/phqidemo.asp (last visited May 13, 2004).

<sup>61.</sup> INST. OF MED., supra note 22, at 1.

<sup>62.</sup> See The Leapfrog Group, Fact Sheet, at

http://www.leapfroggroup.org/FactSheets/LF\_FactSheet.pdf (last visited May 13, 2004).

<sup>63.</sup> For more on the voluntary reporting of hospital performance measures sponsored by CMS, JCAHO, and AMA, see Ctrs. for Medicare & Medicaid Servs., *Hospital Quality Initiative, at* http://www.cms.hhs.gov/quality/hospital/ (last visited May 13, 2004).

The results can be heartening. One integrated care system in Virginia estimates that their new electronic intensive care unit will improve care while generating nearly two million dollars in cost savings.<sup>64</sup> The ultimate impact of these efforts is yet to be measured in full, but would seem to be significant as adoption spreads. It is against this background that the seven recommendations for new initiatives should be weighed. Efforts to improve quality and safety will benefit from provider level data, but comparative data for plans will evolve from the HEDIS-like data of the past and will begin to focus not on average performance, but on how many patients receive the correct care and how efficiently this care is provided. Plans will be held accountable for encouraging reporting on critical measures and for supporting processes that improve care. It is as yet unclear how large a role government funding will play in supporting these efforts, but cost will be an issue, and the cost is likely to be born in part by purchasers. Agency funding has begun enabling research to help this effort.

The authors have also omitted another common argument in discussions about changing the current system of health care delivery. According to economist Milton Friedman, today's system is an aberration of market forces because it is structured around a tax code favoring employers over individual purchasers of health insurance.<sup>65</sup> If individuals could claim the same deductions for health insurance that corporations currently do, a very different market would exist. Friedman may well be right. Products that have not yet been offered, such as an evidence-based benefit design that would pay differentially for highly effective treatments, or share more of the cost of treatment based on the known potential clinical benefit, have not yet been tried and could help shape the market.

For any solution to be successful, it will have to be feasible in today's environment of a dispersed, fee-for-service marketplace with a fragmented physician corps and an increasingly consolidated hospital and specialist system. These are not trivial considerations. Given this, Halvorson and Isham have achieved the goal of providing a clarion call for action and in dismissing the notion that a single payer system is a tenable solution for this nation's health care woes. The seven initiatives that they propose are important and should be recognized as steps in the right direction. The most glaring problem with *Epidemic of Care*, however, is that it fails to

<sup>64.</sup> Cinda Becker, *Telemedicine System Helps Manage ICUs*, MODERN HEALTHCARE, Sept. 4, 2000, at 62.

<sup>65.</sup> See, e.g., Milton Friedman, *How To Cure Healthcare*, THE PUBLIC INTEREST (2001), http://www.thepublicinterest.com/archives/2001winter/article1.html (last visited May 13, 2004).

recognize something that is of critical importance in assessing the feasibility and effectiveness of suggested reforms in the United States: The market matters. Had they recognized that fact and modified their recommendations accordingly, their call to action could have been much more; indeed, it could have served as a roadmap to implementation and, ultimately, to change.