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Does Being a Repeat Player Make a Difference? The Impact of Attorney Experience and Case-Picking on the Outcome of Medical Malpractice Lawsuits

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INTRODUCTION

Empirical analyses explaining litigation outcomes are not often attempted either in legal scholarship or in the sociology of law.[1] There are studies focusing on conversation analysis in mediation, but few other empirical issues in litigation have been examined in depth.[2] In addition, there is little theory addressing the causes of litigation outcomes in legal scholarship.[3] Similarly, there are few micro-level studies or theories in the sociology of law, other than that of Donald Black, that address the litigation process.[4]

There are several reasons for the dearth of studies. Determining outcomes of actual, filed civil cases is difficult, tedious, and time-consuming. There are few databases from which samples may be drawn in a systematic way. Cases must be identified. Court records must be found, read, and abstracted. Critical information about cases is often not a part of the court file. For example, official court records seldom state whether a monetary settlement was reached, and, if so, the terms of that settlement. Instead, court records merely indicate either that the court rendered a judgment or dismissed the case. Why the case was dismissed, or on what terms the case was dismissed, is seldom disclosed.

Nonetheless, there is a great need for the insights to be gained from empirical studies based on court records supplemented by additional sources such as archival data, questionnaires, and interviews. Such studies could lead to a richer understanding of the conflict resolution process as it is conducted in the civil court system. The work of Miller and Sarat provides an example.[5] More than twenty-five years ago, Miller and Sarat described the litigation process in the larger context of what they called the "dispute pyramid," with layers of grievances, claims, disputes, filings (involving lawyers), court filings, trials, and

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1. There are a few exceptions, notably the work of Herbert Kritzer. However, Kritzer himself noted that there are few such studies. HERBERT KRITZER, LET'S MAKE A DEAL 131 (1991).

2. Angela Garcia, *Moral Reasoning in Interactional Contexts: Care and Justice Arguments in Mediation Hearings*, 66 SOC. INQUIRY 197 (1996); David Greatbatch & Robert Dingwell, *Argumentative Talk in Divorce Mediation Sessions*, 62 AM. SOC. REV. 151 (1997).

3. Marc Galanter is one of the few legal scholars who have offered a theoretical frame for understanding case outcomes from a socio-legal perspective. Galanter has pointed out that there is an awareness that little is known about how the tort liability system actually operates. Marc Galanter et al., *How To Improve Civil Justice Policy*, 77 JUDICATURE 185 (1994); Marc Galanter, *Real World Torts: An Antidote to Anecdote*, 55 MD. L. REV. 1093, 1098 (1996) [hereinafter Galanter, *Real World Torts*]; *see also* Michael Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1154-55 (1992).

4. Donald Black, *Dreams of Pure Sociology*, 18 SOC. THEORY 343 (2000); *see also* M.P. Baumgartner, *The Sociology of Law in the United States*, 32 AM. SOC. 99 (2001).

5. Richard Miller & Austin Sarat, *Grievances, Claims and Disputes: Assessing the Adversary Culture*, 15 LAW & SOC'Y REV. 525 (1981).

appeals. They discussed the process of case attrition,[6] and noted that this attrition may be pronounced.[7] The result resembles a pyramid, with only the most durable cases rising through each layer to reach the top. The shape of the dispute pyramid varies by type of case, but what all these pyramids have in common is that very few cases survive to the apex—a pattern supported by considerable empirical evidence.[8] Many, but not all, cases settle for money being paid to the plaintiff. Other cases are simply dropped prior to trial without any money being paid to the plaintiff. Thus, a successful plaintiff's lawyer must have the ability to select cases that are likely to settle or, if a trial occurs, that are likely to result in a plaintiff's verdict.[9]

Lack of understanding of the meaning or significance of various stages of the legal process impedes sociologists and social scientists in their attempts to analyze litigation. By their training, lawyers understand civil procedure—how a complaint is filed, how the lawsuit develops, how discovery works, how cases move towards resolution, how settlement happens, etc. To a sociologist or other social scientist, however, these processes may seem baffling, needlessly complicated, or obscure. Without a background in legal process, a researcher may not know what to investigate when she begins reading court records. But research conducted by lawyers or law professors suffers from serious shortcomings as well. Legal scholars rarely have expertise in empirical research methodologies or familiarity with the more systemic issues social scientists explore. A filed case is, after all, just a part of a larger puzzle. Why did some disputes between a patient and a physician turn into lawsuits? When a lawsuit is filed, what factors predict outcome? While lawyers, and perhaps physicians, may prefer to believe the merits alone predict outcome, there is ample reason to believe that the story is more complicated.[10] For these sorts of questions, the analytical methods of sociologists become very valuable. Sociologists use a combination of theory, methods, and statistics to understand the impact of variables that influence behavior within a social system. In short, sociologists are trained to look for patterns.

Medical malpractice involves "turf conflicts" between professions and raises related organizational issues.[11] These are areas in which sociologists have

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6. Case attrition is inevitable. Disputes may be resolved prior to the retention of attorneys or conduct of a trial.

7. Miller & Sarat, *supra* note 5, at 544-46.

8. KRITZER, *supra* note 1, at 178; Herbert Kritzer, *Contingent Fee Lawyers As Gatekeepers in the Civil Justice System*, 81 JUDICATURE 22, 29 (1997); Miller & Sarat, *supra* note 5, at 544-46.

9. For a discussion of dispute pyramids, see Galanter, *Real World Torts*, *supra* note 3, at 1099-1102.

10. *See, e.g.*, Catherine Harris, Ralph Peeples & Thomas Metzloff, *Placing "Standard of Care" in Context: The Impact of Witness Potential and Attorney Reputation in Medical Malpractice Litigation*, 3 J. EMPIRICAL LEGAL STUD. 467, 470 (2006).

11. Ralph Peeples, Catherine Harris & Thomas Metzloff, *Settlement Has Many Faces: Physicians, Attorneys and Medical Malpractice*, 41 J. HEALTH & SOC. BEHAV. 333, 343-44 (2000).

expertise. Clearly the disciplines of law and sociology have much to offer each other, particularly in the context of medical malpractice. A medical malpractice claim typically involves a challenge to the competency of a member of a learned profession (medicine). Thus, it raises the question of who should assess the merits of the claim: a fellow member of the profession, another physician, or an "outsider," such as a judge or a jury. This is the sort of conflict sociologists are trained to study. By contrast, a claim of medical malpractice is seen by lawyers as a tort, based on negligence. Torts and claims of negligence are the province of the law and the courts. By combining the perspectives of both disciplines, we can get sharper pictures of the litigation process, its problems, and potential solutions. However, until either social scientists or legal scholars gain a thorough understanding of the other field, there will be little fruitful cross-disciplinary analysis. Signs that legal scholars are embracing empirical studies are therefore very promising.

Identifying a theory of litigation that is accessible to both sociologists and lawyers is not easy. After all, almost everything written on how the litigation process functions takes a rules-based (civil procedure) perspective. This is an approach with which lawyers would be more comfortable than sociologists. One of the few theories that address the dynamics of litigation without reference to traditional legal rules is Galanter's seminal discussion of "repeat players."[12] Galanter argues that attorneys acting as repeat players have advantages in the legal system that others do not. These advantages include an understanding of legal rules, ready access to specialists who can provide expert testimony, more readily available information about cases, and lower start-up costs. Daniels and Martin have recently argued, on the basis of data from Wisconsin and Texas, that repeat players within the medical malpractice plaintiffs' bar do exist, and that these repeat players tend to do better than non-repeat players.[13]

Understanding the litigation process of medical malpractice has practical and political, as well as academic, implications. An ability to seek redress for a perceived medical injury is important, but medical malpractice litigation, by its nature, is very expensive. Repeat players may perform a useful function in identifying truly meritorious cases. Interest in medical malpractice reform tends to be cyclical. The level of interest among legislators, scholars, and medical professionals tends to rise dramatically after a crisis, real or perceived, in the availability and cost of malpractice insurance.[14] In addition, questions relating to

12. Marc Galanter, *Why the "Haves" Come out Ahead: Speculation on the Limits of Legal Change*, 9 LAW & SOC'Y REV. 95, 97-102 (1974).

13. Stephen Daniels & Joanne Martin, *Plaintiffs' Lawyers, Specialization, and Medical Malpractice*, 59 VAND. L. REV. 1051, 1059-60 (2006).

14. *See* Ralph Peeples & Catherine Harris, *Learning To Crawl: The Use of Voluntary Caps on Damages in Medical Malpractice Litigation*, 54 CATH. U. L. REV. 703, 704 (2005); William M. Sage, *Understanding the First Malpractice Crisis of the 21st Century*, *in* HEALTH LAW HANDBOOK 1-4 (Alice G. Gosfield ed., 2003); David M. Studdert, Michelle M. Mello & Troyen A. Brennan, *Medical Malpractice*, 350 NEW ENG. J. MED. 283, 284-85 (2004).

the resolution of medical malpractice claims point toward larger issues of health care reform. Although the incidence of medical error far exceeds the rate at which claims are made against physicians and hospitals, the sum of payments made in resolution of malpractice claims is substantial.[15] For example, in 2006, almost 12,500 reports of payments on behalf of physicians were submitted to the National Practitioner Data Bank (NPDB).[16] The mean payment was $308,817, and the median payment was $175,000; the total of payments reported on behalf of physicians was nearly $3.9 billion.[17] When the associated "transaction costs" of claims adjusting, expert opinions, and attorneys' fees are included, the cost of managing medical malpractice claims grows substantially.[18]

Lawyers play a critical role in the process of resolving medical malpractice claims. Understanding this role is a necessary condition for reforming the system. Certainly, lawyers are important because they represent both parties. The parties expect their lawyers to make recommendations regarding settlement offers and trial. Plaintiffs' lawyers also perform a screening function. A lawyer is not required to take a civil case. Because plaintiff's lawyers are customarily compensated on a contingency fee basis,[19] the potential client must present a case that, in the lawyer's estimation, has some potential monetary value. Otherwise, the lawyer will collect no fee. For this reason, potential plaintiffs with weak cases may be unable to find representation.[20] Defense counsel performs a similar, but distinct, screening function. Although defendants' counsel is usually paid on an hourly basis, the client's insurer expects an honest assessment of the likelihood of prevailing if the case goes to trial. Because the defense counsel wishes to receive future cases from the insurer, she has the incentive to assess the viability and value of a particular claim accurately. Thus, for both plaintiffs' and defense counsel, an ability to assess cases accurately is important. Being able to pick cases that are likely to result in settlement or award is a particular concern for plaintiff's counsel.

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15. PATRICIA M. DANZON, MEDICAL MALPRACTICE 19-29 (1985); PAUL WEILER ET AL., A MEASURE OF MEDICAL MALPRACTICE 128-29 (1993). *See generally* COMM. ON QUALITY OF HEALTHCARE IN AM., INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 42-43 (Linda T. Kohn et al. eds., 2000) (summarizing a number of studies that estimate the costs of medical errors).

16. U.S. Dep't of Health & Human Servs., National Practitioner Data Bank, http://www.npdb-hipdb.hrsa.gov/publicdata.html (last visited Apr. 28, 2008) [hereinafter NPDB]. The NPDB was established by Congress in Title 4 of the Health Care Quality Improvement Act, Pub. L. No. 99-660, 100 Stat. 3784 (1986) (codified at 42 U.S.C. § 11101 (2000)). The Act requires that any amount paid by an insurer on behalf of a physician must be reported to the NPDB. *Id.* Whether liability was ever established is not relevant. Thus, both judgments and monetary settlements must be reported.

17. NPDB, *supra* note 16.

18. Studdert, Mello & Brennan, *supra* note 14, at 285-86.

19. PAUL WEILER, MEDICAL MALPRACTICE ON TRIAL 62 (1991).

20. *See* David A. Hyman & Charles Silver, *Medical Malpractice Litigation and Tort Reform: It's the Incentives, Stupid*, 59 VAND. L. REV. 1085, 1102-03 (2006).

Liability insurers also play a central role in medical malpractice disputes. In return for a premium, an insurer provides the insured physician with a defense lawyer and pays any indemnity resulting from settlement or trial, up to the limits of the policy.[21] At the start of the medical malpractice litigation process, an individual patient, the patient's representative, or the patient's lawyer makes a claim. The claim can be simply a written demand for payment, or it can first appear as a summons and complaint, signaling that a lawsuit has been filed. One of the insurer's own staff, usually a claims adjuster, then makes an evaluation of the claim's merits. Medical records are obtained and customarily sent out for review by other physicians whose specialty is the same or similar to that of the insured physician. If the matter appears likely to result in litigation, or if a complaint has already been filed, the insurer retains defense counsel for the physician and arranges for expert witnesses. If the patient files a complaint, depositions of the plaintiff, treating physicians, defendant, and experts for both sides are scheduled and conducted. At any point in the process, either side may initiate settlement discussions. The settlement discussions typically focus on predicting the likely outcome if a trial were held, both as to verdict and as to damages. If the sides cannot settle, the case proceeds to trial.

In a previous article we argued that factors other than an assessment of liability, such as the perceived witness potential of the plaintiff and the defendant, as well as the reputation of the plaintiff's counsel, are frequently taken into account by the insurer in deciding whether to seek a settlement before trial.[22] We have also argued that the insurer's decision to seek a settlement is crucial—when an insurer makes an offer, any offer, the chances are very high that the case will settle.[23] In this Article, we examine another factor, apart from liability: the experience and case-picking ability of plaintiff's counsel.

This Article is the result of an interdisciplinary effort in which data were collected from court records and other archival sources, supplemented by a limited number of questionnaires and interviews with attorneys (both defense and plaintiffs' counsel in the cases we studied). Building on the work of Galanter, we explore the question of whether the experience of opposing counsel affects medical malpractice case outcomes. We look at this question in the context of the case, including severity of alleged injury, whether there was a trial and, for a limited number of cases, insurers' and plaintiffs' counsel's assessment of liability.

In Part I of this Article, we survey the literature that addresses the predictors of outcome in medical malpractice cases. We note that the characteristics of

21. Different insurance companies insure physicians in different parts of the country. Although the process we describe here is based on our observations in North Carolina, we believe this process is typical for most professional liability insurers.

22. Harris, Peeples & Metzloff, *supra* note 10.

23. Ralph Peeples, Catherine Harris & Thomas Metzloff, *The Process of Managing Medical Malpractice Cases: The Role of Standard of Care*, 37 WAKE FOREST L. REV. 877 (2002).

counsel are rarely considered. We argue that in order to understand the litigation process, the impact of lawyer competence and skill needs to be addressed.

Part II explains the steps in our statistical analysis. Our dependent variable is whether money is paid to the plaintiff. There are three categories of independent variables: relevant experience, case context, and insurers' assessment of liability. We begin with a bivariate analysis, move to a multivariate analysis, and finally, in order to understand the relationships among variables, do a series of cross-tabulations, introducing an attorney effectiveness variable.

In Part III, we describe our sample and the variables we used to measure attorney effectiveness. In Part IV, we report our findings. We find that, consistent with our previous research,[24] the insurer's assessment of liability as probable or uncertain predicts whether money is paid to the plaintiff. An in-depth look at the impact of attorney effectiveness and malpractice case experience reveals that more effective attorneys are more likely to settle and less likely to go to trial. If the defense and plaintiff's counsel agree about liability, and liability is probable or uncertain, the plaintiff is more likely to be paid. Finally, plaintiffs' lawyers who handled at least four malpractice cases and who were successful in obtaining money for their clients during the study period are more likely to agree with the insurer's assessment and their clients are more likely to be paid.

In Part V, we discuss our findings in the context of previous literature. In short, attorney experience and skill matter. In this small sample, the ability to pick cases (i.e., to assess them as the insurer does) is associated with effectiveness—experience and skill. We conclude with suggestions for future research and policy implications.

I. PREDICTORS OF OUTCOME IN MEDICAL MALPRACTICE CASES: PREVIOUS LITERATURE

Does counsel make a difference for medical malpractice case outcomes? In other words, does it matter who the plaintiff's lawyer is and who the defendant's lawyer is? Not every observer thinks so. Some earlier work in the area of medical malpractice litigation suggests that the identity of the lawyers does not really matter. For example, Taragin et al. concluded that compensation for medical malpractice claims is closely associated with probable liability, as determined by peer (i.e., fellow-physician) review.[25] Similarly, studies by Sloan and Hsieh[26] and by Farber and White[27] found a connection between negligence, as determined by

24. Harris, Peeples & Metzloff, *supra* note 10.

25. Mark I. Taragin et al., *The Influence of Standard of Care and Severity of Injury on the Resolution of Medical Malpractice Claims*, 117 ANNALS INTERNAL MED. 780 (1992).

26. Frank A. Sloan & Chee Ruey Hsieh, *Variability in Medical Malpractice Payments: Is the Compensation Fair?*, 24 LAW & SOC'Y REV. 997 (1990).

27. Henry S. Farber & Michelle J. White, *Medical Malpractice: An Empirical Examination of the Litigation Process*, 22 RAND J. ECON. 199 (1991).

physicians, and compensation. It follows that the central event in a rational system of compensation is the determination of medical fault by a panel of experts based upon a review of the relevant records.[28] In this account the relative competence and skill of the lawyers for the plaintiff and defendant does not matter greatly, particularly if a schedule of compensation for specified injuries is used.[29] Members of the medical, not legal, profession make the key determination of medical fault.[30] Still, the fit between fault and compensation has never been exact.[31]

Using a different model, Brennan et al. argue that compensation is connected to severity of injury, defined in terms of temporary or permanent disability—but not much else.[32] Recent reviews of the published studies of medical malpractice have concluded that the findings of Brennan et al. are inconsistent with virtually every other study on the subject.[33] Still, if Brennan et al. are correct that severity of injury is the crucial variable, the role of lawyers would not be critical to the outcome of the case. Thus, if medical liability, severity of injury, or some combination of the two adequately predicts payment, it seems that the dynamics of lawyer confrontation may not matter.

Even if negligence and medical liability predict payment, however, that would not mean lawyers have no role. First, even if negligence determines compensation, negligence may be determined by non-physicians (e.g., a lay jury), giving lawyers a role in the process. Second, even if liability predicts payment, liability is not always reducible to a simple yes or no question. Sometimes the key medical facts are subject to interpretation. Sometimes the appropriate course of treatment is a matter of professional debate. Sometimes different reviewers reach different conclusions, even when presented with identical information—whether the reviewers are physicians, insurers, lawyers, or laypersons. As a result, for better or worse, lawyers play a pivotal role in the determination of liability. Finally, there is an informational disparity with respect to "liability": The insurer will know more about potential liability than the plaintiff's attorney will. After all, the insurer may be able to get the unvarnished truth from the doctor, but the plaintiff probably cannot. Thus, for any given claim for compensation, the predictive value of a model based on liability is quite

28. Taragin et al., *supra* note 25, at 783.

29. *See* Catherine T. Harris, Ralph Peeples & Thomas B. Metzloff, *Who Are Those Guys? An Empirical Examination of Medical Malpractice Plaintiffs' Attorneys*, 58 SMU L. REV. 225, 227 (2005).

30. To a substantial extent, this has long been the case. Most medical malpractice claims rely on the testimony of experts, who are invariably physicians and who typically practice in the same field. *See* DAN B. DOBBS, THE LAW OF TORTS § 246, at 639 (2000).

31. Harris, Peeples & Metzloff, *supra* note 10, at 470.

32. Troyen A. Brennan, Colin M. Sox & Helen R. Burstin, *Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation*, 335 NEW ENG. J. MED. 1963 (1996).

33. *See infra* note 35.

limited, at least from the plaintiff's point of view. This is especially true for claims where fault is neither clearly present nor unquestionably absent.

Severity of injury is different. Unlike liability, which represents a reasoned conclusion based on the facts presented, severity of injury is merely an objective attribute of a case.[34] As a result, severity needs to be understood in context and considered in connection with other case attributes, taking into account the experience of opposing counsel.[35]

On the surface, the conclusions of Taragin et al.,[36] who see the crucial variable as assessment of liability, and Brennan et al.,[37] who argue that the crucial variable is severity of injury, seem inconsistent. Severity of injury, as identified by Brennan et al., bears no necessary connection to liability, as described by Taragin et al. We argue that both conclusions present an incomplete picture of the process of medical malpractice litigation, especially since there is evidence that physicians who have been sued do not necessarily agree that they were liable.[38] One might speculate that doctors may not objectively assess their own potential liability.

Over the past several years, a consensus has emerged among academic observers that the medical malpractice system operates, overall, in a rational and predictable way.[39] There is a clear connection between the quality of the case, expressed in terms of likely liability, and compensation. Despite this apparent rationality, some questions remain. The fit between quality and outcome is imperfect. Other factors, such as the expertise of counsel, need to be examined more closely.

As Heinz and Laumann observed almost thirty years ago, the profession of law is less studied and less understood than the profession of medicine.[40] This pattern has not changed. While studies occasionally address issues of professional stratification[41] and specialization,[42] few studies have considered the

34. FRANK A. SLOAN ET AL., SUING FOR MEDICAL MALPRACTICE 22-24 (1993) (describing the National Association of Insurance Commissioners (NAIC) scale for severity of injury, which uses a nine-point scale classifying from (1) emotional only to (9) death).

35. *See* Hyman & Silver, *supra* note 20, at 1094-1100; Philip G. Peters, Jr., *What We Know About Malpractice Settlements*, 92 IOWA L. REV. 1783, 1803 (2007); *see also* Tom Baker, *Reconsidering the Harvard Medical Practice Study Conclusions About the Validity of Medical Malpractice Claims*, 33 J.L. MED. & ETHICS 501, 502-06 (2005).

36. Taragin et al., *supra* note 25.

37. Brennan, Sox & Burstin, *supra* note 32.

38. Peeples, Harris & Metzloff, *supra* note 11, at 333.

39. *See, e.g.*, Hyman & Silver, *supra* note 20, at 1087; Peters, *supra* note 35, at 1831-32.

40. John P. Heinz & Edward O. Laumann, *The Legal Profession: Client Interests, Professional Roles, and Social Hierarchies*, 76 MICH. L. REV. 1111, 1111-12 (1978).

41. JEROME E. CARLIN, LAWYERS ON THEIR OWN: THE SOLO PRACTITIONER IN AN URBAN SETTING (1994); H. LAURENCE ROSS, SETTLED OUT OF COURT: THE SOCIAL PROCESS OF INSURANCE CLAIMS ADJUSTMENT, 73-76 (1970); ERWIN O. SMIGEL, THE WALL STREET LAWYER (1969); Heinz & Laumann, *supra* note 40; Jack Ladinsky, *Careers of Lawyers, Law Practice and Legal Institutions*, 28 AM. SOC. REV. 47 (1963); Rebecca Sandefur, *Work and Honor in the Law: Prestige*

relative importance of competence and skill in determining case outcomes. Given the obvious difficulties in measuring competence and skill, and in determining case outcomes with precision, this is not surprising. What evidence exists on the subject suggests that case evaluation and negotiation skills make a large difference in case outcomes.[43] We previously authored one of the few empirical studies focusing on the impact of relevant experience.[44] We found that "seasoned plaintiffs' attorneys," meaning those who had handled at least four medical malpractice cases during the study period, who had conducted at least one malpractice trial during this period, and who had attended law school in-state, were more successful than other plaintiffs' attorneys in obtaining money for their clients.[45]

In their study of medical malpractice lawsuits in Florida, Sloan et al. suggested that the skill and competence of the lawyer for the plaintiff might be a factor in determining the outcome of specific cases.[46] Sloan et al. concluded that in terms of monetary recovery, claimants represented by "specialist" attorneys fared better than claimants represented by non-specialist attorneys.[47] They further observed that the relative importance of who the lawyers are in a particular medical malpractice case had never been the subject of empirical study.[48] Sloan et al.'s measurement of the impact of specialist attorneys on case outcomes represented a pioneering effort. The study, however, considered only the influence of plaintiff's counsel on case outcomes and payment, while the impact of defense counsel was largely ignored. In addition, the study used a number of different criteria, both objective and subjective, for determining specialist status. Sloan et al. defined "specialist" to include: attorneys who handled four or more medical malpractice cases, whether in or out of their sample, as well as their partners and associate attorneys; lawyers listed as experts in tort law in *The Best Lawyers in America*; members of the Inner Circle of Advocates; and attorneys who identified themselves as medical malpractice specialists in the *Martindale-Hubbell National Directory of Lawyers*.[49] Thus, while perhaps more widely studied than most other areas of law, even in the field of medical malpractice one finds relatively little objective data on the topic of lawyer competence and skill.

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and the Division of Lawyers' Labor, 66 AM. SOC. REV. 382 (2001).

42. ROSS, *supra* note 41; Edward O. Laumann et al., *Washington Lawyers and Others: The Structure of Washington Representation*, 37 STAN. L. REV. 465 (1985).

43. GERALD R. WILLIAMS, LEGAL NEGOTIATION & SETTLEMENT 5-7 (1983); *see also* KRITZER, *supra* note 1, at 54-55.

44. Harris, Peeples & Metzloff, *supra* note 29.

45. *Id.* at 245-47. *See generally* Daniels & Martin, *supra* note 13 (discussing repeat players and specialists in malpractice cases).

46. SLOAN ET AL., *supra* note 34.

47. *Id.* at 196.

48. *Id.* at 164 ("The effects of plaintiff lawyer competence and one-time versus repeat attorney players . . . have not been examined at all.").

49. *Id.* at 170.

Our approach in this Article adds attorney experience to those variables that have traditionally been argued to predict payment in medical malpractice cases, such as the severity of the alleged injury[50] and assessment of liability.[51] We also look at the relationship among attorney experience, the ability to pick cases, and case outcome.

II. APPROACH TO ANALYSIS

We focus our analysis on a single question: whether the plaintiff received any money. It may appear reductive to simply examine whether the plaintiff received an award without considering the size of this award. We rely on this dichotomous variable for two reasons. First, any payment, regardless of amount, triggers the reporting requirements of the NPDB.[52] One must submit a record identifying the physician on whose behalf the payment was made, without regard to the merits of the case, and without regard to whether the payment was made pursuant to a settlement or a verdict. Therefore, the simple fact of payment matters. Second, in practice, many settlement amounts are kept confidential. While it was sometimes possible to learn the specific amount paid, we were unable to obtain this information for all cases.

We begin with a bivariate analysis, looking at whether money was paid to the plaintiff by examining: relevant experience variables, specifically malpractice case experience and general experience; case context variables, specifically severity of the alleged injury and whether a trial occurred; and the insurer's assessment of liability. Utilizing binary logistic regression, we look at what variables predict case outcome, in terms of whether money is paid. For these analyses we enter the three clusters of variables discussed above into the model. First, we enter experience variables, including general experience and medical malpractice case experience—"repeat playing." Second, we add case context characteristics: severity of injury and whether there was a trial. Third, for a limited number of cases for which the data were available (n=72), we add the insurers' assessment of liability to the model.

To understand the circumstances under which money is paid, in the cases in which data for both defense and plaintiffs' counsel were available (n=52), we look at the extent to which plaintiffs' counsel's assessment agreed with that of the insurer. We introduce a variable that measures the effectiveness of plaintiffs' counsel defined in terms of having handled at least four cases during the study period and obtained payment in at least half of them. We look at several questions: Are more effective attorneys more likely to assess liability in a way that matches the assessment of the insurer? How does this agreement, or lack thereof, affect case outcome? Does it affect the occurrence of a trial? Insurers act

50. Brennan, Sox & Burstin, *supra* note 32, at 1966.
51. Taragin et al., *supra* note 25, at 781, 783.
52. *See supra* note 16 and accompanying text.

rationally, settling cases when they evaluate liability as probable and not settling when liability is seen as unlikely.[53] Finally, we look at the extent to which a combination of agreement with the insurer assessment of liability and medical malpractice case experience affects the payment of money to the plaintiff.

It should be noted that although statistical significance is set at $p<0.05$, results that approach but do not reach significance are also reported in the text, in the case of some cross-tabulations, and within the tables in multivariate analyses. This is done to contribute to a greater understanding of the relative impact of the variables.

III. METHODS

In our first analysis, the dependent variable is case outcome (whether money was paid in a given medical malpractice case). Our independent variables include time since admitted to practice (general experience), the number of medical malpractice cases handled during the study period (case experience), whether the case went to trial, severity of the alleged injury and, (in a limited number of cases) assessment of liability by defense and plaintiff's counsel. In our next analyses, we add counsel effectiveness as an independent variable, looking at its impact on assessment of liability and the occurrence of a trial in the case.

A. Sample

Our study is based on the collected data from 348 medical malpractice lawsuits filed in North Carolina between 1992 and 1995. While we do not suggest that our data set is a random sample of a complete population, given the fact that there is no data set of medical malpractice cases in North Carolina, we believe that it is a logical sample for this type of analysis. We determined the final outcomes of these cases using a combination of techniques, including a review of the court files for each case and the use of archival data on attorneys.[54] For each case, we identified the counsel for the plaintiff and the counsel for the defendant; all counsel were licensed in North Carolina. Archival sources provided information about the number of years since the attorney was admitted to practice. Court files provided information about the number of medical malpractice cases handled during the study period as well as the outcomes of these cases. Matching our data sources resulted in an upper limit of 306 usable cases. For a limited number of cases ($n=72$) we have a combination of interview and questionnaire data that utilizes the defense attorneys' evaluation of liability

53. Harris, Peeples & Metzloff, *supra* note 10, at 468-70; Peeples, Harris & Metzloff, *supra* note 23, at 893-94.

54. We relied on a number of sources to obtain this information, primarily directories published by the North Carolina Bar Association and Martindale-Hubbell.

as a proxy for insurers' assessment of liability.[55] We also collected data on plaintiffs' assessment of liability. Matching the data on defense counsel's assessment with that of plaintiffs' counsel resulted in fifty-two usable cases. In all our analyses we used data where they were available. There were missing values for some variables, as is frequently the case with data sets. As a result, the numbers of cases in different analyses varied.

Given that there is no malpractice case database in North Carolina from which a sample could be randomly selected, we focused on durable cases. Following the notion of the dispute pyramid,[56] durable cases, or those that had progressed at least beyond the initial stages of complaint by the plaintiff and answer by the defendant, seemed to be the most appropriate for looking at litigation as a process. Our sample consists of closed cases that progressed far enough to be ordered to mediation by the trial court, under the auspices of a pilot program mandated by the North Carolina General Assembly in 1991. Thus a type of control for case durability is provided since they moved farther along through the dispute resolution pyramid. This means that frivolous cases are excluded from the analysis, enabling us to more clearly focus on the actual litigation process. On the other hand, we recognize that this is not a random sample and that these cases may have characteristics that differ from cases not ordered to mediation. It should be noted that although only eighteen of the state's one hundred counties were a part of the pilot program, the pilot counties included five of the six most populous cities in the state (Charlotte, Raleigh, Greensboro, Winston-Salem, and High Point). In addition, in the eighteen pilot counties, all filed civil cases were ordered to mediation. Thus, we believe that we have collected the vast majority of all medical malpractice cases filed in the pilot counties during the study period. (Today, virtually all medical malpractice cases filed in North Carolina are ordered to mediation.) In short, we believe that the cases we analyze were representative of medical malpractice cases generally in North Carolina during the study period, since the counties that were selected by the state legislature were picked to provide a diverse group of counties, representing all geographic regions and including both sparsely and densely populated counties. Given the nature of the selection process, we also believe that this state-specific data set may be generalized to other parts of the country.

While our sample is limited to North Carolina and includes only eighteen of one hundred counties, the results of our study could inform national discussion of medical malpractice litigation because there are few studies that combine court data, insurance data, and questionnaires. Use of multiple data sources provides a more complete picture of the litigation process.

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55. The defense attorneys' evaluation is based on that of the insurer, which is in turn based on that of the outside physician reviewers. Peeples, Harris & Metzloff, *supra* note 23, at 884-85, 897.

56. Miller & Sarat, *supra* note 5, at 544-46.

B. Dependent Variable: Case Outcome

As a result of our examination of court records, attorney questionnaires, and attorney interviews, we were able to determine for most cases (296/348, 85.1%) if money had been paid, whether in settlement of the case or as a result of a favorable jury verdict. Overall, payment occurred in 50.4% of cases. It should be kept in mind, however, that these were durable cases.[57] Although it was possible to determine whether money was paid, as we mentioned earlier, it was seldom possible to determine the actual amount paid. The settlement terms of medical malpractice lawsuits typically take the form of a private contract between the parties, and thus are not subject to public scrutiny.[58] A common condition of settlement is a pledge extracted from the plaintiff and the plaintiff's counsel not to disclose the amount paid in settlement of the lawsuit.[59] Thus, although we were able to obtain actual settlement amounts for some cases, the insufficient number of such cases precluded utilizing settlement amounts as a dependent variable. Instead, we created a binary variable in which "money paid" was coded as "1" and money not paid was coded as "0." This binary approach regarding payment of money places the payment rate of 50.4% in context. The payment of several thousand dollars in a case might be considered a statistical "win" for the plaintiff, but it is unlikely that either the plaintiff or the plaintiff's counsel would see it that way. Use of "money paid" as the dependent variable has the advantage of acting as a control, since regardless of the amount paid there may be negative consequences for the physician. No matter what amount of money was paid, the defendant-physician will become part of the National Practitioner Data Bank.[60] This may result in negative professional consequences, since hospitals, HMOs, and PPOs have access to this data.

C. Independent Variables

In our first analyses there are three categories of independent variables: attorney experience variables, which included time since admitted to practice (general experience) and number of medical malpractice cases handled (case experience); case context variables (severity of alleged injury and the occurrence of a trial); and insurers' assessment of liability (probable, uncertain, or unlikely). In the second set of analyses, effectiveness of plaintiff's counsel is the independent variable. The variables and their coding are presented in Table 1.

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57. Imposing a filter on medical malpractice cases, such as a requirement that an order to mediate the case has been issued, has the effect of reducing the number of cases in the study that were abandoned early in the process by plaintiffs, for whatever reason.

58. Harris, Peeples & Metzloff, *supra* note 29, at 233.

59. *See id.*

60. *See supra* note 16.

TABLE 1.
Variables and Coding for Attorney Experience and Case Characteristics in Medical Malpractice Cases

Variables	*Definition/Comment*	*Coding*
Dependent variables		
Money paid	Case in which money was paid to the plaintiff.	0=Money not paid 1=Money paid
Performance: Attorney effectiveness plaintiff's counsel	Plaintiff's counsel handled at least four cases and won at least half of them.	0=Less Effective 1=More Effective
Independent variables		
Experience Variables		
Years since admitted to practice	Archival sources were used to determine the number of years in practice. These interval level data were utilized.	Defense Counsel: range=1-46, median=20 Plaintiffs' Counsel: range=1-47, median=18
Malpractice case experience	Number of medical malpractice cases handled as collected from the court files during the study period.	Defense counsel: range=1-29, median=9 Plaintiffs' Counsel: range=1-19, median=2
Case context variables		
Occurrence of a trial	Whether a trial occurred in this case.	1=Yes 0=No
Trial experience: Defense and plaintiff's counsel	If the court records indicated that the attorney had tried a medical malpractice case.	1=Yes 0=No
Severity of alleged injury	Less severe injuries included emotional only, insignificant injury, minor temporary disability and major temporary disability.	1=More severe 0=Less Severe
Assessment of liability	Defense counsel's assessment.	Two dummy variables 1=liability probable 1=liability uncertain 0=liability unlikely, reference category

In our tabular analyses, utilizing Chi-square and appropriate measures of association, interval level variables are recoded to ordinal level variables, appropriate to this statistic (Tables 2, 7, and 8). In our tables with very small numbers (Tables 7 and 8) Fisher's exact test was used. It should be noted that in some tables, also with small samples (Tables 4-6), comparisons using percentages are more meaningful. Interval level and dummy variables are appropriate as independent variables for binary logistic regression in Table 3.

1. Attorney Experience Variables

a. General Experience

Data are available from attorney directories on the year attorneys were first admitted to practice and the law school from which they graduated. Using information from these directories, we computed the years of general experience of the attorneys. For our bivariate analysis we recoded years of experience into greater or less than ten years, mindful of the time it traditionally takes to become a partner in a law firm. Becoming a partner is used as an indicator of sustained successful experience in a law firm.

b. Case Experience: Number of Medical Malpractice Cases Handled by Defense and Plaintiffs' Counsel

We calculated the number of medical malpractice cases each attorney handled during the study period. For cases with more than one defense counsel (due to the involvement of more than one defendant) we determined, based on a review of the court file, the identity of the primary defendant and thus the identity of the primary defense counsel. Only the primary defense counsel was credited with case experience for handling that case. We also looked at the severity of the alleged injury and whether there was a trial.

Experience, particularly specific experience in medical malpractice cases, serves as a useful indicator of competence and skill for several reasons. First, medical malpractice litigation is largely a specialty practice for lawyers, especially on the defense side. Second, simple market principles seem to be at work in this area. Defense counsel for physicians, and often for hospitals, are chosen by the malpractice insurance carrier. Insurers understandably used, and continue to use, attorneys who have demonstrated skill in defending medical malpractice cases. On the plaintiffs' side, market principles also seem to be at work. Plaintiffs' attorneys are compensated on a contingent fee basis. Thus, plaintiffs' counsel receives compensation only if the case results in a payment to the plaintiff. Plaintiffs' attorneys who have handled a substantial number of medical malpractice cases have likely demonstrated their skill in this complex and technical field.[61] The costs of preparing a medical malpractice case are high enough, both in terms of time and money, to deter casual or occasional players.[62]

We measured malpractice case experience in terms of the number of medical

61. Harris, Peeples & Metzloff, *supra* note 29, at 247-48.

62. *See, e.g.*, Daniels & Martin, *supra* note 13, at 1060-66.

malpractice cases handled, apart from the general experience as a practicing lawyer. Because medical malpractice litigation is a specialty practice, we chose this approach. Attorneys for both plaintiffs and defendants tend to specialize in medical malpractice and to devote a substantial portion of their practice to this area. We defined malpractice case experience in terms of the actual number of cases handled during the study period. For our bivariate analysis we recoded this variable into two categories: four or more cases and less than four, as an indicator of the attorney handling an average of at least one case a year during the study period. Although this approach does not adjust for lengthier or more difficult cases, it does reflect the fact that market forces are at work since more cases may flow to attorneys who are perceived to be "better."[63]

Of course, many experienced lawyers handle more than one medical malpractice case per year. This is reflected in our data. Our study was limited to only a portion of North Carolina during the study period; malpractice cases that were not filed in one of the pilot counties were not included in our study. One or more of the attorneys in our study may have handled cases in other counties.

2. Case Context Variables

a. Severity of Alleged Injury

Not every malpractice case is the same. Some cases involve very serious injuries, while others involve less significant harm. The dynamics of resolution for cases involving a very severe injury may differ from those cases involving only a modest or temporary injury. Indeed, previous work in this field has suggested as much.[64]

We identified nine different levels of severity of injury, ranging from emotional injury alone to death. This is consistent with the approach of Sloan and Hsieh who obtained these categories from the National Association of Insurance Commissioners and the General Accounting Office.[65] A binary variable was created in which "1" indicated more severe injuries and "0" less severe injuries. More severe injuries included minor permanent partial disability, major permanent partial disability, major permanent total disability, grave permanent total disability, and death. Less severe injuries included emotional injury only, insignificant injury, minor temporary disability and major temporary disability. We argue that there is a difference between injuries that are temporary and those that are permanent, with the latter being more serious.

63. Referrals from other lawyers to plaintiffs' lawyers who specialize in medical malpractice are common. *See id.* at 1067.

64. Brennan, Sox & Burstin, *supra* note 32, at 1966; Sloan & Hsieh, *supra* note 26, at 1007-08.

65. Sloan & Hsieh, *supra* note 26, at 1004.

b. Occurrence of a Trial

The occurrence of a trial may be associated with certain characteristics of both the lawyers and the cases. Whether counsel for the plaintiff or the defendant had medical malpractice trial experience in a given case was determined by the court records. A binary variable for each case was created, indicating whether or not a trial occurred. The occurrence of a trial was coded as "1" and the nonoccurrence of a trial was coded as "0." Trial experience could be seen as an indicator of a willingness not to back down in the face of an uncertain outcome.[66] Note that the consequences of going to trial differ substantially for defense and plaintiff's counsel. Plaintiff's counsel risk everything since they are compensated on a contingency fee basis. Defense counsel will receive their fee regardless of case outcome. This variable reveals plaintiff's counsel's judgment in deciding to go to trial, although the occurrence of a trial is a case characteristic. Alternatively, a trial could indicate either efficiency or lack of efficiency in settling cases, depending on the nature of the case and the skill of the attorney. There is evidence that if the insurer thinks liability is probable, settlement will occur.[67]

3. Assessment of Liability

Using questionnaire and interview data collected from counsel to the defendant and to the plaintiff, we were able to collect data on assessment of liability in a limited number of cases. Attorneys were asked to evaluate liability as probable, uncertain, or unlikely.[68] These evaluations were made after the case was closed. Defense counsel's evaluations were used as proxies for the insurers' evaluations, since, as noted above, defense counsel work for the insurer and the insurer, with the help of physician reviewers, ultimately evaluates the liability. These reviewers are usually paid consultants in a given malpractice case.[69] We created a design variable with "unlikely liability" as the reference category since we focus on the case outcome of money being paid to the plaintiff. Thus we created two dummy variables: probable liability was coded "1" and not probable liability was coded "0"; uncertain liability was coded "1" and not uncertain liability was coded "0."

66. Galanter, *supra* note 12, at 98-99; Harris, Peeples & Metzloff, *supra* note 29, at 246.

67. Peeples, Harris & Metzloff, *supra* note 23, at 886-87.

68. Attorneys were asked, "which of the following best describes your view of the issue of liability in this case." Choices were that 1) "liability as to at least one of the defendants was probable," 2) "liability was uncertain (a 'toss-up' type of case)," and 3) "liability was questionable or unlikely to be proven."

69. Peeples, Harris & Metzloff, *supra* note 23, at 884-85.

4. Performance Measure: Effectiveness of Plaintiffs' Counsel

To be considered effective, plaintiffs' counsel must have handled on average at least one medical malpractice case a year (so all effective counsel were also case-experienced counsel, as defined above) and have obtained money in at least half of those cases. If a plaintiff's counsel had at least four cases and had been paid money in at least half of them, his or her record was categorized as "more effective" (coded "1"). If counsel either did not have four cases or was not paid money in at least half the cases, counsel was categorized as "less effective" (coded "0"). A percentage of "wins" is useful since winning a medical malpractice case is difficult.[70]

The characteristics for effective defense counsel mirror those of plaintiff's counsel, having at least four cases during the study period and having money paid in no more than half of them. Our focus is on plaintiff's counsel's effectiveness, as insurers select their counsel on the basis of their demonstrated skill. While reputation and past outcomes count for plaintiff's counsel, the information is not always readily available to prospective plaintiffs, who must make decisions based on often incomplete information.

IV. FINDINGS

The median number of years in practice for all defense attorneys for whom data were available (n=323) was twenty years. For plaintiffs' counsel (n=307), it was eighteen years. Data on both number of medical malpractice cases handled and whether money was paid were available for most cases (n=348). The median number of cases handled by defense counsel was seven, while the median was two for plaintiffs' counsel. In terms of general experience, 83.9% of defense counsel had at least ten years experience compared to 70.1% of plaintiffs' counsel. Over 76% of defense counsel had handled at least four cases compared to 39.7% of plaintiffs' counsel. In terms of level of effectiveness, 37.7% of defense counsel were more effective compared to 17.5% of plaintiffs' counsel. Over 19% of the more effective defense counsel had been involved in a trial compared to 22.2% of the more effective plaintiffs' counsel. A comparison of less effective plaintiffs' counsel who did not obtain money for their clients with those who had less than four cases shows little difference between the two. Those who had handled less than four cases lost 53.7% of the time and those who were less effective lost 53.5% of the time.

70. Philip G. Peters, Jr., *Doctors and Juries*, 105 MICH. L. REV. 1453, 1453-60 (2007).

Over 71% of the cases involved more severe injuries, with 21.6% of all cases involving a death. Over 16% of all cases went to trial. Cases that went to trial did not differ significantly (p=0.210) from those that did not by severity of alleged injury. Over 20% of more severe cases went to trial compared to 14.3% of cases with less severe injuries.

A. What Predicts Whether Money Will Be Paid to the Plaintiff?

Bivariate analyses of the impact of relevant experience variables, case context variables, and assessment of liability on the payment of money to the plaintiff are presented in Table 2. Interval level variables (years in practice and number of medical malpractice cases) were recoded, collapsing interval level variables into meaningful categories, the appropriate level of measurement for the analysis. Chi-square and appropriate measures of association were utilized in indicating whether there was a statistically significant difference in whether money was paid to the plaintiff by the independent variables. Significance levels that are just outside our level of significance are reported in the text. All significance levels are reported in Table 2, whether or not they were statistically significant. In terms of recoded relevant experience variables, general experience does not matter for either plaintiffs' or defense counsel. Medical malpractice case experience matters somewhat for plaintiffs' counsel, though the difference only approaches statistical significance. Medical malpractice case experience did not matter for defense counsel, keeping in mind that defense counsel are selected by the insurer and are almost always experienced.[71] Recall that 76% of defense counsel had handled at least four cases compared to only 39.7% of plaintiffs' counsel. In terms of specific medical malpractice experience for plaintiffs' counsel, when counsel had handled four or more cases during the study period, money was paid in 57.1% of cases compared to 46.3% of cases in which counsel had handled less than four cases (p=0.07, Phi=0.106).

Analyzing the impact of case characteristics, severity of the alleged injury mattered in terms of a comparison of the percentages. In cases with more severe injuries, money was paid in 53.6% of the cases, compared to 44% of cases with less severe injuries. If a trial occurred, money was less likely to be paid. When a case went to trial, there was an award in 26.8% of the cases, compared with a settlement in 56.4% of all cases that did not go to trial (p<0.001, Phi=-0.236).

Insurer's assessment of liability also had an effect. Money was paid in 78% of cases that were evaluated as having probable liability, in 73.7% of cases in which liability was assessed as uncertain, and in 33.3% of cases in which liability was viewed at unlikely (p<0.001, Phi=0.423).

Our multivariate analysis utilizes binary logistical regression, appropriate to the binary dependent variable, "money paid to the plaintiff" yes (coded "1") or

71. Peeples, Harris & Metzloff, *supra* note 23, at 880.

no (coded "0"). In this analysis we evaluate the impact of each of the independent variables, controlling for the others, on the outcome of money being paid to the plaintiff. These results are presented in Table 3.

In Model 1, using only experience variables, defense counsel's general experience had some impact on money not being paid (p=0.14), though outside statistical significance. On the other side of the dispute, malpractice case experience apparently was predictive of payment (p=0.06) for plaintiff's counsel.

TABLE 2.
Money Paid to the Plaintiff and Relevant Attorney Experience, Case Context Variables and Insurers' Assessment of Liability

Relevant experience variables	*Was money paid to the plaintiff?* *Yes* n	%	*Total*
Years in practice			
Defense counsel			
≥10 years	126	50.0	252
<10 years	13	54.2	24
		$\chi2$=0.152, df=1, p=0.696, Phi=-0.023, ns	
Plaintiff's counsel			
≥10 years	107	50.5	212
<10 years	28	52.8	53
		$\chi2$=0.094, df=1, p=0.759, Phi=-0.019, ns	
Medical malpractice case experience:			
Defense counsel			
≥four cases	112	49.3	227
<four cases	38	55.1	69
		$\chi2$=0.696, df=1, p=0.413, Phi=-0.048, ns	
Plaintiff's counsel			
≥four cases	68	57.1	119
<four cases	82	46.3	177
		$\chi2$=3.330, df=1, p=0.07, Phi=0.106, ns	
Case context variable: Severity of inquiry			
More severe	113	53.6	211
Less severe	33	44.0	75
		$\chi2$=2.021, df=1, p=0.16, Phi=0.084, ns	
Was there a trial?			
Yes	15	26.8	565
No	128	56.4	227
		$\chi2$=15.746, df=1, p <0.001, Phi=-0.236	
Insurer's assessment of liability			
Probable	32	78.0	41
Uncertain	14	73.7	19
Unlikely	10	33.3	30
		$\chi2$=16.082, df=1, p<0.001, V-0.423	

NOTE: Cases consist of North Carolina state court medical malpractice cases filed between 1991 and 1995, inclusive, in which data are available from court files, interviews, the risk management office of a major teaching hospital, and from one of the principal liability insurers of physicians in North Carolina.

TABLE 3.
Logistic Analysis for Money Paid to the Plaintiff

	Model 1			*Model 2*			*Model 3*		
	Coefficient	*SE*	*Odds Ratio*	*Coefficient*	*SE*	*Odds Ratio*	*Coefficient*	*SE*	*Odds Ratio*
Experience Variables									
General Experience	-0.012	0.015	0.988	-0.023	0.016	0.977	-0.022	0.043	0.978
Defense Counsel									
Plaintiff's Counsel	-0.009	0.014	0.991	-0.008	0.015	0.992	-0.056	0.030	0.946-
Malpractice Case Experience									
Defense Counsel	-0.012	0.015	0.988	-0.020	0.016	0.980	-0.009	0.031	0.992
Plaintiff's Counsel	0.045	0.025	1.049-	0.032	0.027	1.032	0.104	0.050	1.110
Case Context Variables									
Severity of Injury	—	—	—	0.414	0.324	1.509	0.718	0.777	2.051
Trial?	—	—	—	-1.463	0.390	0.232***	-2.036	0.756	.131**
Liability Assessment									
Probable	—	—	—	—	—	—	2.247	0.725	11.679***
Uncertain	—	—	—	—	—	—	2.247	0.859	9.458**
Constant	0.521	0.427	1.659	0.694	0.518	0.180	0.019	1.127	1.010
-2 Log Likelihood	334.740	—	—	259.636	—	—	65.410	—	—
N	246			225			72		

* $p<.05$; ** $p<.01$; *** $p<.001$

NOTE: Cases consist of North Carolina state court medical malpractice cases filed between 1991 and 1995, inclusive, in which data are available from court files, interviews, the risk management office of a major teaching hospital, and from one of the principal liability insurers of physicians in North Carolina.

When case context variables are added to the model (Model 2), the negative coefficient indicates that if a trial occurred, this event was a significant predictor of money *not* being paid to the plaintiff ($p<0.001$). The general experience of the defense counsel apparently continues to influence whether money is paid ($p=0.14$). Severity of the alleged injury was not predictive of money being paid to the plaintiff.

In Model 3, the full model, for a limited number of cases for which the data were available ($n=72$), the insurer's assessment of liability was added. The fact of a trial in the case continued to be a significant predictor of money not being paid ($p<0.01$). An assessment of liability as either probable or uncertain was predictive of money being paid to the plaintiff ($p<0.001$ and $p<0.01$ respectively), as shown by the positive coefficients. The -2 log likelihood steadily diminished from Model 1 to Model 3, indicating that the additional variables contributed to the explanatory power of the model.

Our multivariate analysis indicates that, while plaintiffs' counsel's malpractice experience has an impact on the payment of money, further analysis of the process is needed. To continue the investigation, we look at the

effectiveness of the plaintiff's counsel. Are more effective attorneys better at case-picking? In other words, are they better at evaluating liability in a given case in a way that agrees with the insurer's private assessment? If so, the attorney for the plaintiff would be in a better position to settle and avoid a trial. These analyses are based on defense counsel's assessment of liability (as proxy for the insurer), as well as a subset of plaintiffs' attorneys, who offered their assessment of liability in closed cases. These data are suggestive but must be viewed with caution because of small numbers. Some analyses only utilize percentages because of this limitation. Our findings are presented below.

B. The Effectiveness of Plaintiffs' Counsel and Case-Picking

Since the evaluations of the insurer drive case outcome[72] we compare assessments of plaintiffs' counsel with those of defense counsel, whose evaluations are a proxy for that of the insurer. While data on assessment of liability are limited to fifty-two cases, these cases nonetheless allow us a detailed look at the dynamics of case settlement involving those variables that are shown to be important in both bivariate and multivariate analyses.

Even after the case closed it is interesting to note that plaintiffs' and defense counsel did not always agree on the assessment of liability (Table 4). Of the twenty-six cases that were evaluated by the defense as having probable liability, nineteen (73.1%) of these cases were so evaluated by plaintiffs' counsel. There were twelve cases assessed by defense counsel as having uncertain liability but only two (16.7%) of plaintiffs' counsel agreed. Finally, there were fourteen cases evaluated by defense counsel as having unlikely liability. Plaintiffs' counsel evaluated eight (57.1%) of these cases as having probable liability. Although statistics are not reported because of small numbers and logical issues, it should be noted that the patterns of disagreement are surprising, given the fact that the cases were closed when the attorneys were asked their opinions regarding liability.

72. Peeples, Harris & Metzloff, *supra* note 23, at 880, 887.

TABLE 4.
Defense and Plaintiffs' Counsel's Assessment of Liability: Percentage of Agreement

Plaintiffs' counsel's assessment	*Defense counsel's assessment n=52*					
	Probable		*Uncertain*		*Unlikely*	
	n	%	*n*	%	*n*	%
Probable	19	73.1	9	75.0	8	57.1
Uncertain	6	23.1	2	16.7	3	21.4
Unlikely	1	3.8	1	8.3	3	21.4

NOTE: Cases consist of North Carolina state court medical malpractice cases filed between 1991 and 1995, inclusive, in which data are available from court files, interviews, the risk management office of a major teaching hospital, and from one of the principal liability insurers of physicians in North Carolina.

Table 5 examines agreement between counsel's assessment of liability, controlling for attorney effectiveness. The table reveals that there is a greater likelihood that more effective attorneys are more likely to agree with the assessment of the insurer. This analysis reveals that in the nine cases handled by more effective plaintiffs' counsel, in six of nine (66.6%) there was agreement with the assessment of defense counsel that liability was probable. In the two cases that the defense counsel evaluated as having uncertain liability, and in the case evaluated as having unlikely liability, the more effective plaintiffs' attorneys also saw these cases as having probable liability. The pattern, however, varied with less effective plaintiffs' counsel. While thirteen (65%) of less effective counsel agreed with defense counsel about cases with probable liability, it is interesting to note that seven (53.8%) of less effective plaintiffs' counsel evaluated cases assessed by the insurer as having unlikely liability as having probable liability.

TABLE 5.
Defense and Plaintiffs' Counsel's Assessment of Liability: Percentages of Agreement for More and Less Effective Plaintiffs' Counsel

Defense counsels' assessment	*More effective plaintiff's counsels' assessment n=9*						*Less effective plaintiff's counsels' assessment n=43*					
	Probable		*Uncertain*		*Unlikely*		*Probable*		*Uncertain*		*Unlikely*	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Probable	6	100	--	--	--	-	13	65.0	6	30.0	1	5.0
Uncertain	2	100	--	--	--	-	7	70.0	2	20.0	1	10.0
Unlikely	1	100	--	--	--	-	7	53.8	3	23.1	3	23.1

NOTE: Cases consist of North Carolina state court medical malpractice cases filed between 1991 and 1995, inclusive, in which data are available from court files, interviews, the risk management office of a major teaching hospital, and from one of the principal liability insurers of physicians in North Carolina.

Table 6 looks at case-picking as a shorthand for whether the presence of a trial was related to the insurers' assessment of liability controlling for attorney effectiveness. In short, are more effective attorneys better at evaluating liability and therefore settling the case, thus avoiding a trial? More effective attorneys went to trial in four out of sixteen (25%) of their cases. They went to trial in only one of the nine cases (11.1%) that was evaluated by the insurer as having probable liability, but went in two of the five (40%) cases evaluated by the insurer as having uncertain liability, and one of the two cases (50%) that the defense counsel evaluated as having unlikely liability. It seems clear that the more effective attorneys are picking the good cases and only bringing those to trial if the parties do not settle.

TABLE 6.
Case-Picking in Terms of Level of Liability and Presence of a Trial by Attorney Effectiveness

	Less effective attorneys				*More effective attorneys*			
	Trial n=73				*Trial n=16*			
Insurers' assessment of liability	*Yes*		*No*		*Yes*		*No*	
	n	*%*	*n*	*%*	*n*	*%*	*n*	*%*
Probable	6	18.2	27	81.8	1	11.1	8	88.9
Uncertain	5	35.7	9	64.3	2	40	3	60
Unlikely	9	34.6	17	65.4	1	50	1	50

NOTE: Cases consist of North Carolina state court medical malpractice cases filed between 1991 and 1995, inclusive, in which data are available from court files, interviews, the risk management office of a major teaching hospital and from one of the principal liability insurers of physicians in North Carolina.

Less effective attorneys went to trial in twenty of seventy-three cases (27.4%). Compared to more effective attorneys, they went to trial more often in cases evaluated as having probable liability by the insurer (six out of thirty-three, 18.2%). However, they went less often in cases evaluated as having uncertain liability (five of fourteen, 35.7%), and less often in cases evaluated as being of unlikely liability (nine of twenty-six, 34.6%). Statistics are not reported because of small sample size.

Tables 7 and 8 further clarify the findings in the bivariate and multivariate analyses. Although the results of Fisher's exact test (appropriate for small numbers) are reported here, caution must be taken in drawing conclusions since the numbers are very small. In Table 7, the payment of money is analyzed in terms of whether there was agreement of assessment of liability or not. Table 8 goes a step farther, looking at the question of whether having handled four or more cases matters.

In Table 7 there were twenty-four cases in which plaintiffs' and defense counsel agreed about liability. In the nineteen cases in which there was

agreement that liability was probable, money was paid to the plaintiff in eighteen (94.7%) of the cases. Money was paid in both (100%) of the cases in which there was agreement that liability was uncertain. In the three cases in which there was agreement that liability was unlikely, no money was paid to the plaintiff.

When there was disagreement with the defense's assessment of probable liability, money was paid to the plaintiff in four of seven cases (57.1%). Disagreement with the defense's assessment of uncertain liability resulted in money being paid to the plaintiff in seven of nine cases (77.8%) and in four of eleven (36.4%) cases in which there was disagreement with the defense's assessment of unlikely liability. Fisher's exact test shows whether the independent variable makes a significant difference in the dependent variable and is appropriate for small numbers. The results are reported ($p<0.01$, $V=0.846$), although the percentages are more suggestive. In sum, agreement makes for predictable outcomes, with a very high likelihood of money being paid when liability is probable or uncertain, while disagreement leaves the outcome uncertain.

TABLE 7.
Money Paid to the Plaintiff by Whether There Was Agreement Between Defense and Plaintiffs' Counsel on Assessment of Liability

	Money paid (n35)		*Total*
	n	*%*	
Agreement on liability			
Probable	18	94.7	19
Uncertain	2	100.0	2
Unlikely	-	-	3
Disagreement on liability			
Probable	4	57.1	7
Uncertain	7	77.8	9
Unlikely	4	36.4	11

Fisher's exact test=18.582, df=5, $p<0.01$, V=0.846

NOTE: Cases consist of North Carolina state court medical malpractice cases filed between 1991 and 1995, inclusive, in which data are available from court files, interviews and the risk management office of a major teaching hospital and from one of the principal liability insurers of physicians in North Carolina. Where the assessments differed, the insurers' assessment of the liability is used to classify the cases.

Table 8 examines combinations of agreement on liability and malpractice case experience (fewer than four cases handled during the study period compared to four or more cases). This is intended to separate the impact of agreement on liability from medical malpractice case experience. In summary, Table 8 looks at the relationship between the plaintiff's counsel's ability to agree with the insurer's assessment of liability and the payment of money to the plaintiff for two groups of plaintiffs' counsel–those who had handled at least four cases and those who had not. Again, because the numbers are small the results should be viewed cautiously. Nonetheless, of the ten cases in which there was agreement that liability was probable or uncertain, in combination with counsel having handled four or more medical malpractice cases, money was paid to the plaintiff 100% of

the time. Plaintiffs' counsel who had handled four or more cases simply did not select cases that both sides evaluated as having unlikely liability.

In those cases in which there was agreement about probable liability but plaintiffs' counsel had handled fewer than four cases, money was paid in eight of nine (88.9%) cases. Money was also paid in the one case in which there was agreement that liability was uncertain. Those plaintiffs' counsel with less experience handled three cases in which there was agreement that liability was unlikely and in these cases, no money was paid to the plaintiff. The results of Fisher's exact test are reported ($p<0.001$, $V=0.856$), showing that agreement with the insurer's assessment of liability is associated with the payment of money to the plaintiff. This pattern is more pronounced if counsel had handled at least four cases.

TABLE 8.
Money Paid to the Plaintiff by Agreement Between Defense and Plaintiffs' Counsel on Assessment of Liability and Medical Malpractice Case Experience

	Money paid (n=20)		*Total*
	n	%	
Agreement on liability:			
Those with ≥four cases			
Probable	10	100.0	10
Uncertain	1	100.0	1
Unlikely	-	-	0
Those with <four cases			
Probable	8	88.9	9
Uncertain	1	100.0	1
Unlikely	-	-	3

Fisher's exact test=12.272, df=1, $p<.001$, V=0.856

NOTE: Cases consist of North Carolina state court medical malpractice cases filed between 1991 and 1995, inclusive, in which data are available from court files, interviews and the risk management office of a major teaching hospital and from one of the principal liability insurers of physicians in North Carolina. Where the assessments differed, it is categorized according to the insurance company's assessment

V. DISCUSSION

We have looked at the variables that previous literature reported as having an impact on whether money was paid in medical malpractice cases. In our analyses we have considered the impact of three categories of independent variables: relevant experience variables (years in practice and medical malpractice case experience), case context variables (severity of alleged injury and the occurrence of a trial), and finally, the insurer's assessment of liability.

Our analysis has proceeded in several stages. First, we conducted bivariate analyses of the impact of these three categories of variables on whether money was paid to the plaintiff using Chi-square and appropriate measures of association (Table 2). We found some evidence that malpractice case experience for the plaintiff's attorney had an impact on the payment of money to the

plaintiff. In our bivariate analyses, the variables that were clear predictors of money being paid to the plaintiff were the insurers' assessment of liability and whether there was a trial. If insurers evaluated the liability of a case as probable or uncertain, money was frequently paid. If the case went to trial, it was unlikely that money would be paid. This finding should not be surprising. Insurers tend to settle the cases they believe present a substantial risk of liability, and cases in which the insurer makes an offer of settlement usually settle—regardless of the amount of the first offer.[73] In short, when a case goes to trial, it is because the insurer has chosen not to make an offer of settlement—meaning the insurer has concluded that the case can be won.[74] The ability of insurers to do this sort of case-picking successfully is borne out in the consistently high percentage of defense "wins" at trial reported by researchers.[75]

Next, we utilized binary logistic regression (Table 3) to evaluate the impact of these three categories of variables, relevant experience variables, case context variables, and insurers' assessment of liability, entering them in three separate models. Consistent with the bivariate analyses (Table 2), the presence of a trial and assessment of liability emerged in the multivariate analyses as significant predictors, again, along with evidence that plaintiffs' malpractice case experience was having some impact. Severity of the plaintiff's alleged injury was not a significant predictor of money being paid to the plaintiff.

Finally, we took an in-depth look at the relationships among plaintiffs' counsel's effectiveness, medical malpractice experience, agreement with insurers' evaluations of liability, and case outcome (Tables 4-8). Because these samples are very small, conclusions must be cautiously suggested. Recalling that the insurers' evaluations drive the process, our analyses indicate that the ability of plaintiffs' counsel to pick cases—that is, to evaluate liability as the insurer does—is crucial. Effective plaintiffs' counsel clearly do better at case-picking than less effective counsel.

It also seems that just picking the cases is not enough. Plaintiffs' counsel who had handled at least four cases were more likely to obtain money for the plaintiff, regardless of whether their assessments agreed with that of the defense, than those plaintiffs' counsel who had not handled at least that many cases during the study period. We suggest that the ability to evaluate cases as the insurer does is a necessary but not sufficient condition for money being paid to the plaintiff. In short, we find evidence that being a repeat player matters independent of whether plaintiffs' counsel is good at evaluating cases.

There is another aspect to our findings. While "empathic" case selection is important, the process of case resolution is not one-dimensional.[76] The central

73. Peeples, Harris & Metzloff, *supra* note 23, at 887.

74. *Id.* at 894.

75. Peters, *supra* note 70, at 1459-60. Professor Peters also provides a very useful summary of research over the past three decades on the subject of jury-expert agreement.

76. By "empathic" we simply mean the ability of the plaintiff's counsel to assess a case the

event in the resolution process is the insurer's assessment of liability, based on a number of factors.[77] The traditional tort law requirements of breach of standard of care and causation[78] are of obvious importance, but other factors become relevant as well. The identity of the plaintiff's counsel matters, as does the insurer's view of the witness potential of the plaintiff and the defendant physician.[79] Since plaintiff's counsel will not know all that the insurer knows[80]—particularly the substance of the internal reviews the insurer has conducted—how does plaintiff's counsel make his or her decisions? A large part of the answer may be that an experienced plaintiff's counsel can make many of the same strategic assessments that the insurer can. Plaintiff's counsel will know his or her own prior experience with the insurer, for example—and reputation matters. The insurer is aware of the identity of the plaintiff's counsel, and how he or she has fared over time in other cases involving the insurer, and in malpractice cases not involving the insurer. With experience, furthermore, plaintiff's counsel will be adept at estimating the witness potential of his or her client. There is also the fact that an experienced plaintiff's counsel should know what will be required to prove the case, beyond the evidence of the medical records: for example, credible expert witnesses, a sympathetic story line, and the supporting testimony of family or subsequent treating physicians. Knowing what will be required to prove the case, however, is largely a function of knowing what will be necessary to persuade the insurer to seek a settlement—empathic case selection, in other words.

In the end, meaningful discussion of how the medical malpractice claims process might be reformed ought to be based on a thorough understanding of how the existing process really operates. Experienced plaintiffs' lawyers—"repeat players"—operate as the gatekeepers to the medical malpractice liability system. In this specialized area of litigation, the reputations of plaintiffs' lawyers are known to the insurers. Experienced plaintiffs' lawyers understand what will be required in order to obtain a payment from the insurer. Thus experienced plaintiffs' lawyers play an important role in filtering out non-meritorious cases—by and large, those cases are left to other lawyers. Because of their repeat player status, the decisions of experienced plaintiffs' lawyers—specifically, as to which cases to take and which cases to reject—are rational, based on an expectation of

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way the insurer would. On the importance of empathy in negotiations generally, see Robert H. Mnookin, Scott R. Peppet & Andrew S. Tulumello, *The Tension Between Empathy and Assertiveness*, 12 NEG. J. 217 (1996).

77. Harris, Peeples & Metzloff, *supra* note 10, at 471-72, 492; Peeples, Harris & Metzloff, *supra* note 23, at 893-94.

78. DOBBS, *supra* note 30, § 242; WEILER ET AL., *supra* note 15, at 19.

79. Harris, Peeples & Metzloff, *supra* note 10.

80. The internal reviews conducted by the insurer are confidential and not subject to discovery. It is not uncommon, however, for plaintiffs' counsels who specialize in medical malpractice to have their own medical professionals, such as registered nurses, on staff or under contract.

compensation both for their clients and themselves. Is the involvement of experienced plaintiffs' counsel worth the price? That answer is beyond the scope of this Article. Perhaps a "no-fault" system would lessen the value of being represented by a repeat player. However, under a system that assumes the potential involvement of a lay jury, and that is premised on "fault," the function of experienced plaintiffs' counsel is essential.

CONCLUSION

The medical malpractice compensation system may be inefficient, but it is rational. Meritorious claims are more likely to be paid than non-meritorious claims. The status of plaintiff's counsel as a repeat player, skilled at evaluating cases, is the basis for the system's rationality. In this Article, we have attempted to provide a more detailed picture of the claims resolution process in medical malpractice by focusing not just on trial but also on settlement, and by looking at the attributes that predict a claim's outcome. Breach of the standard of care matters, as does causation. Other factors also make a difference. High on the list of other factors is the experience level of plaintiff's counsel because it informs his or her case-picking ability.

A larger, random sample, including both quantitative and qualitative data, is necessary for a continuing analysis of the important variables that have an impact on case outcome, as well as the litigation process itself. More information on actual settlement amounts would also advance our understanding of the claims resolution process. For example, by controlling for severity of injury, it might be possible to compare the effectiveness of plaintiff's counsel with more precision, and to isolate the repeat player effect in more detail.

Predicting Probability: Regulating the Future of Preimplantation Genetic Screening

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INTRODUCTION

At the intersection of two rapidly developing areas of biotechnology, a revolution is about to take place. Although this revolution involves reproduction, it will not be sexual. A medical procedure, known as preimplantation genetic diagnosis (PGD), combines genetic testing and assisted reproductive technology (ART) to enable parents to screen their potential children before implantation for genetic or chromosomal characteristics. The technology has been a godsend to couples with family histories of genetic disorders and chromosomal mutations causing infertility. However, expanding its use to permit prospective parents to select embryos based on a wide array of genetic characteristics presents substantial risks to individuals involved in the procedure and to society as a whole.

Although PGD use has remained extremely limited due to technological constraints, expense, and moderate success rates, recent advances in genetic testing procedures will remove many of these obstacles and significantly increase the benefits of its use. Better tests, providing better information, will expand the use of this technology from embryos known to be at risk for serious disease – preimplantation genetic *diagnosis* – to the testing of all or almost all in vitro embryos for multiple genetic characteristics – preimplantation genetic *screening* (PGS).[1]

Future couples might select their potential children based on knowledge of their genetic susceptibility to serious diseases, like breast cancer[2] and Alzheimer's disease;[3] their propensity for cardiac arrhythmia;[4] the probability that they will develop more common diseases, like diabetes;[5] the probability that they will have childhood asthma;[6] their sex;[7] their likely body-mass index and

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1. Throughout the paper, preimplantation genetic diagnosis (PGD) will refer to genetic and chromosomal screening for diseases, and preimplantation genetic screening (PGS) will refer to genetic and chromosomal screening for all other conditions. In addition, PGS will be used to encompass both ideas at once.

2. *See* Rosalind A. Eeles, *Future Possibilities in the Prevention of Breast Cancer: Intervention Strategies in BRCA1 and BRCA2 Mutation Carriers*, 2 BREAST CANCER RES. 283 (2000).

3. *See* Charles R. Harrington et al., *Influence of Apolipoprotein E Genotype on Senile Dementia of the Alzheimer and Lewy Body Types: Significance for Etiological Theories of Alzheimer's Disease*, 145 AM. J. PATHOLOGY 1472 (1994).

4. *See* Daniel J. Gudbjartsson et al., *Variants Conferring Risk of Atrial Fibrillation on Chromosome 4q25*, 448 NATURE 353 (2007).

5. *See* Jose C. Florez et al., *TCF7L2 Polymorphisms and Progression to Diabetes in the Diabetes Prevention Program*, 355 NEW ENG. J. MED. 241 (2006).

6. *See* Miriam F. Moffat et al., *Genetic Variants Regulating ORMDL3 Expression Contribute to the Risk of Childhood Asthma*, 448 NATURE 470 (2007).

weight;[8] their hair, eye, and skin color;[9] their propensity for aggression;[10] and their likely height.[11] As our knowledge of genetics expands, geneticists will be able to test embryos for the presence of gene variants, known as alleles,[12] associated with a range of conditions through the use of a DNA microarray, a testing device that can screen for thousands of alleles at one time. Combining these genetic advances with ART procedures will permit parents to select embryos based upon their potential future traits.[13]

While scientists and consumers pursue the promise of PGS, we must also acknowledge the potential harms associated with its widespread adoption. Recent studies suggest that while PGS has great potential, its benefits may not always outweigh its risks. A number of variables contribute to the risks associated with PGS. Assisted reproduction procedures performed as part of PGS, such as in vitro fertilization (IVF),[14] intracytoplasmic sperm injection (ICSI),[15] and embryo

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7. *See* Medline Plus, Genetics, http://www.nlm.nih.gov/medlineplus/ency/article/002048.htm (last visited Apr. 18, 2008).

8. *See* Angelo Scuteri et al., *Genome-Wide Association Scan Shows Genetic Variants in the FTO Gene Are Associated with Obesity-Related Traits*, 3 PLOS GENETICS 1200 (2007), http://www.plosgenetics.org/article/info%3Adoi%2F10.1371%2Fjournal.pgen.0030115 (follow link to PDF version).

9. *See* Maarten T. Bastiaens et al., *Melanocortin-1 Receptor Gene Variants Determine the Risk of Nonmelanoma Skin Cancer Independently of Fair Skin and Red Hair*, 68 AM. J. HUM. GENETICS 884 (2001) (finding that the MC1R gene is associated with red hair and fair skin in individuals of European descent); David L. Duffy et al., *A Three-Single-Nucleotide Polymorphism Haplotype in Intron 1 of OCA2 Explains Most Human Eye-Color Variation*, 80 AM. J. HUM. GENETICS 241 (2007).

10. *See* Kevin M. Beaver et al., *A Gene x Gene Interaction between DRD2 and DRD4 Is Associated with Conduct Disorder and Antisocial Behavior in Males*, 3 BEHAV. & BRAIN FUNCTIONS 30 (2007); Giovanni Frazzetto et al., *Early Trauma and Increased Risk for Physical Aggression During Adulthood: The Moderating Role of MAOA Genotype*, 2 PLOS ONE 1 (2007), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0000486 (follow link to PDF version); Essi Viding & Uta Frith, *Genes for Susceptibility to Violence Lurk in the Brain*, 103 PROC. NAT'L ACAD. SCI. 6085 (2006).

11. *See* Jianfeng Xu et al., *Major Recessive Gene(s) with Considerable Residual Polygenic Effect Regulating Adult Height: Confirmation of Genomewide Scan Results for Chromosomes 6, 9, and 12*, 71 AM. J. HUM. GENETICS 646 (2002).

12. Alleles are different variations of a gene. If only one gene controlled eye color, alleles would exist for blue, green, brown, and hazel eyes.

13. A number of companies are working on incorporating the DNA microarray and other high throughput testing devices into ART procedures, and these developments are rapidly approaching commercialization. *See, e.g.*, Gene Security Network, http://www.genesecurity.net/services.html (last visited Mar. 30, 2008) (stating that its high throughput technology will offer parents information on all twenty-three chromosome pairs and multiple disease-linked genetic loci in 2008).

14. In vitro fertilization is a process through which eggs are removed from a woman's ovaries

biopsy,[16] are associated with increased risks to the embryo, the mother, and the future child. Uncertainties inherent in the genetic testing process, such as inaccurate genetic tests,[17] embryo mosaicism,[18] and low gene penetrance,[19] have

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and fertilized with sperm in a Petri dish. Embryos are cultured in the dish for two to five days and then transferred to the uterus for implantation. *See* IVF-Infertility.com, Fertilization (Fertilisation), http://www.ivf-infertility.com/ivf/standard/procedure/fertilization.php (last visited Apr. 18, 2008); *see also* Jane Halliday, *Outcomes of IVF Conceptions: Are They Different?*, 21 BEST PRAC. & RES. CLINICAL OBSTETRICS & GYNAECOLOGY 67 (2007) (finding that perinatal outcomes such as preterm delivery, low birth weight and some birth defects occurred with increased frequency in single-child (singleton) IVF births); Dorte Hvidtjørn et al., *Cerebral Palsy Among Children Born After In Vitro Fertilization: The Role of Preterm Delivery - A Population-Based, Cohort Study*, 118 PEDIATRICS 475 (2006) (finding that IVF procedures that result in preterm deliveries posed an increased risk of cerebral palsy); Reija Klemetti et al., *Health of Children Born as a Result of In Vitro Fertilization*, 118 PEDIATRICS 1819 (2006) (finding that singleton IVF babies had higher incidences of perinatal problems, congenital malformations and problems of the genitourinary system than naturally conceived children; interestingly, the study also revealed a slight decrease in respiratory disease in children born via IVF).

15. ICSI, a procedure in which a single sperm is injected into the egg through the use of a micropipette, is commonly used in IVF and PGS procedures to ease fertilization when there are abnormalities in the function, number or quality of the sperm. See Am. Soc'y for Reprod. Med., Patient's Fact Sheet: Intracytoplasm Sperm Injection (ICSI) (2001), *available at* http://www.asrm.org/Patients/FactSheets/ICSI-Fact.pdf; *see also* M. Bonduelle et al., *A Multi-Centre Cohort Study of the Physical Health of 5-Year-Old Children Conceived After Intracytoplasmic Sperm Injection, In Vitro Fertilization and Natural Conception*, 20 HUM. REPROD. 413, 416 (2005) (finding that 4.2% of children born via ICSI have a major congenital malformation, which is 2.77 times the rate of children naturally conceived; this result remained statistically significant when controlled for age, country, maternal age, education level, social class, maternal smoking habits, drinking, and number of previous pregnancies).

16. Embryo biopsy is the procedure in which the clinician removes one to two cells from an eight-cell embryo for genetic testing. *See* Sebastiaan Mastenbroek et al., *In Vitro Fertilization with Preimplantation Genetic Screening*, 357 NEW ENGL. J. MED. 9 (2007) (suggesting that the decrease from the live birthrate associated with IVF procedures alone (37%) to the live birthrate associated with PGS procedures (25%) might result from the embryo biopsy).

17. SUSANNAH BARUCH ET AL., GENETICS & PUB. POLICY CTR., PREIMPLANTATION GENETIC DIAGNOSIS: A DISCUSSION OF CHALLENGES, CONCERNS, AND PRELIMINARY POLICY OPTIONS RELATED TO THE GENETIC TESTING OF HUMAN EMBRYOS 5-6 (2004), *available at* http://www.dnapolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf.

18. Mosaic embryos contain certain cells with chromosomal and genetic structures that differ from those in the rest of the embryo. *See* Medline Plus, Mosaicism, http://www.nlm.nih.gov/medlineplus/ency/article/001317.htm (last visited Mar. 15, 2008). If tests are performed on these cells, they will provide an inaccurate depiction of the overall embryo.

19. Gene penetrance refers to the likelihood that the presence of a gene will result in the specific physical characteristic or phenotype associated with the gene. Some genes have one hundred percent penetrance, such that presence of the gene indicates that the resulting individual

also lead to embryo misdiagnosis, rendering the procedure ineffective. More broadly, widespread use of the technique can harm not only the individuals involved in it, but also society in general by increasing discrimination, stigmatization, and health disparities. The potential for individual and social harm resulting from these risks grows in proportion to the use and number of genetic tests available for PGS.

Now is the time for the United States to consider the potential impacts of PGS, and decide what role, if any, the federal government should play in overseeing its use. Over the past few years, a number of scholars have called for regulation of ART procedures in the United States.[20] This Article offers further evidence in support of more general ART regulation by examining the risks and benefits associated with recent advances in reproductive genetic testing and PGS.

In developing an appropriate response to recent advances in assisted reproductive technology and genetic testing, the United States should address three critical questions: 1) Does PGS need oversight?; if so, 2) What entities can best regulate PGS?; and 3) How should PGS be regulated?

After briefly describing the technologies involved, this Article will consider

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will definitely have the disorder or characteristic. Other genes have lower penetrance, indicating that only some individuals with the gene will have the disorder or condition. Human Genome Project, Evaluating Gene Tests: Some Considerations, http://www.ornl.gov/sci/techresources/Human_Genome/resource/testeval.shtml (last visited Mar. 15, 2008).

20. *See, e.g.*, FRANCIS FUKUYAMA & FRANCO FURGER, BEYOND BIOETHICS; A PROPOSAL FOR MODERNIZING THE REGULATION OF HUMAN BIOTECHNOLOGIES 293-300 (2006); June Carbone & Paige Gottheim, *Markets, Subsidies, Regulation, and Trust: Building Ethical Understandings into the Market for Fertility Services*, 9 J. GENDER, RACE & JUST. 509 (2006); Alexander N. Hecht, *The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology*, 1 HOUS. J. HEALTH L. & POL'Y 227 (2001); Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past—Present, and Future?*, 36 CONN. L. REV. 125 (2003) [hereinafter Malinowski, *Choosing*]; Michael J. Malinowski, *A Law-Policy Proposal To Know Where Babies Come from During the Reproduction Revolution*, 9 J. GENDER, RACE & JUST. 549 (2006) [hereinafter Malinowski, *A Law-Policy Proposal*]; Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603 (2003); Vicki G. Norton, *Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation*, 41 UCLA L. REV. 1581 (1994); Eric Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations*, 33 HASTINGS CENTER REP. S18-21 (2003); Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Can the Law Protect Them from Harm?*, 2004 UTAH L. REV. 57 (2004); Lindsey A. Vacco, *Preimplantation Genetic Diagnosis: From Preventing Genetic Disease to Customizing Children. Can the Technology Be Regulated Based on the Parents' Intent?*, 49 ST. LOUIS L.J. 1181 (2005); Aaron R. Fahrenkrog, Note, *A Comparison of International Regulation of Preimplantation Genetic Diagnosis and a Regulatory Suggestion for the United States*, 15 TRANSNAT'L L. & CONTEMP. PROBS. 757, 779 (2006); Note, *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574 (2006).

each of these three questions, starting with an examination of the medical and social risks associated with PGS. Given these risks, the Article critiques the current lack of oversight in the United States. It then examines the ability of existing regulatory options to address the coming dilemma of reproductive genetic selection. Finding the current options wanting, the Article concludes with an outline for the development of a regulatory infrastructure for ART.

The proposed regulatory infrastructure is based upon the relevant stakeholders and their interests. With respect to PGS, the stakeholders include prospective parents, ART providers, children born via the procedure, and members of society affected by its use. To balance and protect their interests, this Article argues for the creation of an independent federal entity, the Assisted Reproductive Technology Authority (ARTA). Initially, ARTA should pursue regulation that will benefit all or most stakeholders, such as ensuring the safety and efficacy of all procedures involved in ART; improving access to information regarding the risks and benefits of various uses of ART; and analyzing the effect of ART, especially PGS, on both individuals and society.

ARTA should then focus on developing a framework to address stakeholders' conflicting interests. The most glaring conflict associated with PGS will arise from parental and practitioner desires to conduct procedures or screen embryos in ways that threaten harm to other individuals or society as a whole. Initially, ARTA should monitor the use patterns of ART and PGS to determine whether these interests conflict in ways that will result in substantial harm to other members of society. As PGS use expands, it will be imperative to have a working infrastructure to monitor potential harms and address these conflicts as they arise.

While the full scope of ethical, social, and technological challenges associated with ART and PGS is not yet visible, as is common at the outset of the use of most disruptive technologies, the United States can take steps to address current concerns associated with the technology and prepare for future dilemmas. Establishing the principles on which to base policy decisions in the future, as well as the infrastructure required to do so, will greatly improve the ability to assimilate and respond quickly to new information on the scientific developments, health risks, and public sentiment associated with PGS. Given the potential of these recent technological advances to alter our reproductive practices dramatically and permanently, we can no longer ignore the questions of whether and how we should regulate ART and, more specifically, PGS.

Rather than leaving regulation to professional societies, states, or Congress, the United States can best monitor and regulate ART via an independent federal agency. Unlike prior calls for change, this Article proposes a novel balancing approach to guide the way the federal agency addresses expanding PGS technology, along with a mechanism for monitoring the effects of PGS on individuals and society. Part I provides background information on the current

and future capabilities of PGS. Part II argues that PGS should be subject to oversight and regulation, and Part III considers which entities are best suited to oversee PGS. Finally, Part IV proposes a structure and an agenda for a new regulatory agency to govern ART practice in the United States.

I. PREIMPLANTATION GENETIC DIAGNOSIS AND SCREENING

PGD currently offers prospective parents the opportunity to select embryos based on their susceptibility to a range of genetic and chromosomal disorders, such as Down syndrome,[21] Tay-Sachs,[22] and cystic fibrosis.[23] To perform PGD, parents must go through a cycle of IVF, in which a clinician harvests a number of eggs from the woman and combines each with sperm in a Petri dish in hopes of producing healthy embryos. Some eggs will not fertilize successfully; others will be fertilized, but will not successfully divide. For those embryos that successfully divide, on the third day of growth, when they consist of about eight cells, the clinician will perform an embryo biopsy to remove a cell or two for genetic or chromosomal testing.[24] The testing must be completed within about forty-eight hours for the embryo to remain useful.[25]

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21. Down syndrome impacts one in 733 live births. Nat'l Down Syndrome Soc'y, Information Topics, http://www.ndss.org/index.php?option=com_content&task=view&id=1812&Itemid=95 (last visited Mar. 30, 2008). The disease is associated with impairment of physical growth, reduced cognitive ability, congenital heart defects and distinctive facial features. Nat'l Inst. of Child Health & Human Dev., Down Syndrome, http://www.nichd.nih.gov/health/topics/Down_Syndrome.cfm (last visited Apr. 5, 2008).

22. Tay-Sachs disease causes a relentless deterioration of mental and physical abilities. Over time, the disease inhibits the child's ability to see, hear, and swallow. The muscles progressively deteriorate, and paralysis eventually results. Most children die by the age of four. *See, e.g.*, Medline Plus, Tay-Sachs Disease, http://www.nlm.nih.gov/medlineplus/taysachsdisease.html (last visited Mar. 15, 2008).

23. Cystic fibrosis is a genetic disease that affects the mucus and sweat glands. Sticky mucus caused by the disorder leads to impairment throughout the entire body, affecting the lungs, pancreas, liver, intestines, sinuses, and sex organs. These difficulties persist over the life of the individual; with treatment, individuals with cystic fibrosis generally live longer than thirty-five years. *See* Medline Plus, Cystic Fibrosis, http://www.nlm.nih.gov/medlineplus/cysticfibrosis.html (last visited Mar. 15, 2008).

24. *See, e.g.*, IVF-Infertility.com, Preimplantation Genetic Diagnosis (PGD), http://www.ivf-infertility.com/ivf/pgd.php (last visited Apr. 5, 2008).

25. The embryo should then be transferred to the uterus on or before the fifth day after fertilization. As a result, genetic testing laboratories have less than a forty-eight-hour window to receive DNA samples from the embryo, conduct the genetic tests, and provide the results to the PGS clinic and transfer the embryo to the uterus of the woman for implantation. Interview with Barry Behr, Director, IVF/ART Laboratories, Dep't of Obstetrics & Gynecology, Stanford Sch. of Med., in Palo Alto, Cal. (Oct. 16, 2006).

After getting the test results, the clinician usually transfers two to three embryos that meet the parents' approval to the uterus in hopes of establishing pregnancy.[26] Embryos with undesired genes are typically discarded or donated to research.[27] Over 12,000 cycles of PGD have been performed worldwide since its creation in 1989, with the number of cycles growing substantially every year.[28]

A. Current PGS Use

Scientists can now examine DNA through a number of different methods, each with its own benefits and drawbacks for PGS use. Different tests are used depending on whether the goal is to examine the chromosomes or the genes. Chromosomal structure analysis, performed by fluorescence in situ hybridization (FISH), examines whether the embryo has two copies of a chromosome and whether those copies are intact.[29] While FISH analysis provides useful information on common chromosomal abnormalities, it cannot provide information on all forty-six chromosomes because only five to nine chromosomes can be examined accurately at one time.[30] To examine a specific gene on a chromosome, geneticists have to make numerous copies of the DNA

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26. Requirements for an embryo to meet parents' approval vary, including having the correct number of chromosomes, being the desired sex or tissue type, or being unaffected with a genetic disease.

27. Interview with Barry Behr, *supra* note 25.

28. *See* SUSANNAH BARUCH, DAVID KAUFMAN & KATHY L. HUDSON, GENETICS & PUB. POLICY CTR., GENETIC TESTING OF EMBRYOS: PRACTICES AND PERSPECTIVES OF U.S. IVF CLINICS 3 (2006), *available at* http://www.dnapolicy.org/resources/PGDSurveyReportFertilityandSterilitySeptember2006withcoverpages.pdf (reporting a survey of "substantially all" U.S. ART clinics; 45% of these clinics responded, and together these clinics reported conducting 3379 cycles of PGS in 2005); Yury Verlinsky et al., *Over a Decade of Experience with Preimplantation Genetic Diagnosis: A Multicenter Report*, 82 FERTILITY & STERILITY 292, 293 (2004) (reporting in August 2004 that 4748 cycles of PGD had been performed in three of the world's most active PGD centers). According to a recent report from ESHRE, forty-five clinics worldwide conducted 12,397 cycles of PGD and PGS between 1997 and 2004, with 3358 performed in 2004 alone. J.C. Harper et al., *ESHRE PGD Consortium Data Collection VII: Cycles from January to December 2004 with Pregnancy Follow-Up to October 2005*, 23 HUM. REPROD. 741, 742 (2008). If this rate has remained fairly constant, I conservatively estimate that at least 25,000 cycles of PGD have been performed worldwide to date.

29. *See* Dagan Wells & Brynn Levy, *Cytogenetics in Reproductive Medicine: The Contribution of Comparative Genomic Hybridization (CGH)*, 25 BIOESSAYS 289, 291-92 (2003). FISH detects chromosomal abnormalities by labeling DNA probes that are perfect complements to the chromosomal region of interest with a fluorescent molecule. When mixed with sample DNA from the embryo, the probes will attach to their complementary chromosomal region on the embryo DNA, and the fluorescent molecules will emit colored signals to indicate certain abnormalities.

30. *Id.*

region of interest through a process known as polymerase chain reaction (PCR).[31] Conducting PCR for a single gene takes a significant amount of time, which limits the number of tests that can be performed during the forty-eight hours available for testing.[32]

1. Chromosomal Analysis

Chromosomal abnormalities can cause embryo death or lead to significant disorders in children.[33] While normal embryos have twenty-two pairs of autosomal chromosomes and one pair of sex chromosomes, abnormal embryos often have too many or too few copies of a chromosome, a condition known as aneuploidy. The most serious aneuploidies are lethal. PGS has been used to improve fertility by allowing parents to avoid the transfer of aneuploid embryos.[34] In current IVF practice, clinicians examine the shape and structure of embryos to determine which embryos are healthiest.[35] This physical examination, otherwise known as morphology analysis, fails to identify chromosomal abnormalities that occur in approximately 30% to 60% of embryos in women over thirty-five.[36] In theory, PGS should improve IVF success rates by allowing clinicians to identify chromosomal abnormalities that are undetectable by looking at the physical features of the embryo, although whether this improvement occurs in practice has been the subject of recent debate within the ART community.[37]

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31. *See, e.g.*, Harper et al., *supra* note 28, at 746-47 (listing numerous conditions for which PCR is used); C.S. Salvado, A.O. Trounson & D.S. Cram, *Towards Preimplantation Diagnosis of Cystic Fibrosis Using Microarrays*, 8 REPROD. BIOMEDICINE ONLINE 107, 107-08 (2003).

32. Interview with Barry Behr, *supra* note 25.

33. March of Dimes, Chromosomal Abnormalities, http://www.marchofdimes.com/professionals/14332_1209.asp (last visited Apr. 5, 2008).

34. *See* V. Baltaci et al., *Relationship Between Embryo Quality and Aneuploidies*, 12 REPROD. BIOMEDICINE ONLINE 77 (2005); Y. Verlinsky et al., *Preimplantation Testing for Chromosomal Disorders Improves Reproductive Outcome of Poor-Prognosis Patients*, 11 REPROD. BIOMEDICINE ONLINE 219 (2005). *But see* Mastenbroek et al., *supra* note 16, at 13 (demonstrating that PGS use to screen for chromosomal abnormalities in infertile women of advanced maternal age decreased the likelihood that the woman will become pregnant when compared to traditional IVF).

35. Embryos with a more spherical shape that have progressed to a mature blastocyst state with evenly sized cells may be more promising candidates for transfer to the uterus. *See, e.g.*, Baltaci et al., *supra* note 34, at 77; Santiago Munné, *Chromosome Abnormalities and Their Relationship to Morphology and Development of Human Embryos*, 12 REPROD. BIOMEDICINE ONLINE 234, 245 (2006).

36. Munné, *supra* note 35, at 245 (2005) (finding a chromosomal abnormality frequency of 30% for women aged thirty-five to thirty-nine and 60% for women over forty).

37*I See id.* at 248. *But see* Mastenbroek et al., *supra* note 16, at 15-17. The medical evidence does not yet fully support the idea that PGS can improve IVF success rates. Clinicians disagree about whether the improvement in embryo selection provided by PGS outweighs any additional

The use of PGS to screen for chromosomal structure can also detect which embryos will develop significant disorders. Infants can survive with three copies

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risk to the embryo development caused by conducting the embryo biopsy required for PGS. Mastenbroek et al. found that in women of advanced maternal age, PGS was associated with reduced ongoing pregnancy rates from 37% to 25%, and reduced live birth rates from 35% to 24% when compared with traditional IVF. *Id.* at 13. This study is the second large, multi-center, randomized controlled trial to investigate the benefits of PGS in women of advanced maternal age, a large subset of the infertility population. *Id.* at 10, 15. Despite these results, the underlying theory that selecting embryos based upon the presence of an intact set of chromosomes should improve pregnancy and live birth rates has not been disputed. Mastenbroek et al. offered numerous possible explanations for the difference in pregnancy rates. *Id.* at 15-17. First, the embryo biopsy hindered implantation and development. *Id.* at 16. This could result from either the removal process in general or the technique used by researchers. Other PGS practitioners have questioned the quality of the embryo biopsy procedures performed, as approximately 20% of embryos in the PGS group had "undetermined" chromosomal status compared with 5% in experienced laboratories. *See id.* at 16 tbl. 4; *Preimplantation Genetic Diagnosis Pioneers from the USA and Europe Refute New England Journal of Medicine Article*, Med. News Today, July 10, 2007, http://www.medicalnewstoday.com/articles/76269.php [hereinafter PGD *Pioneers*]. When transferred, these embryos had only a 6% implantation rate, significantly lower than that of chromosomally "normal" PGS embryos (16.8%) and IVF embryos that did not undergo PGS (14.8%). Mastenbroek et al., *supra* note 16, at 15-16. Of the 642 embryos transferred to the uterus after PGS in this study, 100 were of undetermined status; this lowered the implantation, pregnancy and live birth rates associated with PGS in the study. *Id.* at 13; *PGD Pioneers*, *supra.* Secondly, researchers tested only one-third of the chromosomes, enabling some chromosomally abnormal embryos to be classified as "normal" and transferred. Mastenbroek et al., *supra* note 16, at 11, 16. These challenges can be alleviated through the use of DNA microarrays, and other advances in genetic testing technology can provide information on all twenty-three pairs of chromosomes. *Id.* at 16. Third, embryos created through IVF tend to be mosaic, a condition in which not all cells in the embryo have the same chromosomal structure, which can cause errors in classification. *Id.*; *see also supra* note 18 and accompanying text. For instance, a mosaic embryo with a majority of normal cells could be labeled "abnormal." Improvements in genetic testing and embryo biopsy procedures may enable researchers to identify mosaic embryos in the future. Finally, more embryos from the PGS group were formed through ICSI than in the control group, also potentially compromising the integrity of the PGS embryos. Mastenbroek et al., *supra* note 16, at 16 tbl. 4. More research should be performed to determine the cause of the reduction in pregnancy and live birth rates. In the meantime, PGS use for infertility should be performed only in cases of repeat miscarriage and recurrent IVF failure. The use of PGS for infertility is most beneficial for couples that have experienced repeated miscarriages or otherwise have a poor prognosis related to the chromosomes. *See* Verlinsky et al., *supra* note 34, at 221 (demonstrating that in a group of poor-prognosis patients, PGS increased the implantation rate five-fold, cut the rate of spontaneous abortion by more than half, and more than doubled the take home baby rate in comparison to prior IVF cycles); *see also* Santiago Munné et al., *Preimplantation Genetic Diagnosis Significantly Reduces Pregnancy Loss in Infertile Couples: A Multicenter Study*, 85 FERTILITY & STERILITY 326, 329 (2006).

(trisomies) of chromosomes 8, 9, 13, 18, and 21 and substantial deletions (monosomies or partial monosomies) of regions on chromosomes 4, 5, and 15.[38] Each trisomy or monosomy is associated with a specific disorder, most of which result in mental retardation and premature death.[39] The most common aneuploidy disorder is Down syndrome (trisomy 21).[40] In addition to having too many or too few copies of a chromosome, abnormalities can also result when chromosomes break and, in some cases, reattach to other chromosomes – chromosomal translocation – which can lead to certain kinds of cancer and other abnormalities.[41]

Chromosomal testing can also be used for sex selection. Because males have only one copy of the X chromosome, mutations on that chromosome can result in disorders in male offspring.[42] Sex selection is often performed to select against

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38. Trimsomies include Trisomy 8 (Warkany Syndrome), Trisomy 9, Trisomy 13 (Patau Syndrome), Trisomy 18 (Edwards Syndrome), Trisomy 21 (Down Syndrome), and Trisomy 22 (Cat's Eye Syndrome); monosomies include Monosomy 4 (Wolf-Hirschhorn Syndrome), Monosomy 5 (Cri du chat), Monosomy 15 (Angelman Syndrome/Prader-Willi Syndrome). *See* Genetics Home Reference, Cri-du-chat Syndrome, http://ghr.nlm.nih.gov/condition=criduchatsyndrome (last visited Apr. 18, 2008); Genetics Home Reference, Prader-Willi Syndrome, http://ghr.nlm.nih.gov/condition=praderwillisyndrome (last visited Apr. 18, 2008); Healthline, Trisomy 8 Mosaicism Syndrome, http://www.healthline.com/galecontent/trisomy-8-mosaicism-syndrome (last visited Apr. 18, 2008); Medline Plus, Down Syndrome, http://www.nlm.nih.gov/medlineplus/downsyndrome.html (last visited Apr. 18, 2008); Medline Plus, Trisomy 13, http://www.nlm.nih.gov/medlineplus/ency/article/001660.htm (last visited Apr. 18, 2008); Medline Plus, Trisomy 18, http://www.nlm.nih.gov/medlineplus/ency/article/001661.htm (last visited Apr. 18, 2008); Online Mendelian Inheritance in Man, Wolf-Hirschhorn Syndrome, http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=194190 (last visited Apr. 18, 2008); WebMD, Chromosome 9, Trisomy Mosaic, http://children.webmd.com/chromosome-9-trisomy-mosaic (last visited Apr. 18, 2008); WebMD, Chromosome 22, Trisomy Mosaic, http://children.webmd.com/chromosome-22-trisomy-mosaic (last visited Apr. 18, 2008).

39. *See* sources cited *supra* note 38.

40. *See* National Down Syndrome Society, *supra* note 21; *see also* Online Mendelian Inheritance in Man, Down Syndrome, http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=190685 (last visited Mar. 31, 2008).

41. The Philadelphia chromosome is an example of a reciprocal translocation where a portion of both the ninth chromosome and the twenty-second chromosome break off and reattach on the other chromosome. The Philadelphia chromosome causes the malignant transformation in chronic myelogenous leukemia, a form of cancer that weakens a patient's immune system and ability to fight infection. See Michael Savona & Moshe Talpaz, *Getting to the Stem of Chronic Myeloid Leukaemia*, 8 NATURE REV. CANCER 341 (2008); Online Mendelian Inheritance in Man, Leukemia, Chronic Myeloid, http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=608232 (last visited Mar. 31, 2008).

42. Richard Twyman, *X-Linked Diseases*, HUM. GENOME, Apr. 16, 2003, http://genome.wellcome.ac.uk/doc_wtd020851.html.

all male embryos produced by a couple at risk for X-linked disorders in cases where no specific genetic test for the disorder exists.[43] As scientists develop more specific gene tests for disorders on the X chromosome, the need for sex selection for medical purposes will decrease. Sex selection for non-medical purposes, such as family balancing, however, continues to increase.[44]

Chromosomal analysis for medical purposes represents the most common use of preimplantation screening in the United States. The Genetics and Public Policy Center in Washington, D.C. recently surveyed 137 ART clinics in the United States and found that out of the 3379 PGD cycles they performed in 2005, 66% of the cycles were for aneuploidy (2197), 9% were for chromosomal translocations (403), and 3% were for X-linked diseases (96).[45] The Genetics and Public Policy Center also found that 42% of ART clinics reported that they had enabled parents to choose the sex of their child for non-medical reasons, such as family balancing or parental preference.[46] In addition, after undergoing PGS to screen their embryos for chromosomal disorders, 35% of clinics gave parents the option to select girls and boys for implantation from among the remaining healthy embryos.[47]

2. Genetic Analysis

In contrast to analyzing entire chromosomes, clinicians can also use PGD to look for specific genetic traits. The Genetics and Public Policy Center survey found that clinicians performed 12% of PGD procedures to avoid transferring embryos that would develop severe genetic disorders,[48] such as Fanconi anemia,[49] cystic fibrosis, and Tay-Sachs. Often these disorders begin early in life and have no known cure. Couples have also begun to screen embryos for late-onset conditions that do not present until adulthood, such as Huntington's disease

43. BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 5.

44. *See id.* at 6 (indicating that "sex selection [was] frequently mentioned" as a source of "ethical questions" for clinics).

45. *See id.* at 3.

46. *Id.*

47. *Id.* at 6.

48. *See id.* at 4 (stating that 12% of reported cycles were provided to detect autosomal single gene disorders).

49. Fanconi anemia is a rare, recessive blood disorder that is associated with an increased incidence of tumor growth and failure of the bone marrow to produce blood cells. Many patients develop acute myelogenous leukemia and die at a young age (between twenty and thirty years). Nat'l Heart & Lung Inst., Disease and Conditions Index, What Is Fanconi Anemia?, http://www.nhlbi.nih.gov/health/dci/Diseases/fanconi/fanconi_whatis.html (last visited Mar. 30, 2008); *see also* Harper et al., *supra* note 28, at 743-44 (grouping Fanconi anemia in a list of monogenic diseases).

and Alzheimer's disease, and for genetic predispositions to diseases like hereditary breast cancer and colon cancer.[50]

Genetic analysis can also permit parents to select embryos based on their non-medical traits. Couples have undergone PGS to select an embryo that could be a cord blood donor for a sick family member by virtue of having the same genetic Human Leukocyte Antigen (HLA) or tissue type.[51] In families with a history of a genetic disorder, such as Fanconi anemia, parents can use PGS to select unaffected embryos that can be tissue donors for their sick child. If the sick child has a disease without a genetic cause, parents can also use PGS solely to select embryos that could be a tissue type match for the sick child. This use of PGS has inspired much ethical debate around whether it is appropriate to create a child to save another, or to put the future child at risk to save another.[52] Only 6% of ART clinics surveyed have provided tissue typing in the absence of testing for a genetic disorder.[53]

Some individuals have sought to use PGS to select embryos that will fit into their culture by choosing embryos that have a specific genetic condition, such as deafness or acondroplasia (dwarfism).[54] Three percent of ART clinics surveyed have enabled couples to use PGS to select for disabilities.[55] While embryo selection for non-medical purposes still remains a small percentage of overall PGS use, this type of selection will continue to grow as the number of genetic tests increases and public knowledge of PGS expands.

B. Limitations on Current PGS Use

Currently PGS has a number of drawbacks that limit its use. The largest of these results from its reliance on the IVF process to create embryos for genetic and chromosomal testing. IVF is expensive and unpleasant. One cycle of IVF ranges in price from $10,000 to $12,000.[56] While a handful of states require insurance companies to cover all or a portion of the costs associated with IVF, a substantial percentage of IVF patients remain uncovered by insurance and are

50. *See* BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 4.

51. *Id.* at 5.

52. *See, e.g.*, S. Sheldon & S. Wilkinson, *Should Selecting Saviour Siblings Be Banned?*, 30 J. MED. ETHICS 533 (2004). The United Kingdom originally banned the use of PGS solely to create a child with a matching tissue type, but then overturned the decision in light of public outcry and more liberal policies in other countries.

53. *See* BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 5.

54. *Id.*; *see also* Darshak M. Sanghavi, *Wanting Babies Like Themselves, Some Parents Choose Genetic Defects*, N.Y. TIMES, Dec. 5, 2006, at F5.

55. *See* BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 5.

56. BARUCH ET AL., *supra* note 17, at 22.

forced to pay for the procedure out of pocket.[57]

Given the discomfort and inconvenience associated with IVF,[58] women may be reluctant to try PGS. In order to stimulate the ovaries to produce eggs for the IVF cycle, women must undertake daily hormone injections for ten to twelve days.[59] The mature eggs must be retrieved through a minor surgical procedure conducted under sedation or anesthetic.[60] Egg retrieval can result in pain, bleeding, nausea, and vomiting.[61] In addition, the long-term risks of fertility drugs remain largely unexamined and unknown.[62]

In addition to the problems associated with IVF, certain features of PGS also limit its use. PGS testing adds an additional $2500-$7000 to the price of IVF, making it even more financially inaccessible.[63] Second, the embryo biopsy procedure may hinder embryo implantation and development, reducing live birth success rates.[64] Finally, the amount of information currently available through PGS testing is significantly constrained by genetic testing restrictions and the fragile state of the preimplantation embryo.[65] Having only the biopsied cell's DNA available for testing greatly limits testing options and accuracy. Currently, couples must choose between conducting an analysis on five to nine chromosomes and conducting one to two genetic tests,[66] as these tests examine

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57. DEBORAH SPAR, THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION 213 (2006).

58. *See, e.g.*, IVF-Infertility.com, Egg Collection, http://www.ivfinfertility.com/ivf/standard/procedure/egg.php (last visited Apr. 4, 2008); IVF-Infertility.com, Superovulation, http://www.ivf-infertility.com/ivf/standard/procedure/superovulation.php (last visited Apr. 4, 2008).

59. *See* IVF-Infertility.com, Superovulation, *supra* note 58. In up to 3% of women, these hormones can result in moderate or severe ovarian hyperstimulation, a serious condition that results in hospitalization and in rare cases death. *See* David A. Grainger, Linda M. Fraizer & Courtney A. Rowland, *Preconception Care and Treatment with Assisted Reproductive Technologies*, 10 MATERNAL & CHILD HEALTH J. S161, S162 (2006). Some researchers and patients are concerned that fertility drugs may lead to an increased risk of hormone-dependent cancers, such as breast, ovarian, and uterine cancers. While the limited research that has been done does not support a relationship between fertility drugs and breast and ovarian cancer, more research is imperative to determine the long-term cancer risks of fertility drugs. *See* ASSESSING THE MEDICAL RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH: WORKSHOP REPORT 2 (Linda Giudice, Eileen Santa & Robert Pool eds., 2007), *available at* http://www.nap.edu/catalog.php?record_id=11832 [hereinafter WORKSHOP REPORT].

60. *See* IVF-Infertility.com, Egg Collection, *supra* note 58.

61. *Id.*

62. WORKSHOP REPORT, *supra* note 59, at 2.

63. Reprod. Genetics Inst., Price List as of 1/05, www.reproductivegenetics.com/docs/pgd_pricelist_022305.pdf (last visited Mar. 31, 2008).

64. *See* Mastenbroek et al., *supra* note 16.

65. *See supra* note 25.

66. BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 2.

the DNA in different ways. These technological constraints have greatly limited the information PGS can provide prospective parents, and therefore the use of the procedure in general.

Even if scientists resolve these technical dilemmas, current understanding of gene function and how genes produce certain physical characteristics or phenotypes is also limited. For most common heritable diseases, like heart disease and diabetes, the genetic contribution to the development of the disorder is complicated. "[T]he interplay of multiple genes and multiple non-genetic factors, not a single allele, usually dictates disease susceptibility and response to treatments."[67] Computer scientists, geneticists, and statisticians are developing strategies to decipher the role of gene-gene interaction and gene-environment interaction in common disorders and individual characteristics.[68] As our understanding of these interactions expands along with our ability to test for numerous genes at one time, the value of the information PGS can provide to couples will grow quickly and exponentially.

Alleviating these technical and informational difficulties may tip the balance for many couples in favor of using PGS. This hope of an increased market demand has inspired numerous scientists to try to resolve the technical and financial challenges associated with PGS.

C. Future Capabilities of PGS

Even with current limitations, recent innovations in genetic testing will soon increase the information available to prospective parents through PGS by enabling them to simultaneously evaluate embryos on both their chromosomal integrity and the presence of numerous gene variants.[69] The most promising advance involves the use of DNA microarrays. A DNA microarray provides a medium for the orderly arrangement and matching of known and unknown DNA samples.[70] When performed for a full sample of DNA, microarrays can identify

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67. Francis S. Collins et al., U.S. Nat'l Hum. Genome Res. Inst., *A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era*, 422 NATURE 835, 840 (2003).

68. *Id.* at 838; *New Technology Predicted To Revolutionize Genetic Analysis of Preimplantation Embryos*, MED. NEWS TODAY, Oct. 22, 2006, http://www.medicalnewstoday.com/articles/54745.php [hereinafter *New Technology Predicted*].

69. *See* Munné, *supra* note 35; Dagan Wells, *Advances in Preimplantation Genetic Diagnosis*, 115 EUR. J. OBSTETRICS & GYNECOLOGY & REPROD. BIOLOGY S97 (Supp. I 2004); *New Technology Predicted*, *supra* note 68.

70. Salvado, Trounson & Cram, *supra* note 31, at 108. Microarrays are easier to conduct than FISH and more sensitive, in some cases increasing the resolution to 100-200 kilobases. Wells & Levy, *supra* note 29, at 297. The presence of either normal or abnormal genetic variations in a sample can be detected by allowing the sample DNA to bond with complementary DNA that codes for the respective variations. Microarrays permit geneticists to test for the presence of numerous

mutations and abnormalities at the level of the chromosome, gene or even single nucleotide polymorphism.[71] Geneticists have developed a new technique, array-based comparative genomic hybridization, to screen for small sequences of DNA in a manner that will enable them to examine the integrity of all forty-six chromosomes as well as hundreds of genes from a single embryonic cell.[72] While this procedure is relatively new and has not been performed clinically in ART, the future of PGS lies in screening technology that can provide complete chromosomal information along with significant DNA sequencing information from one cell in forty-eight hours or less.

The ability to combine chromosomal analysis with specific gene tests will revolutionize PGS. Couples undergoing PGD to select against embryos affected with a serious genetic disorder will be able to select from the remaining unaffected embryos based upon a range of characteristics. While PGD was initially created for disorders that were guaranteed to develop if the gene was present,[73] PGS will rely much more heavily on detecting genes that increase the probability that a disorder will develop.

The shift to probability is occurring because the vast majority of human characteristics or conditions with any genetic component are multigenic and multifactorial.[74] As scientists' understanding of genetics develops, they will be able to create statistical models that use the presence of numerous gene variants to provide a more complete picture of an embryo's probability of developing a specific disorder or condition.[75] This type of genetic modeling could be used to

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genetic variants at one time by placing hundreds of complementary sequences of DNA onto the array and then permitting the sample DNA to bind with its complementary sequences. Salvado, Trounson & Cram, *supra* note 31, at 112.

71. Salvado, Trounson & Cram, *supra* note 31, at 112. A single nucleotide polymorphism (SNP) is a change in the single nucleotide, the building block of DNA. A single gene will often have thousands of nucleotides. *See* Human Genome Project Information, Information, http://www.ornl.gov/sci/techresources/Human_Genome/publicat/primer/prim1.html (last visited Apr. 18, 2008); Human Genome Project Information, SNP Fact Sheet, http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml (last visited Apr. 18, 2008).

72. *See* Wells & Levy, *supra* note 29.

73. *See* BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 1.

74. *See* Collins et al., *supra* note 67, at 840.

75. *See, e.g.*, Marylyn D. Ritchie et al., *Optimization of Neural Network Architecture Using Genetic Programming Improves Detection and Modeling of Gene-Gene Interactions in Studies of Human Diseases*, 4 BMC BIOINFORMATICS 28 (2003), http://www.biomedcentral.com/1471-2105/4/28; Quanhe Yang et al., *Improving the Prediction of Complex Diseases by Testing for Multiple Disease-Susceptibility Genes*, 72 AM. J. HUM. GENETICS 636, 644 (2003). For instance, if seventeen genes are associated with heart disease, knowledge of the allelic makeup of all seventeen genes and how much each allele contributes to the development of heart disease could provide prospective parents with valuable information on the likelihood that a specific embryo would

provide probability information on all types of genetic traits, as well as to inform parents regarding the potential impact of certain environmental stimuli.

Improvements in our understanding of gene function will also provide information on non-disease-related genetic traits, such as height, hair color, skin color, eye color, and possibly some behavioral characteristics. Geneticists investigating pigmentation in skin, hair, and eyes are beginning to make substantial discoveries.[76] The genetic determinants of behavior are much more complex, but scientists may discover genes that govern certain behavioral characteristics through research into psychiatric disorders and other conditions.[77]

The future capabilities of PGS are best described by a hypothetical. Imagine a couple that, because of fertility problems, plans to use IVF. The clinician harvests fourteen eggs from the prospective mother and fertilizes them with the prospective father's sperm. Ten of the eggs are successfully fertilized, and eight of those develop normally to the eight-cell stage. At that point, PGS is used to screen the eight remaining embryos for various chromosomal and genetic conditions. Results might indicate that chromosomal defects exist in embryos 1, 3, and 8 that make it unlikely that those embryos would result in a live birth. Embryo 2 can produce a baby, but the child would have Down syndrome. Embryo 6 would have cystic fibrosis. Embryos 1, 2, and 8 would carry one copy of the cystic fibrosis gene, which would not affect them but could result in their offspring having the disease. Embryos 5 and 7 have twice the normal chance of developing Alzheimer's disease in older age; embryos 1 and 7 have double the normal risk of breast cancer. Embryos 1, 3, 4, and 7 are female; embryos 3, 4, and 7 would likely be taller than average; embryos 1, 4, and 8 would have blue eyes.

Physicians are likely to present their patients with charts describing the characteristics of each of their embryos and offer them genetic counseling services to ensure that they understand the risks associated with each condition. At some point, the potential advantages of avoiding disease, limiting disease risks, and choosing non-disease traits may make PGS (even with its associated need for IVF) worthwhile even for fertile couples who are not at any known risk for children with a serious genetic disease. For many couples, "more information about the medical status of embryos and pregnancies is likely to be perceived as preferable," even if it is only probabilities.[78] While PGS presents prospective couples with numerous potential benefits, it is also poses some significant risks.

In deciding whether to intervene in reproductive aspects of citizens' lives,

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develop heart disease. In some cases, this could be as high as 90% or more.

76. *See* Bastiaens et al., *supra* note 9; Duffy et al., *supra* note 9.

77. Ridha Joober, Sarojini Sengupta & Patricia Boksa, *Genetics of Developmental Psychiatric Disorders: Pathways to Discovery*, 30 J. PSYCHIATRY & NEUROSCIENCE 349, 351-52 (2005).

78. Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 558.

the government should consider the nature of the people involved and the potential for government intervention to improve their situation. The people put at risk by unrestricted PGS use are some of the most vulnerable in American society: the disabled, the poor, children, the infertile, the stigmatized, and prospective parents desperate for a healthy child. The government has an obligation to protect the interests of vulnerable groups in the face of risks put upon them by the actions of others. For each vulnerable group, extending government oversight – whether to reduce discrimination, increase access, mitigate health risks, or provide better information – should reduce the risk of harm.

II. IS PGS OVERSIGHT NECESSARY?

In order to protect vulnerable groups, the government must first decide how extensively to intervene into the lives of its citizens. If the government limits the freedom of individuals to use a technology, it should do so in a principled, systematic manner.[79] The principles the government selects as the foundation of its regulatory agenda will determine the scope of the potential public policy. As the regulation of assisted reproductive technologies affects some of the most important and personal decisions of the citizenry, the government should exercise caution when deciding whether and how to intervene.[80]

A. The Authority of Society over the Individual

In determining the extent to which the government should regulate the use of PGS by prospective parents, John Stuart Mill's discussion of the limits of the authority of society over the individual is instructive.[81] Mill argues that "[a]s soon as any part of a person's conduct affects prejudicially the interests of others, society has jurisdiction over it, and the question whether the general welfare will or will not be promoted by interfering with it becomes open to discussion."[82] This general principle can be applied to define the boundaries of PGS regulation.

Mill's principle establishes a high threshold for governmental intervention that protects individual autonomy while not ignoring the interests of other

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79. *See* ALAN BUCHANAN ET AL., FROM CHANCE TO CHOICE: GENETICS AND JUSTICE 4, 15 (2000) (discussing the need to identify basic moral principles to guide public policy, and noting that "institutional ethical principles . . . are most essential for a just and humane society equipped with robust capabilities for genetic intervention").

80. *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 849 (1992) (holding that "the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood").

81. J.S. MILL, ON LIBERTY 73-91 (Elizabeth Rapaport ed., Hackett Publ'g Co. 1978) (1863).

82. *Id.* at 73.

members of society. Under this approach, the government should intervene only if the use of PGS threatens unjust harm to either the individuals involved in the procedure[83] or the members of society affected by use of the procedure. The latter category might include those who do not have access to these technologies but must compete with those who do; those with diseases and conditions screened out by PGS who may receive less understanding and support from society; those who have to pay for others' medical care; and possibly those who are greatly disturbed by widespread use of these technologies.[84] Mill's libertarian standard generally opposes government intervention unless it is absolutely necessary;[85] regulations that would be acceptable under this standard represent the minimum that the government should do to oversee PGS. Many would argue that the government should do even more.

Federal and state governments have generally followed Mill's approach in regulating health care. They have been reluctant to interfere in individual medical decisions, intervening only when it has been necessary to protect the patient or society. For patients, the government has acted 1) to require physicians to provide patients with material information necessary to give informed consent;[86] 2) to ensure the competence or safety of the personnel, clinic, hospital, and laboratory providing medical care;[87] and 3) to eliminate the use of unsafe, ineffective, or counterfeit drugs.[88]

When an individual's medical decision could negatively affect others, the

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83. This includes both prospective parents and children. The government should intervene to protect parents from the potential harms caused by information asymmetries common in medical practice and from unsafe or ineffective health care practices.

84. Mill's original principle would not include "distaste," "outrage," or discomfort to others as a harm that constitutes grounds for governmental regulation. MILL, *supra* note 81, at 81-82. However, in this context, given the passionate nature of the debate over abortion and status of the embryo in the United States, I have elected to include this as a harm that should warrant government consideration and possibly intervention, albeit a harm of lesser value than other more direct harms caused by PGS.

85. *See id.* at 73-74, 76-77.

86. *See* Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429 app. at 493-501 (2006) (listing state informed consent statutes and relevant cases).

87. 42 U.S.C. § 263a(b) (2000) (requiring all laboratories that solicit or accept materials derived from the human body for laboratory examination to be certified).

88. 21 U.S.C. § 393(b) (2000) (stating that the mission of the FDA is to ensure the safety and efficacy of drugs and medical devices). Outside of medical treatment decisions, the government intervenes in the health care system significantly in its capacity as payor for Medicare and Medicaid services. As a payor, the government determines which services it will reimburse physicians for and at what rates. This has a substantial impact on the overall practice of medicine. *See, e.g.*, PAUL J. FELDSTEIN, HEALTH POLICY ISSUES: AN ECONOMIC PERSPECTIVE 109-13, 115-18, 202-03 (3d ed. 2003).

government has restricted the individual's autonomy to protect society. States may use their police power to quarantine individuals or mandate vaccinations in order to protect the public's health.[89] The government also has the power to regulate individual medical decisions based on non-health-related social interests.[90] With respect to reproductive autonomy, the Supreme Court in *Gonzales v. Carhart* recognized the right of the federal government to prohibit the use of a medical procedure, partial-birth abortion, on the basis of social interests in respecting the life of the unborn and protecting the integrity of physicians.[91] To determine whether intervention is appropriate, the government must understand the individual and social risks associated with PGS.

B. Risks Associated with PGS

While PGS offers numerous benefits to prospective parents, its unfettered use threatens harm to both individuals and society. Although many of the known risks rarely materialize, these harms can be substantial for both the offspring and the parents, ranging from minor inconveniences to serious physical and mental disabilities and death. Expanding PGS use also raises social concerns regarding discrimination, disparities in access, and devaluing the embryo.

1. Risks to Offspring Born via PGS

Risks to offspring born via PGS result from the transfer of multiple embryos,[92] the ART procedures used to create the embryo, like IVF and ICSI, and the embryo biopsy.[93] Although ART procedures used to give an individual life cannot be said to harm that individual, unless the life was not worth living, the risks associated with such procedures are important for physicians, patients, and the government to consider in making decisions regarding their use.[94]

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89. *See, e.g.*, Jacobsen v. Massachusetts, 197 U.S. 11 (1905); O'Neil v. State, 32 So. 667 (Ala. 1902); *see also* Lawrence O. Gostin, Jeffery P. Koplan & Frank P. Grad, *The Law and the Public's Health: The Foundations*, *in* LAW IN PUBLIC HEALTH PRACTICE 3, 16 (Richard A. Goodman et al. eds., 2003).

90. *See, e.g.*, Gonzales v. Carhart, 127 S. Ct. 1610, 1617 (2007) (holding that partial-birth abortion could be regulated for the purposes of "protecting innocent human life from a brutal and inhumane procedure and protecting the medical community's ethics and reputation").

91. *Id.*

92. *See* Klemetti et al., *supra* note 14, at 1821 (discussing the number of multiple births resulting from IVF).

93. *See* Sirpa Soini et al., *The Interface Between Assisted Reproductive Technologies and Genetics*, 14 EUR. J. HUM. GENETICS 588, 608-09 (2006).

94. DEREK PARFIT, REASONS AND PERSONS, 358-61 (1984) (describing the "non-identity problem" as the dilemma that an individual cannot be said to be harmed by a decision that led to his or her birth, unless the life was not worth living, which can be applied to parental decisions to use

Parents and clinicians often decide to transfer more than one embryo per cycle of IVF or PGS to improve success rates.[95] This practice increases the incidence of multiple births from 3% with natural conception to 33% with IVF,[96] and as a result, harms the overall health of children born via IVF.[97] In a study published in *Pediatrics*, Reija Klemetti and colleagues found that IVF infants "showed much worse" perinatal health indicators than naturally conceived children, which was partly explained by multiple gestations.[98] Klemetti found that IVF infants were more likely to be born through Cesarean section (35.8% vs. 15.3%), to be born preterm (23.6% vs. 5.5%), to have low birth weight (24% vs. 4.8%), to require treatment in the newborn intensive care unit (23% vs. 8.2%), to require hospitalization for seven days or more (23.8% vs. 6.4%), and to die perinatally (1.3% vs. 0.6%) compared to naturally conceived controls.[99] Practice guidelines or regulations limiting the number of embryos that clinicians can transfer could significantly reduce the incidence of adverse health outcomes associated with IVF multiple births, albeit at the cost of lowering the percentage of IVF cycles that result in a live birth.[100]

ART that risk harm to the resultant child).

95. *See* Michael Le Page, *Fertility Experts Call for One Embryo per IVF Cycle*, NEW SCIENTIST, Oct. 18, 2006, http://www.newscientist.com/channel/sex/dn10326-fertility-experts-call-for-one-embryo-per-ivf-cycle.html.

96. CTRS. FOR DISEASE CONTROL & PREVENTION, 2004 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 22 (2006), *available at* http://ftp.cdc.gov/pub/Publications/art/2004ART508.pdf (stating that approximately 33% of all live births from IVF produced more than one infant (30% twins, 3% triplets or more) compared with 3% incidence in the normal population).

97. Bonduelle et al., *supra* note 15, at 416-18; Michèle Hansen et al., *The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and In Vitro Fertilization*, 346 NEW ENG. J. MED. 725, 727 (2002); Klemetti et al., *supra* note 14, at 1822 (2006); Soini et al., *supra* note 93, at 606-07.

98. Klemetti et al., *supra* note 14, at 1822. Perinatal health indicators are those surrounding the time of birth, both before and immediately after. Klemetti et al. found that nearly half of IVF infants born from multiple births required hospitalization beyond seven days (47.4% vs. 6.4%) and treatment in the NICU (42.1% vs. 8.2%) compared with naturally conceived infants. The risk of perinatal death also nearly quadrupled from 0.6% in naturally conceived infants to 2% in IVF infants from multiple births.

99. *Id.* at 1822 tbl. 2 (comparing 4559 infants conceived by IVF and 190,398 infants conceived naturally).

100. The American Society for Reproductive Medicine recently issued practice guidelines that recommend transferring a limited number of embryos based upon the woman's age and reproductive history. *See* Practice Comm., Soc'y for Assisted Reprod. Tech. & Practice Comm., Am. Soc'y for Reprod. Med., *Guidelines on Number of Embryos Transferred*, 86 FERTILITY & STERILITY S51 (2006). Whether clinicians will abide by the voluntary guidelines remains in question as transferring fewer embryos reduces the pregnancy success rates of the procedure, which

However, practice guidelines and regulations limiting the number of embryos transferred cannot eliminate all of the risks associated with IVF and ICSI. Studies performed in the last few years have consistently shown that singleton babies born via IVF and ICSI also have higher rates of mortality, preterm delivery, congenital malformations, and low birth weight compared to naturally conceived babies.[101] Likewise, by the age of five, IVF and ICSI children were more likely to have had a childhood illness and significantly more likely to have had a surgical operation than naturally conceived children.[102] However, the data remain unclear as to what portion of the negative health outcomes of IVF and ICSI result from the underlying cause of parental infertility, rather than the ART procedures themselves.[103] While the health of IVF and ICSI children appears to be worse than naturally conceived children, it is not overwhelmingly so.[104] Nonetheless, these risks should be balanced against the relevant interests in undergoing IVF or ICSI.

In cases of infertility, the government should weigh the above risks against the parents' interests in having a healthy biological child and against the

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is often undesirable for prospective parents and clinicians. Prospective parents likely prefer higher success rates per cycle, as they often pay for the procedure out of their own pocket and desire a child sooner rather than later. Clinicians may prefer higher success rates per cycle because clinics gain reputations based on the ratio of pregnancies and live births per cycle.

101. *See* Bonduelle et al., *supra* note 15; Halliday, *supra* note 14; Hvidtjørn et al., *supra* note 14; Klemetti et al., *supra* note 14; Mastenbroek et al., *supra* note 16. *But see* Tracy Hampton, *Panel Reviews Health Effects Data for Assisted Reproductive Technologies*, 292 JAMA 2961, 2961 (2004) (meta-analysis found "evidence generally suggestive of no association" between ART procedures and serious malformations); I. Ponjaert-Kristoffersen et al., *International Collaborative Study of Intracytoplasmic Sperm Injection-Conceived, In Vitro Fertilization-Conceived, and Naturally Conceived 5-Year-Old Child Outcomes: Cognitive and Motor Assessments*, 115 PEDIATRICS e283 (2005), http://pediatrics.aappublications.org/cgi/reprint/115/3/e283 (finding no statistical difference between the cognitive and motor skills of children born via ICSI and naturally conceived children).

102. Bonduelle et al., *supra* note 15, at 417.

103. In October 2006, Professor Mary Croughan found that women who had experienced fertility problems had children with 2.7 times the risk of having autism, mental retardation, cerebral palsy, seizures and cancer than women without such conditions. *Infertility Link to Autism Risk*, BBC NEWS, Oct. 26, 2006, http://news.bbc.co.uk/go/pr/fr/-/1/hi/health/6086824.stm. For autism alone, Croughan and colleagues found that the risk increased 400% for offspring of patients with fertility problems. This research leaves open the contribution that procedures such as IVF and ICSI made to these negative health outcomes. Harms could have resulted from health problems already present in the parents, from the procedures they used to try to overcome their infertility, or from a combination of both.

104. *See* Bonduelle et al., *supra* note 15, at 415 (stating that "74% of ICSI children and 77% of IVF children experienced significant childhood illness compared with only 57% of [naturally conceived] children").

embryo's interest in being born. Are the risks to the embryo of being born with a higher risk of a disease or defect so great as to outweigh the benefit of life itself? The question of whether a child can be harmed by a procedure that gives it life has been the topic of debate among scholars and in many court cases.[105] While legal scholars continue to disagree on this issue, the majority of courts have refused to hear claims brought by children on the basis that they should not have been born, so called "wrongful life claims";[106] however, parents have successfully brought "wrongful birth claims" to recover the cost of raising a disabled child from physicians for failure to diagnose the disorder or prevent its occurrence.[107] Currently, the risks of IVF and PGS do not make an individual's life so miserable as to negate its value, therefore its use for fertility purposes remains appropriate in those populations where PGS can improve IVF success rates.[108] In contrast, in cases where IVF and PGS are not necessary for the parents to give birth, the risk to the child from the procedures should be weighed against the benefits of selecting for a certain characteristic.

More investigation is necessary to determine the full extent and magnitude

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105. *See, e.g.*, PARFIT, *supra* note 94, at 358-61 (describing the "non-identity problem"); Carl H. Coleman, *Conceiving Harm: Disability Discrimination in Assisted Reproductive Technologies*, 50 UCLA L. REV. 17, 56 (2002) (stating that it is "possible to object to efforts to bring about the birth of a child likely to suffer considerably even if the child, once born, would not consider her life a disadvantage"); Philip G. Peters, Jr., *Protecting the Unconceived: Nonexistence, Avoidability, and Reproductive Technology*, 31 ARIZ. L. REV. 487, 502-03 (arguing that a miserable life may be worth continuing, but not worth receiving); John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J.L. & MED. 7, 14 (2004) (arguing that if the child's life is not so miserable as to be wrongful, then the child would have benefited from being born, and the use of the ART cannot be restricted on the basis of harm to the child).

106. *See, e.g.*, Walker *ex rel* Pizano v. Mart, 790 P.2d 735, 741 (Ariz. 1990) (holding that a child bringing a "wrongful life" claim had suffered no legally cognizable injury); Kassama v. Magat, 792 A.2d 1102, 1115-23 (Md. 2002) (noting that twenty-eight other states had rejected wrongful life claims); Viccaro v. Milunsky, 551 N.E.2d 8, 12 (Mass. 1990) (refusing to recognize a cause of action for wrongful life). A few jurisdictions will permit wrongful life claims. *See, e.g.*, Galvez v. Frields, 107 Cal. Rptr. 2d 50, 57-59 (Cal. Ct. App. 2001) (noting that California explicitly acknowledges a child's right to bring a wrongful life claim); Harbeson v. Parke-Davis, Inc. 656 P.2d 483, 495 (Wash. 1983) (reasoning that "a child may maintain an action for wrongful life").

107. *See, e.g.*, Keel v. Banach, 624 So. 2d 1022, 1026 (Ala. 1993) (recognizing a cause of action for wrongful birth); Turpin v. Sortini, 643 P.2d 954, 957 (Cal. 1982) (citing a number of cases in which parents were permitted to recover general damages for the wrongful birth of their children); Emerson v. Magendatnz, 689 A.2d 409 (R.I. 1997) (recognizing a parent's claim against a physician after a sterilization procedure failed); Noah, *supra* note 20, at 638-40.

108. These populations include couples that have experienced repeated miscarriages or otherwise have a poor prognosis related to chromosomal abnormalities. *See* Munné et al., *supra* note 37, at 329; Verlinsky et al., *supra* note 34, at 221.

of the risks associated with IVF. However, the known risks of IVF alone warrant regulation of uses outside of infertility to ensure that the benefits of the procedure outweigh the risks to both mother and offspring. Improved data collection and research regarding benefits and risks of PGS on the lives of children born through the technology is needed. Without such information, parents will continue to make under-informed decisions that may jeopardize the health of their children.

In addition to the risks from transferring multiple embryos and embryo creation, couples that use PGS may subject their offspring to additional harm caused by the embryo biopsy procedure. While the bulk of available evidence suggests that infants born via PGS have roughly similar health outcomes to those born via IVF, the question of whether removing cells for genetic testing harms development still looms over the practice of PGS.[109] Harm from the embryo biopsy was one of the first reasons suggested for the drop in live birth rates from 37% in IVF patients to 25% in IVF patients undergoing PGS as shown in a recent study from the Netherlands.[110] Other scientists have suggested that imprecise or unskilled embryo biopsy can substantially harm the embryo, preventing implantation and development.[111] In addition, whether the embryo biopsy can cause developmental and other health problems that may arise later in life remains unknown, as few children born through PGS have reached puberty.

Some of the risks associated with PGS may also be psychological. The President's Council on Bioethics expressed concern that even "the present, more modest, applications of PGD – screening for severe medical conditions, screening for genetic predispositions for a given disease, elective sex selection, and selection with an eye to creating a matching tissue donor" treat the child as merely a "means to the parents' ends."[112] Under this view, embryo selection based on genetic traits establishes the child as an instrument of the parents' goals, as opposed to a gift in and of himself or herself. Jurgen Habermas and Michael Sandel have argued that this level of parental control limits the sense of freedom and personal control children born through PGS will have over their lives.[113] However, in the absence of PGS, many parents exercise extensive control over

109. Mastenbroek et al., *supra* note 16, at 15-17; Verlinsky et al., *supra* note 28, at 292-94; *Preimplantation Genetic Diagnosis Okay for Test-Tube Babies, Study Finds*, SCIENCE DAILY, June 18, 2007, http://www.sciencedaily.com/releases/2007/06/070616191628.htm.

110. Mastenbroek et al., *supra* note 16. For further explanation, see *supra* note 37.

111. Munné et al., *supra* note 37.

112. PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 95 (2004), *available at* http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf [hereinafter PRESIDENT'S COUNCIL].

113. JURGEN HABERMAS, THE FUTURE OF HUMAN NATURE 75 (2003); MICHAEL J. SANDEL, THE CASE AGAINST PERFECTION 82-83 (2007).

their children's lives and use their children as instruments of their own ends. Psychological research is needed to substantiate the view that PGS would significantly increase this risk.

While continued research is necessary to better understand the health implications of PGS for offspring, the government should make efforts in the present to educate physicians and prospective parents on the known risks to offspring from IVF and the potential risks associated with embryo biopsy, despite their uncertain scope and magnitude.

2. Risks to the Prospective Parents

Risks also exist for the prospective parents who engage in PGS. IVF poses several health risks to women. The hormone stimulation procedures required to retrieve the eggs can lead to ovarian hyperstimulation, which can result in nausea, vomiting, shortness of breath, distended abdomen, and hospitalization.[114] The multiple gestations common with IVF also increase maternal risks, such as pregnancy-induced hypertension, gestational diabetes, and excessive bleeding in labor and delivery.[115] IVF also doubles the risk of an ectopic pregnancy, which can necessitate surgery and in rare cases result in death.[116] Serious concern also exists about the long-term risks associated with IVF.[117] Some researchers hypothesize that the hormones included in the ovarian stimulation injections may increase the risk of breast, ovarian, and endometrial cancer.[118] However, to date research has found no association between these cancers and IVF use, but more studies should be performed in the future to confirm these early findings.[119]

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114. *See* WORKSHOP REPORT, *supra* note 59, at 17-19; Grainger, Fraizer & Rowland, *supra* note 59, at S162.

115. *See, e.g.*, Barbara Luke & Morton B. Brown, *Contemporary Risks of Maternal Morbidity and Adverse Outcomes with Increasing Maternal Age and Plurality*, 88 FERTILITY & STERILITY 283, 286 (2007). For instance, the risk of pregnancy-induced hypertension doubles from just under 4% in women pregnant with one fetus to just under 8% in those carrying twins and over 11% in those carrying triplets. *Id.*

116. Willem M. Ankum, *Diagnosing Suspected Ectopic Pregnancy*, 321 BRIT. MED. J. 1235, 1235 (2000) (stating that the maternal death rate associated with ectopic pregnancies is estimated to be 0.3-0.4 per 1000 ectopic pregnancies); Ctrs. for Disease Control & Prevention, *Ectopic Pregnancy – United States, 1990-1992*, 27 MORBIDITY & MORTALITY WKLY. REP. 44, 46-48 (1995) (finding 19.7 ectopic pregnancies out of 1000); Soini et al., *supra* note 93, at 606 (finding IVF pregnancies had a 4% chance of being ectopic); Stephen K. Van Den Eeden et al., *Ectopic Pregnancy Rate and Treatment Utilization in a Large Managed Care Organization*, 105 OBSTETRICS & GYNECOLOGY 1052, 1052 (2005) (finding a rate of 20.7 ectopic pregnancies per 1000).

117. WORKSHOP REPORT, *supra* note 59, at 22.

118. *Id.* at 22-24.

119. *Id.* at 24-26.

Clinicians and policymakers frequently overlook the risks to women from engaging in ART because the women are often willing to accept almost any personal risk to have a healthy child. Due to the vulnerability of the ART patient population, the government in conjunction with physicians should develop practice guidelines designed to reduce the risk of ART. The government should also help ensure that clinicians inform women of the risks and benefits associated with IVF, as well as alternatives, such as natural IVF and mild IVF, that may mitigate these risks.[120]

In addition to determining the risks to the offspring and the mother, prospective parents should also consider two additional factors that may impact the benefit of making a particular genetic selection: the accuracy of the genetic tests and the complex risk factors associated with embryo selection.[121] Inaccurate genetic tests can produce false positives or false negatives, thereby negating the benefit of the selection.[122] Certain features of embryo selection may also result in parents' selecting for a specific trait and inadvertently also selecting for an undesired trait. Both factors can easily result in a miscalculation of the benefit gained by undergoing PGS.

The potential for genetic testing errors creates risk within PGS. These errors can arise from the limited genetic sample available for PGS, inaccuracy of the tests themselves, and human laboratory errors. Despite public beliefs to the contrary, the government conducts very little oversight or regulation of genetic tests in comparison to other healthcare products.[123] The FDA has not approved

120. Natural IVF, which does not use hormone injections to stimulate the ovaries, but removes only one egg as the woman ovulates, eliminates the need for stimulation hormones altogether. For other women who need ovarian stimulation, clinicians have started to successfully use milder doses of hormones to reduce the negative side effects for women, the costs of IVF, and the risk of pharmaceutical interference with embryo development. F. Ubaldi et al., *Hopes and Facts About Mild Ovarian Stimulation*, 14 REPROD. BIOMEDICINE ONLINE 675, 679 (2007).

121. The risks associated with misdiagnosis and embryo selection are risks to the parents as opposed to risks to the children born through PGS because any child born as a result of these errors could not have been born in their absence. A misdiagnosis that caused parents to select an affected embryo over a non-affected embryo could not be said to have harmed the resultant child, as that child would not otherwise been born. *See* PARFIT, *supra* note 94, at 356-61 (arguing that such an action cannot be said to harm the resultant child because a different person would have been born had the error not occurred); Robertson, *supra* note 105, at 27 (arguing that "if enabling the birth of children with diseases such as cystic fibrosis, Tay-Sachs, deafness, sickle cell anemia, or Huntington's disease is ethically problematic, it would have to be on some ground other than harm to the children themselves").

122. BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 4.

123. Genetics & Pub. Policy Ctr., Genetic Testing Quality Initiative, http://www.dnapolicy.org/policy.gt.php (last visited Mar. 30, 2008) (noting the results of a recent study finding that the public widely believed that the government regulated the quality of genetic tests, and that the government

genetic tests as safe and effective unless they are sold commercially as test kits, which rarely occurs.[124] Laboratories conducting genetic tests are not required to go through any accreditation or approval process outside of the very basic requirements that the Clinical Laboratory Improvement Amendments of 1988 (CLIA) places on all laboratories.[125] These requirements do not address any of the specific complexities associated with genetic testing, such as penetrance, gene-gene interaction, and gene-environment interaction.[126]

Devastating errors in PGS practice have occurred as a result.[127] The level of misdiagnoses in PGS remains largely unknown, but while conducting interviews with couples that had undergone PGS, members from the Genetics and Public Policy Center found that the embryos of three of seven women who had become pregnant following PGS had been misdiagnosed.[128] Due to error rates that are "not negligible," the Preimplantation Genetic Diagnosis International Society recommends that all PGS patients undergo prenatal screening during pregnancy, either through amniocentesis or chorionic villus sampling, to confirm the diagnosis.[129] In the absence of comprehensive data collection on PGS procedures and their outcomes, the frequency and impact of misdiagnosis are impossible to calculate.[130]

More so than in nearly any other area of medical testing, every effort should be made to ensure the accuracy of the tests and procedures performed for PGS. Secondary genetic tests cannot be performed to confirm results in the forty-eight hours required to implant the embryo. Extra DNA is not available if a sample is

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should perform this function).

124. Gail H. Javitt, *Policy Implications of Genetic Testing: Not Just for Geneticists Anymore*, 13 ADVANCES IN CHRONIC KIDNEY DISEASE 178, 179 (2006) (stating that of the more than 900 genetic disease tests available, test kits are available for only around a dozen).

125. *See* Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a (2000); *see also* Javitt, *supra* note 124, at 178.

126. *See supra* note 19.

127. In one documented case, a couple that already had a child with Fanconi anemia underwent PGD to select an embryo that was unaffected by Fanconi anemia and was a genetic tissue match for their sick child. Instead of transferring two unaffected embryos that could serve as cord blood donors to save the existing child, laboratory error resulted in the transfer of two embryos with the Fanconi anemia genetic mutation. *See, e.g.*, GENETICS & PUB. POLICY CTR., ISSUE BRIEF ON OVERSIGHT OF PREIMPLANTATION GENETIC DIAGNOSIS 1 (2006), *available at* http://www.dnapolicy.org/images/issuebriefpdfs/Oversight_of_PGD_Issue_Brief.pdf.

128. *Id.*

129. *The Preimplantation Genetic Diagnosis International Society (PGDIS): Guidelines for Good Practice in PGD*, 9 REPROD. BIOMEDICINE ONLINE 430, 433 (2004) (stating that "[g]iven that the error rate after single-cell analysis is not negligible, conventional prenatal diagnosis should be recommended to confirm and complete the analysis").

130. *See* GENETICS & PUB. POLICY CTR., *supra* note 127, at 1.

lost, contaminated or destroyed. For parents, the risk of misdiagnosis can have extreme consequences, such as the loss of a young child to a severe genetic disorder, the loss of a potentially healthy, viable embryo, or being faced with the difficult decision of whether to carry an affected child to term.

The embryo selection process also generates uncertainties. First, even with one hundred percent accurate genetic testing, PGS may cause a couple, and quite frequently an infertile couple, to discard an embryo that would never have developed the undesired disease or condition. Not all genetic conditions are one hundred percent penetrant, meaning that having the allele associated with a disorder or condition may not always result in its physical presentation.[131] Additional genetic or environmental factors that affect gene expression are often difficult to identify. Physicians and patients should consider gene penetrance in weighing the benefits of screening for a certain condition or discarding an embryo based on a specific result.

Second, our knowledge of the human genome and its functional mechanisms remains in its infancy. Prior to the completion of the human genome project, scientists estimated that the human genome contained approximately 100,000 protein-coding genes based upon the breadth of human function.[132] Now that the project is "essentially 'finished,'" its findings suggest that there are only 20,000 to 25,000 protein-coding genes, indicating that each gene performs substantially more functions than scientists originally thought.[133] Permitting parents to select for or against certain alleles based upon the first function discovered may have significant consequences, as they may unwittingly screen in certain detrimental traits or screen out certain positive traits.

This point is illustrated by sickle cell anemia, a recessive genetic disease with severe health consequences, such as severe pain episodes, strokes, anemia, kidney damage, and lung blockage.[134] In families with a high prevalence of sickle cell anemia, PGS could screen out affected and carrier embryos. Doing so may result in an evolutionary disadvantage, however, because having only one of the sickle cell alleles produces no disease, but instead provides malarial resistance.[135] While malaria is not a major health concern for many Americans, alleles linked

131. Human Genome Project, Evaluating Genetic Tests: Some Considerations, http://www.ornl.gov/sci/techresources/Human_Genome/resource/testeval.shtml (last visited Mar. 30, 2008).

132. Human Genome Project, How Many Genes Are in the Human Genome?, http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml (last visited Mar. 30, 2008).

133. *Id.*

134. Ga. Comprehensive Sickle Cell Ctr. at Grady Health Sys., The Sickle Cell Information Center, http://www.scinfo.org/sicklept.htm (last visited Mar. 30, 2008).

135. *Id.*

to other disorders or undesirable characteristics may confer different forms of evolutionary advantage, which could explain their continued existence in the gene pool.

Many alleles associated with desirable characteristics may also be unexpectedly associated with negative ones. For example, a couple may wish to select alleles associated with red hair and freckled skin, but will discover that this phenotype also carries a heightened risk of melanoma.[136] Obtaining more data about the range of harms and benefits associated with a certain allele will be imperative to enable people to weigh the benefits of screening out the allele against screening out a potential benefit or screening in a certain detriment.

Along with the benefit of being able to select the genetic traits of one's children comes the responsibility of taking the opportunity to choose genetic traits and choosing them correctly.[137] In a world where PGS is more common, parents may experience personal and social pressure to undergo PGS to select children based on the presence of desirable traits and to avoid the responsibility for children born with undesirable traits.[138]

Government intervention could mitigate the above risks to prospective parents. Efforts to improve the safety and efficacy of PGS procedures, increase research into the long-term health risks of ART, and disseminate information on the risks and benefits of PGS could improve the practice of PGS and the ability of parents to make informed treatment decisions. Specific regulatory objectives will be discussed in Part IV.

3. Risks to Society

In addition to the risks individuals face from PGS, the government should consider the impact PGS could have on society as a whole. As use of the technology increases and the range of genetic tests performed expands, the effects of PGS will no longer be limited to the individuals who use it or are created by it.[139] Unregulated, the widespread practice of PGS threatens to increase health disparities due to lack of access, discrimination, and tensions over the value of an embryo.

136. L.P. Fernandez et al., *MC1R: Three Novel Variants Identified in a Malignant Melanoma Association Study in the Spanish Population*, 28 CARCINOGENESIS 1659, 1659 (2007).

137. SANDEL, *supra* note 113, at 87.

138. *Id.* at 88-89 (noting that parents of children with Down syndrome and other genetic disabilities feel judged or blamed); PRESIDENT'S COUNCIL, *supra* note 112, at 96.

139. PRESIDENT'S COUNCIL, *supra* note 112, at 96-98.

a. Access and Health Disparities

Access to ART, including PGS, is limited both financially and culturally.[140] Financially, PGS is already out of reach for many couples. One cycle of PGS, including IVF, can cost between $12,500 and $16,000.[141] While some insurance companies have provided coverage for PGD to screen out a serious genetic disorder, most companies generally do not provide coverage for PGS for infertility.[142] As DNA microarrays enable parents to screen for multiple genetic conditions, the price for PGS will only increase.[143]

Cultural and educational factors can also inhibit access to PGS. While income and health insurance are important factors leading to disparities in health across populations, health care researchers also argue that "much of the answer has to be found elsewhere."[144] It remains important to consider that discriminatory practices,[145] educational inequality,[146] and cultural biases[147] also

140. Mary Crossley, *Dimensions of Equality in Regulating Assisted Reproductive Technologies*, 9 J. GENDER, RACE & JUST. 273, 278-79 (2005); Eve C. Feinberg et al., *Economics May Not Explain Hispanic Underutilization of Assisted Reproductive Technology Services*, 88 FERTILITY & STERILITY 1439 (2007); Lynn White, Julia McQuillan & Arthur L. Greil, *Explaining Disparities in Treatment Seeking: The Case of Infertility*, 85 FERTILITY & STERILITY 853, 855-56 (2006).

141. BARUCH ET AL., *supra* note 17, at 22 (estimating the cost of IVF to be $10,000-$12,000 and the cost of PGD to be $2500-$4000); Reproductive Genetics Institute, *supra* note 63 (charging up to $5000 for PGD screening plus $2000 for embryo biopsy and other mandatory services).

142. Crossley, *supra* note 140, at 278. Some states require some form of insurance coverage for IVF. Seven states – Arkansas, Hawaii, Illinois, Maryland, Massachusetts, New Jersey, and Rhode Island – have passed legislation mandating that insurance companies provide coverage for IVF. Three other states – Montana, Ohio and West Virginia – have laws requiring insurance companies to cover infertility treatments, but not specifically IVF. Finally, California and New York require coverage for infertility, but specifically exclude coverage for IVF. *See* Nat'l Conference of State Legislators, 50 State Summary of State Laws Related to Insurance Coverage for Infertility Therapy, http://www.ncsl.org/programs/health/50infert.htm (last visited Mar. 30, 2008). To date, no state has extended mandatory insurance coverage to PGS screening.

143. *See, e.g.*, WORLD HEALTH ORG., GENETICS, GENOMICS AND THE PATENTING OF DNA: REVIEW OF THE POTENTIAL IMPLICATIONS FOR HEALTH IN DEVELOPING COUNTRIES 13-14 (2005), *available at* http://www.who.int/genomics/FullReport.pdf (discussing the restrictive licensing practices of Myriad Genetics and high costs of tests for the BRCA1 and BRCA2 genes, which are associated with breast, ovarian, and prostate cancer).

144. White, McQuillan & Greil, *supra* note 140, at 855; *see also* Feinberg et al., *supra* note 140, at 1439-41.

145. Michelle van Ryn & Jane Burke, *The Effect of Patient Race and Socio-Economic Status on Physicians' Perceptions of Patients*. 50 SOCIAL SCI. & MED. 813, 813-17 (2000).

146. Tarun Jain & Mark D. Hornstein, *Disparities in Access to Infertility Services in a State with Mandated Insurance Coverage*, 84 FERTILITY & STERILITY 222 (2005).

147. Feinberg et al., *supra* note 140, at 1441.

create significant barriers to care. In Massachusetts, which mandates insurance coverage for IVF services, researchers found that Hispanic/Latino women used IVF significantly less than expected, based on population demographics, while Chinese and other Asian/Pacific Islanders used IVF significantly more than expected.[148] Some of this disparity may result from reduced access to health insurance amongst Hispanic/Latino women.[149] However, disparities in use by level of education were much more striking. None of the infertility patients studied had less than a high school education, compared with 15.1% of the state population.[150] Likewise, almost half (49.6%) of the patients had advanced degrees, compared with 12.4% in the state.[151] Other researchers have corroborated these results by finding that among individuals in the military health care system, who have relatively equal access to care and higher education rates than the average population, Hispanics were still strongly underrepresented among ART patients despite similar levels of infertility.[152]

Inequalities in access can increase both health and socioeconomic disparities. Health disparities between socio-economic groups often result in disparities in educational, occupational, and income opportunities, which can in turn further exacerbate existing inequalities.[153] Unregulated PGS use has the

148. Jain & Hornstein, *supra* note 146.

149. The Massachusetts mandate requires insurance companies that provide pregnancy coverage to also cover medically necessary infertility diagnosis and treatment, which would include IVF. MASS. GEN. LAWS ch. 175, § 47H (1998). However, the mandate does not provide access to infertility treatments to women who do not have any insurance coverage at all. Therefore, the disparity may result from a lack of insurance coverage in general amongst Latino/Hispanic women, as opposed to a reluctance to use the technology.

150. Jain & Hornstein, *supra* note 146, at 222.

151. *Id.*

152. Feinberg et al., *supra* note 140, at 1439. The authors examined the use of ART services at Walter Reed Medical Center within the military health care system, which closely resembles an equal-access-to-care model. In the Department of Defense, only 6.5% of the Hispanic population did not graduate from high school, compared with 36.4% of the general U.S. Hispanic population. Hispanics represented 9% of the Department of Defense population, but only 4% of the ART population at Walter Reed. The authors concluded that this result is "markedly less than expected if use was primarily driven by cost." *Id.* at 1440.

153. Nancy E. Adler & Katherine Newman, *Socioeconomic Disparities in Health: Pathways and Policies*, 21 HEALTH AFF. 60 *passim* (2002). The link between disparities in socioeconomic status and disparities in health status is established in the medical literature, as is the severity of health disparities within the U.S. health care system. U.S. DEP'T HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2010: UNDERSTANDING AND IMPROVING HEALTH 2, 11-16 (2000), *available at* http://www.healthypeople.gov/document/pdf/uih/2010uih.pdf (identifying eliminating health disparities as one of two major goals for improving the health of the nation); Ernest Moy, Elizabeth Dayton & Carolyn M. Clancy, *Compiling the Evidence: The National Healthcare Disparities Reports*, 24 HEALTH AFF. 376, 376 (2005).

potential to increase health disparities across a number of medical conditions. Prospective parents undergoing PGS will have every incentive to screen embryos for genes linked to known health conditions. Doing so creates two health benefits: Their offspring will likely have fewer harmful genetic health conditions, and the parents will be aware of additional disease susceptibilities. This advance awareness will enable parents to better address the future needs of their child and possibly to mitigate or eliminate the effects of the genetic disease.

Since wealthier members of society already receive better health care and numerous other benefits, it is reasonable to question whether the advantages provided by PGS raise any additional cause for government intervention to alleviate health disparities. Two factors differentiate benefits provided via PGS from other health benefits derived by wealth after birth. First, all subsequent generations will benefit from selection against disease genes, disease susceptibility, or certain genetic conditions. Not only will the individual be advantaged, but this advantage will most likely extend to his or her immediate descendants. While other advantages, like wealth and opportunity, can be passed down to children, genetic selection offers this kind of advantage to a greater degree and with greater certainty. Individuals with a parent that has an autosomal dominant disorder, like Huntington's disease, have a 50% chance of developing the disease.[154] PGD offers parents the opportunity to minimize this worry for their children and their children's descendants.[155] Second, selection against diseases and disease susceptibility prior to implantation eliminates any suffering or medical treatment associated with a disorder. Often wealthy individuals can obtain better treatment or care, but many diseases are incurable. For instance, selecting against genes that have been linked to an increased risk of Alzheimer's disease[156] provides an advantage that cannot be obtained by any amount of money for treatment. Those lacking access to PGS will not be able to obtain these benefits. Not only will the burden of disease be placed on those least able to afford care, but it will also be placed on those least able to lobby for research and treatments. Over time, the shifts in the burden of disease will further exacerbate health disparities.

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154. Individuals with an autosomal dominant disorder will have the disease if they have one allele associated with the disorder, as opposed to autosomal recessive disorders, which require individuals to have two disease alleles to have the disease. Children of individuals with autosomal dominant disorders have a 50% chance of having the disease. Medline Plus, Autosomal Dominant, http://www.nlm.nih.gov/medlineplus/ency/article/002049.htm (last visited Mar. 30, 2008).

155. While the children could marry an individual with Huntington's disease and then have this concern arise again, being able to eliminate the immediate risk and worry is highly valuable.

156. *See* Harrington et al., *supra* note 3.

b. Eugenics and the Impact on Individuals Living with Disabilities

The government should also consider whether individuals' use of PGS directly harms other members of society. In many ways, PGS is the technological manifestation of the early twentieth-century eugenicists' goal to "improve the human condition through genetic selection."[157] The seductive nature of this goal should not be underestimated. In the absence of genetic selection technology, more than thirty U.S. states enacted involuntary eugenic sterilization laws, which resulted in the forced sterilization of over 60,000 Americans deemed "unfit" to procreate during the twentieth century.[158] Although the U.S. government is unlikely to require individuals to undergo PGS, we should not ignore the argument claiming that "through ART, the genetics revolution, and carte blanche procreative liberty, we could do unto ourselves via the collective impact of individual decision-making what governments have imposed in the past in the name of bettering the human condition."[159]

A number of legal and ethical scholars have argued that in the absence of governmental regulation and enforcement, individual eugenic practices to select desirable genetic traits, such as PGS, cease to be morally problematic.[160] Judith Daar has noted that in a diverse society like the United States, "concerns about eugenics must be viewed from a perspective of 'individual-relativism,'" such that "one parent's idea of a 'good birth' may be a disappointment, or worse, for another parent."[161] Other liberal pluralists argue that while most parents will want to improve the overall health and well-being of their children, their ideas of how to do so are likely to differ significantly.[162] This argument has merit in that multi-use PGS will provide parents with significantly more choice over the types of characteristics their offspring possess. In contrast to state eugenic policies of the past, individual embryo selections do not violate others' reproductive rights or

157. Malinowski, *Choosing*, *supra* note 20, at 204; *see also* Judith F. Daar, *ART and the Search for Perfectionism: On Selecting Gender, Genes and Gametes*, 9 GENDER, RACE & JUST. 241, 260-62 (2005).

158. Daar, *supra* note 157, at 261.

159. Malinowski, *Choosing*, *supra* note 20, at 204; *see also* BUCHANAN ET AL., *supra* note 79, at 177.

160. BUCHANAN ET AL., *supra* note 79, at 27-60, 156-91, 304-45; ROBERT NOZICK, ANARCHY, STATE AND UTOPIA 315 (1974); Nicholas Agar, *Liberal Eugenics*, 12 PUB. AFF. QUART. 137 (1998); Daar, *supra* note 157, at 260-66.

161. Daar, *supra* note 157, at 265, 271-72 (arguing that "both parents and children can be harmed if a parent is denied the opportunity to select to birth a child" possessing a much desired trait, such as gender).

162. This notion of liberal pluralism and autonomy has been discussed in greater depth elsewhere. *See, e.g.*, BUCHANAN ET AL., *supra* note 79, at 176-79; SANDEL, *supra* note 113, at 75-83; Agar, *supra* note 160, at 137.

personal autonomy, thereby mitigating some of the social risk associated with reproductive genetic selection.

However, the liberal eugenics argument fails to address how PGS affects the lives of individuals with the undesired conditions. In a recent survey, 81% of Americans believed that PGS could lead to further discrimination against the disabled.[163] A subsection of the disability community, known as the Expressivists, has argued that the use of preimplantation and prenatal genetic tests to select for certain traits sends a hurtful message to people with those traits.[164] Disability activist Marsha Saxton has commented that this message represents "the greatest insult: some of us are 'too flawed' in our very DNA to exist; we are unworthy of being born."[165] While the desire to bring a child into the world without seriously limited capabilities does not imply a belief that individuals with those disabilities should not exist, policymakers should be aware of these concerns and be prepared to address them.[166]

Governments seeking to address these concerns face a daunting task. Permitting parents to discard embryos with "undesirable" genetic traits and conditions without any government oversight appears to sanction overtly eugenic practices. In this vein, the President's Council on Bioethics has argued that unregulated PGS risks "normalizing the idea that a child's particular genetic makeup is quite properly a province of parental reproductive choice, or the idea that entrance into the world depends on meeting certain genetic criteria."[167] Alternatively, Adrienne Asch has spoken out against any regulatory attempt at delineating which genetic tests are appropriate for physicians to offer for reproductive purposes.[168] By permitting individuals to select against some traits, but refusing to let people select against other traits, Asch argues that the

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163. ANDREA KALFOGLOU ET AL., GENETICS & PUB. POLICY CTR., REPRODUCTIVE GENETIC TESTING: WHAT AMERICA THINKS 36 fig. 6.1 (2004), *available at* http://www.dnapolicy.org/images/reportpdfs/ReproGenTestAmericaThinks.pdf (surveying a nationally representative sample of 4834 Americans).

164. Erik Parens & Adrienne Asch, *The Disability Rights Critique of Prenatal Genetic Testing: Reflections and Recommendations*, *in* PRENATAL TESTING AND DISABILITY RIGHTS 3, 13-14 (Erik Parens & Adrienne Asch eds., 2000). Adrienne Asch has specified that the message offends because it permits a single trait to stand in for the whole person, and in doing so, implies that it is unnecessary to learn about the rest of that individual. *Id.* at 13 (citing Adrienne Asch, *Why I Haven't Changed My Mind About Prenatal Diagnosis: Reflections and Refinements*, *in* PRENATAL TESTING AND DISABILITY RIGHTS 234, 235-36 (Erik Parens & Adrienne Asch, eds., 2000)).

165. Marsha Saxton, *Disability Rights and Selective Abortion*, *in* ABORTION WARS: A HALF CENTURY STRUGGLE, 1950-2000, at 391 (Rickie Solinger ed., 1998).

166. BUCHANAN ET AL., *supra* note 79, at 274.

167. PRESIDENT'S COUNCIL, *supra* note 112, at 95.

168. Adrienne Asch, *Disability Equality and Prenatal Testing: Contradictory or Compatible?*, 30 FLA. ST. U. L. REV. 315, 338-39 (2003).

government makes a determination that some lives are valued and some lives are not, which "will surely exacerbate the discrimination and stigmatization of future children with the listed conditions."[169] However, passing regulation to limit the use of PGS to certain disorders and traits does not necessitate the inference that the government does not value the lives of its existing citizens with those disorders.[170] Regulation to ensure resources and protection for individuals with disabilities should accompany regulation for PGS.

Governments that have examined issues relating to eugenics and discrimination arising from PGS have taken a range of approaches. Germany,[171] Switzerland,[172] Austria,[173] and Italy[174] have all passed legislation banning the practice of PGS entirely, ostensibly to avoid any implications of eugenic practices. Countries like Canada[175] and the United Kingdom[176] have established administrative agencies to review and regulate PGS. The Japanese government has not passed legislation limiting PGS, but the Japanese Society of Obstetricians and Gynecologists enacted a strict licensing system that carefully considers the potential effect of a specific use of PGS on disabled members of society before permitting a clinic to use PGS for that indication.[177] To date, use of PGS has been extremely limited in Japan.[178]

The U.S. government should not ignore the ability of thousands of individual reproductive decisions to increase discrimination against individuals with

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169. *Id.* at 339.

170. BUCHANAN ET AL., *supra* note 79, at 278.

171. Gesetz zum Shutz von Embryonen [Act for Protection of Embryos], Dec. 19, 1990, BGBl. I, 69 at 2746 (F.R.G); *see also* Henning M. Beier & Jacques O. Beckman, *German Embryo Protection Act (October 24, 1990)*, 6 HUM. REPROD. 605, 605-06 (1991).

172. Bundesgesetz über die medizinisch unterstützte Fortpflanzung [FMedG] [Federal Law on Assisted Reproduction] Dec. 18, 1998, Die Bundesverslammiung der Schweizerischen Eidgenossenschaft, art. 24, 1-2 (Switz.); *see also* Bartha M. Knoppers & Rosario M. Isasi, *Regulatory Approaches to Reproductive Genetic Testing*, 19 HUM. REPROD. 2695, 2695 (2004).

173. Gentechnikgesetz – GTG und Änderung des Produkthaftungsgesetzes [The Austrian Gene Technology Act] Bundesgesetzblatt [BGB1] No. 510/1994 (Austria); *see also* Knoppers & Isasi, *supra* note 172, at 2695.

174. Norme in material di Procreazione Medicalmente Assistita [Medically Assisted Reproduction Law]. Racc. Uff., Presidential Decree, Feb. 19, 2004, Feb. 24, 2004, No. 4 (Italy).

175. Assisted Human Reproduction Act, 2004 S.C, ch. 2 (Can.) (establishing Assisted Human Reproduction Canada (AHRC) a federal regulatory agency to oversee the use of AHR in Canada); *see also* Health Canada, Assisted Human Reproduction Canada, www.hc-sc.gc.ca/hl-vs/reprod/agenc/index_e.html (last visited Mar. 30, 2008).

176. Human Fertilisation and Embryology Act, 1990, c. 37, § 5 (U.K.).

177. *See* M. Sugiura-Ogasawara, *Reply to: Preimplantation Genetic Diagnosis for Translocations*, 21 HUM. REPROD. 840 (2006).

178. *See* Santiago Munné, *Preimplantation Diagnosis for Translocation*, 21 HUM. REPROD. 839 (2006).

negatively perceived genetic conditions. While the Americans with Disabilities Act[179] and the Civil Rights Act[180] provide legal protection for some individuals that may face increased discrimination as a result of widespread PGS use, future advances in genetic testing may result in discrimination against many other individuals with unprotected conditions or characteristics, such as sexual preference.[181] In instances where there is direct evidence of harm to a population, and where anti-discrimination laws are absent or inadequate to reduce the discriminatory impact, the government should limit parents' ability to use PGS for the related condition.

c. Respecting and Protecting Potential Human Life

The government should also consider the sentiments of those individuals who will be outraged by any procedure that permits prospective parents to discard embryos. Many religious individuals oppose the use of IVF and PGS for any purpose.[182] As the reasons for discarding embryos become less about avoiding severe disorders or infertility and more about selecting for desirable genetic characteristics, many other members of the population may join the opposition.[183] This opposition may stem in part from the belief that discarding embryos for treatable medical conditions, disorders with mild symptoms, and non-medical traits does not account for the embryos' moral worth.[184]

In *Gonzales v. Carhart*, the Supreme Court recently reaffirmed the state's ability to regulate reproductive medicine in an effort to express its "profound

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179. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified at 42 U.S.C. §§ 12101-12213 (2000)).

180. Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (codified as amended in scattered sections of 5, 28, 42 U.S.C.).

181. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327, 376 (codified at 42 U.S.C. § 12211 (2000)) (specifically stating that "homosexuality and bisexuality are not impairments and as such are not disabilities"); Desantis v. Pacific Tel. & Tel., 608 F.2d 327 (9th Cir. 1979) (holding generally that Title VII of the Civil Rights Act did not prohibit discrimination on the basis of sexual orientation); *see also* Pekka Santtila et al., *Potential for Homosexual Response Is Prevalent and Genetic*, 77 BIOLOGICAL PSYCHOL. 102, 102-05 (2008).

182. *See, e.g.*, Mo Woltering, *The Clone Wars: Have We Surrendered* Donum Vitae*?*, SEQUELA, www.rc.net/org/humanfamily/clonewars.html (last visited Mar. 30, 2008) (arguing against the use of IVF for any purpose).

183. KALFOGLOU ET AL., *supra* note 163, at 27 (finding that individuals' approval of PGD use decreased as the severity of the conditions involved moved from fatal childhood disorders to selection of traits).

184. *Id.* at 26-27 (finding that individuals' approval of PGD for less severe genetic conditions was somewhat, but not entirely related to their belief in the moral status of the embryo, and that many people gave the embryo an "intermediate" status between person and non-person).

respect for the life of the unborn."[185] The Court granted the state the right to promote respect for fetal life both before and after viability.[186] The Court based this finding, however, on the notion that "a fetus is a living organism while in the womb, whether or not it is viable outside the womb."[187] In *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the Supreme Court held that the state could "from the outset . . . show its concern for the life of the unborn."[188] While it has not been settled that the government's interest in protecting the unborn extends to embryos outside a mother's body, given the language in *Carhart* and *Casey,* and the prohibition on federal funding for embryo research, the government's ability to restrict some uses of PGS in an effort to demonstrate respect for the unborn seems probable enough to warrant further consideration.[189]

The question is how to weigh society's interests in the life of the unborn against the interests of the prospective parents. In examining similar questions relating to embryo experimentation while on the Human Embryo Research Panel, Alta Charo recommended that the interests of those opposed to embryo research on moral grounds be considered in terms of the harm directly caused to them by embryo research.[190] Such an approach can be used to weigh societal objections to PGS based on the status of the embryo. The government should consider the following: 1) How strongly felt are the objections?; 2) Does the practice cause any form of physical, financial or emotional harm to the individuals?; 3) Are there structural obstacles that prevent individuals opposing the use from politically expressing their views?; and 4) Would their opposition deny constitutional or international human rights to others?[191] Since individuals opposing IVF and PGS will not be forced to engage in or conduct the procedures, their harms will be limited. This analysis would grant little weight to third-party interests when compared with using PGS to select against a serious disorder, but in cases of negligible parental benefit in selecting for a particular gene, such as eye or hair color, strong public opposition may warrant government restriction of the procedure on grounds that the practice of discarding embryos for less significant reasons harms others in society. Such an analysis protects individual reproductive autonomy, but acknowledges the moral opposition to embryo destruction in instances where an individual uses PGS to screen out traits that do

185. Gonzales v. Carhart, 127 S. Ct. 1610, 1615 (2007) (quoting Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 877 (1992)).

186. *Id.* at 1627.

187. *Id.*

188. *Casey*, 505 U.S. at 869.

189. A more complete explication of the constitutional limitations on regulation of PGS will be provided in Part III.

190. *See* R. Alta Charo, *The Hunting of the Snark: The Moral Status of Embryos, Right-to-Lifers, and Third World Women*, 6 STAN. L. & POL'Y REV. 11, 20-21 (1995).

191. *Id.* at 21.

not trigger reproductive liberty protections. While establishing the right balance between reproductive liberty and moral opposition to embryo destruction will remain a thorny area of law, attempting to negotiate a middle ground will prove safer than a laissez faire approach and more palatable than a highly precautionary approach.

While recent advances in ART pose significant regulatory challenges, the risks to both individuals and society are sufficiently credible to require government intervention. As discussed above, governments in most of the developed world have heavily regulated ART, including PGS and PGD.[192] In contrast, federal and state governments in the United States have neglected to regulate PGS.

C. Why Has the United States Not Regulated PGS?

One of the main reasons the United States has not regulated PGS is because American politicians do not find it politically advantageous. The lack of political interest has occurred for three reasons: 1) few studies have demonstrated harm to children from PGS; 2) the current technological limitations of PGS have restricted both patient demand and the frequency of its use for controversial purposes; and 3) PGS regulation is politically divisive. As a result, politicians have effectively tabled the issue until a significant harm or risk demands political action.

Scientific research is just beginning to reveal some of the health risks associated with IVF and PGS. This research is time-consuming, and funding is scarce. Examining the health outcomes of children born via ART requires gathering data before the pregnancy and through many years into childhood. To determine the long-term risks, studies will need to continue from before pregnancy well into adulthood.

Another difficulty is that, since the 1970s, the federal government has either greatly limited or banned the use of federal funds for embryo and fetal research.[193] The Dickey-Wicker Amendment currently prevents the use of federal funds for any activity that involves "the creation of a human embryo or embryos for research purposes; or . . . research in which human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater

192. *See* Knoppers & Isasi, *supra* note 172, at 2695.

193. PRESIDENT'S COUNCIL, *supra* note 112, at 127-31. The restrictions began with a prohibition on using federal funds to conduct research on IVF without approval from the Ethics Advisory Board (EAB). In 1979, the EAB attempted to authorize IVF research under certain conditions, but its recommendation was not accepted by the Department of Health, Education and Welfare. The EAB was disbanded shortly thereafter in 1980, leaving a de facto moratorium on the use of federal funds for IVF research. *Id.* at 127-28.

than that allowed for research on fetuses in utero under 45 [C.F.R. §] 46.208(a)(2) or 42 U.S.C. [§] 289g(b)."[194] Since PGS research entails the possibility of injuring, destroying, and discarding human embryos, it will likely run afoul of the Dickey-Wicker Amendment.[195]

The absence of federal research funding has pushed reproductive genetics out of the laboratory and into medical practice. Advances in reproductive technology, such as PGS, have been widely achieved on the basis of theory-driven rather than data-driven hypotheses,[196] given the lack of funds for research and the absence of legislation that requires safety and efficacy research prior to clinical use. As a result, couples often have to make treatment decisions with little evidence of safety and efficacy, and policymakers have little data to suggest a need for regulation.

The lack of PGS oversight is also due in part to the relative seriousness of current PGS indications and the small number of procedures performed each year. The small patient population and the current limitations of the technology largely have tempered concerns that PGS might be used by many people to screen for a wide range of medical and non-medical conditions. John A. Robertson, one of the field's most prominent legal scholars, has argued that it is "highly unlikely that many traits would be controlled by genes that could be easily tested in embryos"[197] due to the fact that most genetic conditions result from interactions between multiple genes and between the genes and the environment. Leading scientists, policymakers, and scholars have echoed Robertson's sentiment that the technological limitations associated with PGD will prevent the dystopias predicted by many ethicists and science fiction authors related to "designer babies."[198] Armed with reassurance that PGS is likely to have little social impact, politicians have remained reluctant to act. This view ignores the ability of recent technological advances to expand the power of PGS to screen for numerous genetic loci at one time.

Finally, politicians have been especially hesitant to consider regulating PGS because it requires consideration of the status of the embryo. Given the extreme divide in the United States regarding abortion, reaching consensus on the status

194. Balanced Budget Repayment Act of 1996, Pub. L. No. 104-99 sec. 128, 110 Stat. 26, 34.

195. Jacques Cohen & Santiago Munné, *Letter to the Editor*, 20 HUM. REPROD. 2363, 2364 (2005) (stating that evidence suggests that removing two cells from cleaved embryos can harm the embryo beyond repair).

196. John A. Collins, *Preimplantation Genetic Screening in Older Mothers*, 357 NEW ENG. J. MED. 61, 61-62 (2007).

197. John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 466 (2003).

198. PRESIDENT'S COUNCIL, *supra* note 112, at 94-97 (2004); *see also* FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION 4-10 (2002) (describing the dystopia of future PGS use).

of the embryo appears impossible.[199] Political debate over embryo creation and destruction often causes people to retreat to their firmly entrenched positions on abortion, which contributes significantly to the regulatory stalemate with respect to ART in the United States.[200]

Despite this reluctance on the part of politicians, the government no longer has the luxury of delaying consideration of regulation and oversight.[201] PGS will soon offer parents the opportunity to screen embryos for hundreds of genetic and chromosomal characteristics. The development of PGS will expand the demand for the procedure and its use for controversial ends, in turn creating new individual and social risks.[202] The government should put in the political infrastructure to balance the potential benefits to parents of unrestricted use against the probability and severity of the risks associated with PGS.

III. WHO SHOULD OVERSEE PGS?

Once the government decides that regulation is appropriate, the next challenge is to determine who should regulate. Deciding what type of body should oversee PGS helps to determine the scope and strength of the possible oversight. In the last five years, medical, legal, and ethical scholars have proposed that a variety of entities oversee ART and PGS, including 1) professional societies, 2) state agencies, 3) existing federal agencies, or 4) a new federal agency.[203] While oversight by each of these entities has benefits, the

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199. *See* Charo, *supra* note 190, at 27 (describing the search for consensus on the status of the embryo as being "as doomed as the hunting of the illusive snark").

200. The difficulty of passing legislation relating to ART and the appropriate uses of embryos is exemplified by the failure of Congress to pass a bill prohibiting reproductive cloning, despite general consensus that it should be illegal. *See* FUKUYAMA & FURGER, *supra* note 20, at 129-31, 243 (2006) (chronicling the numerous failed attempts to pass a prohibition on human cloning in the House and Senate). While the Human Cloning Prohibition Acts of 2001 and 2003 both passed the House, no prohibition on cloning has passed the Senate. *See* Human Cloning Prohibition Act, H.R. 534, 108th Cong. (2003); Human Cloning Prohibition Act, H.R. 2505, 107th Cong. (2001). To date, no federal prohibition on reproductive cloning exists.

201. *See* Malinowski, *Choosing*, *supra* note 20, at 205 ("Arguably, there is a moral imperative to not assume the luxury of time.").

202. *Cf.* Mastenbroek, *supra* note 16, at 13 (demonstrating that PGS use was associated with reduced rates of ongoing pregnancy in women of advanced maternal age when compared to traditional IVF alone). While the findings of Mastenbroek et al. may reduce the immediate demand for PGS among women of advanced maternal age, many of the reasons the team suggested for the difference in rates of ongoing pregnancy resulted from technological limitations, which may be overcome. *Id.* at 16. In addition, other researchers have challenged these findings due to the study's low embryo biopsy success rates. *See PGD Pioneers*, *supra* note 37.

203. *See, e.g.*, FUKUYAMA & FURGER, *supra* note 20, at 14-23 (proposing an independent federal agency to address human biotechnologies and ART); Malinowski, *A Law-Policy Proposal*, *supra*

creation of a new federal agency to license and monitor ART practice is the most promising approach.

A. Professional Societies

Medical and professional societies, such as the American Society of Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART), offer one avenue for oversight of PGS.[204] These organizations, formed by members from a particular medical field or specialty, typically offer educational services for members and develop guidelines on appropriate clinical practice.[205] Some consider professional societies to be capable of providing "more nuanced oversight" than would be possible through legislation.[206] Moreover, some health care providers who oppose government interference have argued that choices regarding reproductive technologies should remain a joint matter for doctors and patients.[207]

SART is the primary professional society for physicians that perform ART.[208] It performs four main functions to assist its members – data collection and dissemination, development of practice guidelines and recommendations,

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note 20, at 566 (arguing that the United States should create a regulatory system based on existing federal regulatory schemes); Noah, *supra* note 20, at 607 (suggesting that the FDA might consider reviewing their approval of fertility drugs); Norton, *supra* note 20, at 1642-50 (suggesting that Congress and state legislatures should ban nontherapeutic PGS); Parens & Knowles, *supra* note 20, at S18-21 (suggesting the creation of a federal Reprogenetics Technolgies Board similar to the United Kingdom's HFEA); Rosato, *supra* note 20, at 79-95 (proposing a "double-decker" approach to state and federal ART regulation); Joe Leigh Simpson, Robert W. Rebar & Sandra Ann Carson, *Professional Self-Regulation for Preimplantation Genetic Diagnosis: Experience of the American Society for Reproductive Medicine and Other Professional Societies*, 85 FERTILITY & STERILITY 1653 (2006) (supporting professional society regulation); *Model Assisted Reproductive Technology Act*, 9 J. GENDER, RACE & JUST. 55 (2005-2006) (proposing that states oversee the practice of ART).

204. *See* Simpson, Rebar & Carson, *supra* note 203, at 1653 (listing ASRM, SART, the American College of Obstetricians and Gynecologists, the American College of Medical Geneticists, the European Society of Human Reproduction and Embryology, and the Preimplantation Genetic Diagnosis International Society as professional societies that have a stake in the regulation of PGS).

205. BARUCH ET AL., *supra* note 17, at 9. For a list of ASRM and SART guidelines and practice standards issued on ART, see Malinowski, *Choosing*, *supra* note 20, at 185-87.

206. *See* Simpson, Rebar & Carson, *supra* note 203, at 1653.

207. Andrea L. Kalfoglou et al., *Opinions About New Reproductive Genetic Technologies: Hopes and Fears for Our Genetic Futures*, 83 FERTILITY & STERILITY 1612, 1612 (2005).

208. *See* Soc'y for Assisted Reprod. Tech., Welcome to SART, http://www.sart.org (last visited Mar. 30, 2008).

governmental interaction, and quality assurance within ART.[209] SART requires its members to have their embryo laboratories accredited and submit data on annual success rates to the Centers for Disease Control and Prevention (CDC) in accordance with the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA).[210] ASRM is closely affiliated with SART and performs many of the same political and advisory functions, but also has members that focus on other types of reproductive medicine.[211]

While medical societies currently play a lead role in ART oversight,[212] their ability to monitor, evaluate, and regulate PGS is insufficient to protect vulnerable groups from harm.[213] The practice guidelines issued by medical societies are voluntary and unenforceable.[214] Medical societies do not have the ability to prosecute members for non-compliance; all they can do is revoke a clinic's membership.[215] SART membership is not required to operate an ART clinic or to provide PGS. Given the substantial demand for ART services, the threat of membership loss has not served as a sufficient deterrent to force compliance with guidelines.[216] Despite ASRM's Ethics Committee's strong recommendations against using PGS solely for the purposes of non-medical sex selection,[217] the Genetics and Public Policy Center survey found that 39% of clinics were willing to provide non-medical sex selection in the absence of another reason to undergo PGS, and just under 10% of the PGS procedures performed in the surveyed clinics were for non-medical sex selection.[218] As the market for PGS expands and

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209. *See* Soc'y for Assisted Reprod. Tech., What is SART?, http://www.sart.org/WhatIsSART.html (last visited Mar. 30, 2008).

210. *Id.*; *see also* Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. § 263a-1 to 263a-7 (2000)).

211. *See* Am. Soc'y for Reprod. Med., http://www.asrm.org (last visited Mar. 30, 2008). ASRM also publishes the journal *Fertility & Sterility*.

212. *See* Simpson, Rebar & Carson, *supra* note 203, at 1653 (noting that the FSRCA bill's reporting requirements are fulfilled by the ASRM, SART, and the CDC).

213. *See generally* BARUCH ET AL., *supra* note 17, at 9; Malinowski, *Choosing*, *supra* note 20, at 125; Noah, *supra* note 20, at 606; Parens & Knowles, *supra* note 20, at S1-25. *But see* David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 FERTILITY & STERILITY 932, 938 (2002) (stating that professional societies and individuals involved with ART have worked with one another and federal and state governments to develop an improved process that should insure higher quality care, protect the public interest, and create public confidence in ART services); Simpson, Rebar & Carson, *supra* note 203, at 1653 (arguing that self-regulation is the most appropriate policy in the United States).

214. BARUCH ET AL., *supra* note 17, at 9-10.

215. *Id.*

216. Malinowski, *Choosing*, *supra* note 20, at 187.

217. Ethics Comm. of the Am. Soc'y of Reprod. Med., *Sex Selection and Preimplantation Genetic Diagnosis*, 72 FERTILITY & STERILITY 595, 598 (1999).

218. BARUCH , KAUFMAN & HUDSON., *supra* note 28, at 5. The figure of 39% (the percentage of

demand increases for certain PGS tests, the professional societies will not be able to enforce restrictions on genetic tests.

While ASRM and other professional societies are skilled at producing guidelines for proper medical care and procedures, such societies may not be best suited to address the broader social and moral implications of PGS. They have not conducted national surveys of public opinion nor engaged the public in discourse regarding PGS's potential to shape society.

A conflict of interest also hampers the credibility of professional associations in relation to PGS. Their members benefit most from practice guidelines that limit PGS just enough to prevent government regulation, but otherwise permit widespread practice. Clinicians who perform ART, PGS, and other reproductive genetic tests comprise the leadership of the professional societies and set their policies. While these individuals should have a seat at the table to discuss potential PGS regulations, they represent only a few of many stakeholders. Recent advances in PGS testing dramatically elevate the importance of public participation in developing a policy approach.

B. State and Federal Governments

Prior to examining any state or federal regulatory proposals, it is important to examine the constitutional limitations placed on government action. The Constitution constrains state and federal governments' abilities to interfere in the reproductive decisions of individuals. In designing a regulatory approach that touches reproductive decision-making, the government should not infringe the constitutionally protected privacy rights of American citizens. During the last seventy-five years, the Supreme Court has established a Fourteenth Amendment due process right granting persons the privacy to make reproductive decisions free from undue governmental interference.[219] In order to survive a Fourteenth Amendment Challenge, the government intervention must be closely tailored to a

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clinics that are willing to provide non-medical sex selection in the absence of another reason for undergoing PGS) was calculated from the data in the article, which stated that 42% of 137 clinics offered PGS for non-medical sex selection and only 7% of those would only provide the procedure if there was another reason to undergo PGS.

219. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992) (reaffirming the major holding of *Roe*, but permitting the government to make laws to protect the life of the mother and to demonstrate respect for the embryo after viability); Roe v. Wade, 410 U.S. 113 (1973) (granting women the right to decide whether to have an abortion within the first two trimesters of pregnancy without governmental intervention); Eisenstadt v. Baird, 405 U.S. 438 (1972) (extending the constitutional right granted in *Griswold* to unmarried persons); Griswold v. Connecticut, 381 U.S. 479 (1965) (granting constitutional privacy protection to a married couple's decision to use contraception); Skinner v. Oklahoma, 316 U.S. 535 (1942) (protecting an individual's right to reproduce from unwanted government sterilization).

legitimate and significant state interest that outweighs the parental privacy interest.[220] Fourteenth Amendment protection extends to decisions regarding "marriage, procreation, contraception, family relationships, child rearing, and education" as they involve "the most intimate and personal choices a person may make in a lifetime."[221]

Without question, PGS involves some of the most intimate and private issues of human life.[222] In certain instances, the decision to use PGS is highly analogous to other constitutionally protected reproductive rights.[223] In *Skinner v. Oklahoma*, the Supreme Court recognized the right to reproduce as one of the most fundamental civil rights.[224] For some infertile individuals, PGS provides the best opportunity to have a child.[225] In the absence of a compelling state interest, the state should not deny infertile couples the ability to obtain fertility treatment.[226]

Other uses of PGS are directly linked to the decision of whether to reproduce. John Robertson has eloquently argued that a decision should fall under the sphere of protected procreative liberties if it is "centrally connected with reproductive choice" and if its use is unlikely to cause harm to others.[227] From this basis, Robertson argued that if the information provided by PGS might "strongly and plausibly impact a couple's willingness to reproduce," PGS is sufficiently related to the decision to procreate that it should be protected.[228] While this principle provides a plausible standard, Robertson applies it too broadly. He argues that the importance of a genetic selection should rest "within a broad spectrum with the couple."[229] For decisions that could be rationally related to reproductive goals, Robertson argues that the decision to use PGS

220. *Casey*, 505 U.S. at 838; Zablocki v. Redhail, 434 U.S. 374 (1978) (holding that when a "statutory classification significantly interferes with the exercise of a fundamental right it cannot be upheld unless it is supported by *sufficiently important state interests and is closely tailored to effectuate those interests*" (emphasis added)); *see also* Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2805-08 (2005).

221. *Casey*, 505 U.S. at 851.

222. PRESIDENT'S COUNCIL, *supra* note 112, at 10.

223. Robertson, *supra* note 105, at 20-21.

224. *Skinner*, 316 U.S. at 536.

225. *See, e.g.*, Munné et al., *supra* note 37, at 331 (finding that in a sample of 301 patients with a history of recurrent miscarriage, patients had lost 87% of their pregnancies before PGD compared to losing only 16.7% after using PGD); Verlinsky et al., *supra* note 34, at 219.

226. Robertson, *supra* note 105, at 20-21. Infertility does not create a positive right to ART, such that the government must secure and pay for treatment, only a negative right that the government must not prevent couples from attempting to have a child.

227. Robertson, *supra* note 197, at 455.

228. *Id.* at 456-57, 460-68.

229. *Id.* at 465.

should demonstrate sufficient importance to the couple to warrant protection.[230] Such an interpretation would provide constitutional protection for parents to use PGS to screen for nearly any genetic condition.[231]

The Supreme Court's recent decision in *Gonzales v. Carhart* places Robertson's analysis of the breadth of parental autonomy into question.[232] The Court held that "[w]here it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn."[233]

As noted above, the language in *Carhart* and *Casey* may open the door for the government to extend its interest in the unborn to all embryos, even those outside the uterus.[234] In that case the government could enact policies to demonstrate respect for preimplantation embryos created through IVF and PGS. Under current IVF practice, parents are at liberty to discard morphologically unsound embryos or embryos they do not intend to use. Constitutional protection for reproductive liberties should extend to the decision to discard unsound or unused embryos. To avoid the destruction of unwanted embryos, the government may seek to reduce the number of excess embryos created, but it should not be able to require a couple to undergo additional cycles of IVF just to avoid discarding embryos.

The question is whether the decision to discard embryos because one chooses not to reproduce differs fundamentally from the decision to discard embryos for specific genetic reasons through PGS. While both decisions entail discarding an embryo, the first decision necessarily involves a reproductive choice, while the other does not. Selecting one embryo over another because of a

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230. *Id.* Robertson continues this analysis to argue in favor of protected selection for genes associated with gender, perfect pitch, and sexual orientation. He argues that only selection for eye color and hair color might be trivial enough to fall outside constitutional procreative liberty protections. *Id.*

231. *Id.* at 461-68.

232. *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007), upheld the Partial-Birth Abortion Ban Act of 2003, after finding that Nebraska's partial birth abortion statute violated the Constitution in *Stenberg v. Carhart*, 530 U.S. 914 (2000). The Court also held that the government may prohibit previability abortion procedures on the basis that "a fetus is a living organism while within the womb, whether or not it is viable outside the womb." *Carhart*, 127 S. Ct. at 1627.

233. *Carhart*, 127 U.S. at 1633.

234. *See infra* Subsection III.B.2; *see also Carhart*, 127 S. Ct. at 1611 (stating that the government's interest in unborn human life exists previability and postviability); Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 846 (1992) (concluding that "[t]he State has legitimate interests from the outset of the pregnancy in protecting . . . the life of the fetus that may become a child").

preferential trait, such as eye color or hair color, does not constitute a reproductive choice that should be protected with constitutional force. For uses of PGS not deemed directly determinative of the decision to procreate, the government may be able to regulate PGS in an effort to express its respect for unborn human life by prohibiting embryos from being discarded for more "trivial" reasons.[235]

The recent advances in PGS further complicate this analysis because they will enable parents to select for numerous traits that may not determine the reproductive decision. Parents who would not have undergone PGS solely to select embryos based on hair or eye color, sex, or a 40% probability of having asthma, will be able to make those choices if they are initially undergoing PGS for infertility or to screen out a severe disorder. Moreover, the ability to select embryos based on the presence of a wide range of genetic traits and probabilities may determine the decision to use PGS, even in the absence of infertility or a severe disorder. Many of these choices would still reflect the overall goal of having a healthy child, but the couple's decision to reproduce may not turn on whether they can select for many of the genetic tests available through PGS. In an unregulated market, individuals will use PGS to select for a wide range of traits because they can, not because the ability to select for each individual genetic condition shapes their decision to reproduce; thereby diminishing the parental claim to constitutional protection. In instances where the genetic test is not reasonably tied to the reproductive decision, the government will have more leeway in passing regulation. The parents' interest in reproductive autonomy must be balanced with the competing obligations of the government to protect individuals and society from harms associated with PGS.

1. State Government

Within the above constitutional bounds, state governments could regulate PGS. The ability to govern the practice of medicine has generally been retained by the individual states, rather than ceded to the federal government.[236] State governments currently run medical licensing boards, state health departments, and the general practice of medicine within each state.

Despite the states' experience, few scholars have endorsed state regulation of ART practices.[237] In seeming agreement, few individual states have sought to

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235. Full explication of this issue is largely beyond the intended scope of this paper, but poses an important question for future research.

236. Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 201-02 (1999).

237. *See generally* Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 565-66; Noah, *supra* note 20, at 603; Parens & Knowles, *supra* note 20, at S18-21. *But see* Rosato, *supra* note 20, at 80-

regulate the practice of ART.[238] To encourage states to do so, Congress passed FCSRCA, which required the CDC to develop a model certification program for embryo laboratories for the states to adopt voluntarily.[239] The program requires states to inspect and certify embryo laboratories.[240] To do so, the states must ensure that embryo laboratories meet and maintain the standards for consistent performance, quality assurance, record maintenance, and personnel qualifications established by the CDC.[241] To date, no state has enacted the model certification program, preferring to leave certification regulation to the federal government and professionals through FCSRCA and SART.[242]

State regulation faces collective action challenges. Passing legislation in all fifty states will take significant time. In contrast, if researchers uncover new individual or social harms associated with PGS, altering one federal administrative rule would be more expedient and feasible than action by fifty legislative bodies. In addition, permitting each state to regulate PGS independently will invariably lead to some states that are more lax in oversight or that do not address the practice at all. Under this scenario, the nation's PGS practices will be as permissive as the least restrictive state. Individuals who do not like the laws in their state could travel to another state with lesser restrictions and have PGS performed there, diminishing the purpose of the original statute. Finally, and most importantly, all fifty states are not well positioned to collect data and monitor the broader social impact of different uses of PGS. Examining use patterns from a national vantage point will provide much more information. A federal agency could act to initiate public discussion, centralize expertise and

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95 (2004) (proposing a "double-decker" approach to state and federal ART regulation).

238. Louisiana prohibits any person from destroying a fertilized human ovum, unless that ovum fails to develop after thirty six hours. LA. REV. STAT. ANN. § 9:129 (2000); *see also* LA. REV. STAT. ANN. § 9:128 (2000) (requiring ART clinics to adhere to professional organization guidelines). Sixteen states have passed laws regarding the disposition of embryos, eggs and sperm. *See generally* Nat'l Conference of State Legislatures, State Laws on Frozen Embryos: Gamete (Egg/Sperm) and Embryo Disposition, http://www.ncsl.org/programs/health/embryodisposition.htm (last visited Mar. 30, 2008). Other states have passed laws relating to embryo research, which could limit PGD or PGS to the extent that it is perceived as research on the embryo. *See* 720 ILL. COMP. STAT. 510/12.1 (1993) (prohibiting research on embryos aborted for therapeutic purposes, scientific research, or laboratory experimentation); LA. REV. STAT. ANN. § 9:122 (2007) (prohibiting research on IVF embryos); ME. REV. STAT. ANN. tit. 22, § 1593 (2003) (prohibiting research on any live product of conception, intra or extra-uterine); R.I. GEN. LAWS § 11-54-1 (2002) (prohibiting any kind of experimentation on embryos before or after implantation).

239. 42 U.S.C. § 263a (2000).

240. *Id.* §§ 263a(d)(1), 263a(g).

241. *Id.* § 263a(d)(1).

242. Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 551-52. In the absence of a state program, the responsibility remains with the CDC and SART.

data collection, analyze that data for individual and social harm, and swiftly regulate harmful practices.

2. Federal Government

Regulation by the federal government could result from congressional legislation or administrative agency regulation. Regardless of the approach chosen, new legislation will be needed to regulate ART, either to expand the roles of existing agencies or to establish the authority of a new agency. In order to do any of the above, Congress must demonstrate that the regulation of ART and PGS falls under the authority granted to it by the Commerce Clause of the Constitution.[243]

Congress has the authority to regulate three aspects of interstate commerce: 1) the channels of interstate commerce; 2) the instrumentalities of interstate commerce and persons or things in interstate commerce; and 3) the activities that substantially affect interstate commerce.[244] Congress previously found that reproductive clinics engage in interstate commerce when it passed the Freedom to Access Clinic Entrances Act of 1994.[245] Subsequently, all eight circuit courts of appeals that visited this issue upheld Congress's finding as "rational."[246] ART clinics draw staff and patients from other states and other countries.[247] They purchase highly specialized medical supplies and equipment in interstate commerce.[248] DNA samples must often be sent across state lines to one of a handful of genetic testing laboratories willing to perform PGS tests.[249] These actions constitute participation in interstate commerce. In addition, in *Carhart*, which challenged the constitutionality of a federal ban on partial birth abortion, Congress's ability to regulate the practice of reproductive clinics under the

243. U.S. CONST. art. I, § 8, cl. 3.

244. Gonzalez v. Raich, 545 U.S. 1, 16-17 (2005) (citing Perez v. United States, 402 U.S. 146, 150 (1971) and NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 37 (1937)).

245. Freedom to Access Clinic Entrances Act of 1994, Pub. L. No. 103-259, 108 Stat. 694 (codified at 18 U.S.C. § 248 (2000)).

246. United States v. Gregg, 226 F.3d 253 (3d Cir. 2000); United States v. Weslin, 156 F.3d 292 (2d Cir. 1998); United States v. Bird, 124 F.3d 667 (5th Cir. 1997); Terry vs. Reno, 101 F.3d 1412 (D.C. Cir. 1996); United States v. Dinwiddie, 76 F.3d 913 (8th Cir. 1996); Am. Life League v. Reno, 47 F.3d 642 (4th Cir. 1995); United States v. Wilson, 73 F.3d 675 (7th Cir. 1995); Cheffer v. Reno, 55 F.3d 1517 (11th Cir. 1995).

247. *See Wilson*, 73 F.3d at 680-81 (holding that there is substantial interstate travel involved in reproductive health care).

248. *See Id.* at 680; *see also* Wickard v. Filburn, 317 U.S. 111, 127-28 (1942); United States v. Soderna, 82 F.3d 1370, 1373 (7th Cir. 1996).

249. *See Wilson*, 73 F.3d at 680.

Commerce Clause was not before the Court.[250] Carefully crafted legislation aimed at licensing, monitoring, and regulating the practice of ART and PGS in the United States should come within the federal government's authority granted by the Commerce Clause.

The federal government has two possible regulatory avenues for attempting to balance the interests associated with ART: direct legislation and administrative agency regulation. Legislative action is particularly ill-suited to address the concerns of a controversial and rapidly developing industry like ART. "Legislative decision-making costs are likely to be higher when conflict of interest makes it difficult to reach a collective decision and when uncertainty makes it difficult to chart a desirable course of action . . . ."[251] Reaching a legislative majority on issues surrounding appropriate use of human embryos, parental reproductive autonomy, and the perception of disability will likely prove extremely time-consuming, if not impossible.[252] In the meantime, the risks of unregulated ART and PGS use will go unchecked. At the rate that ART and genetics technology are developing, if legislation is passed, it will most likely be outdated by the time it is enacted. The uncertainty of risks surrounding present and future PGS practice also makes governance by legislative action especially difficult. Rather than attempting to define for all future circumstances how the law will apply or face the daunting task of amending the legislation with each new development in ART, Congress should delegate the authority to regulate ART to a specific agency and let the agency resolve the issues as they arise over time.[253]

Legislation aimed at expanding the mandate of an existing administrative agency or creating a new administrative agency could pass more easily by delegating controversial decisions to the expertise of the regulatory body.[254] Agency decisions could reflect the most up-to-date scientific and sociological research on the use of PGS. A regulatory body would also have the ability to operate faster and with more freedom than legislative action. This more nimble administrative approach implemented by the federal government could take two possible forms: 1) a decentralized model with responsibilities shared among existing federal agencies, or 2) the creation of a single federal entity to license and monitor the use of ART in the United States.

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250. Gonzales v. Carhart, 127 S. Ct. 1610 (2007); *id.* at 1640 (Thomas, J., concurring) (noting that the parties did not challenge Congress's Commerce Clause authority in this case).

251. MURRAY J. HORN, THE POLITICAL ECONOMY OF PUBLIC ADMINISTRATION 14 (1995).

252. In all areas related to embryos and reproductive rights, achieving any policy that can be agreed upon by a majority is highly difficult in the United States. *See* FUKUYAMA & FURGER, *supra* note 20, at app. D (listing legislative activity in this field from 2001 to 2004).

253. *See* HORN, *supra* note 251, at 15-17.

254. *See generally id.*

a) Existing Federal Agencies

Three existing federal agencies possess authority to regulate a portion of PGS practice: the CDC, the Centers for Medicare and Medicaid Services (CMS), and the FDA. However, no agency has the jurisdiction to govern the practice of PGS as a whole, including the individual and social risks associated with the procedure.[255] Current oversight is limited to monitoring ART program success rates, requiring general clinic sanitation and safety standards, and setting basic laboratory requirements. None of these requirements specifically address the unique aspects of IVF and PGS, including the challenges of genetic testing on a single cell's DNA, the safety and efficacy of the procedures for mothers and offspring, the ethical implications of providing PGS to screen out certain conditions, or the social implications of increased PGS use. In order to provide comprehensive oversight within existing federal agencies, Congress will either need to expand the mandate of a single agency, or expand the authority of several agencies and significantly improve their coordination.[256]

i) The Centers for Disease Control and Prevention

The CDC administers FCSRCA, the most specific regulation relating to ART in the United States.[257] The Act requires that each ART program annually report to the CDC the "pregnancy success rates[,]. . . the identity of each embryo laboratory . . . used by such program[,] and whether the laboratory is certified . . . or has applied for such certification."[258] FCSRCA requires the CDC to publish this information annually, along with a list of the programs that refuse to

255. *See* 21 U.S.C. § 393(b)(2) (2000) (stating that the mission of the FDA is to protect the public health by ensuring that "(A) foods are safe, wholesome, sanitary, and properly labeled; (B) human and veterinary drugs are safe and effective; (C) there is reasonable assurance of the safety and effectiveness of devices intended for human use; (D) cosmetics are safe and properly labeled; and (E) public health and safety are protected from electronic product radiation"); 42 U.S.C. § 263a(b) (2000) (granting CMS the authority to require all laboratories that "solicit or accept materials derived from the human body for laboratory examination or other procedure" to receive certification); *id.* § 263a-2 (granting CDC the authority to promulgate procedures to approve accreditation organizations and States to inspect and certify embryo laboratories); Ctrs. for Disease Control & Prevention, Vision, Mission, Core Values and Pledge, http://www.cdc.gov/about/organization/mission.htm (last visited Mar. 31, 2008) (stating that the mission of the CDC is "[t]o promote health and quality of life by preventing and controlling disease, injury and disability"). None of these laws permit the agency to intervene into treatment decisions or consider the harms associated with a particular procedure.

256. Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 566-68.

257. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. § 263a-1 to 263a-7 (2000)).

258. 42 U.S.C. § 263a-1(a) (2000).

report.[259] The CDC has turned over all responsibility for collecting and analyzing this information to SART.[260] FCSRCA does not require any information on whether PGS was performed, what genetic tests were included, or whether a couple met diagnostic criteria for receiving such services.

Overall, the CDC has very limited power over ART clinics. FCSRCA specifically states that the "Secretary [of the Department of Health and Human Services] may not establish any regulation, standard or requirement which has the effect of exercising supervision or control over the practice of medicine in ART programs."[261] The CDC does not have the power to sanction any program that does not report information.[262] SART, which performs inspections on behalf of the CDC, has conducted on-site inspections on less than 10% of clinics to ensure the accuracy of reporting.[263] In addition, neither the CDC nor SART examines whether the clinics provide care to clinically indicated patients or abide by practice guidelines. Without the authority to regulate the practice of ART directly or the ability to mandate that all embryo laboratories receive certification, the CDC under FCSRCA has less power than a professional society.

ii) The Center for Medicaid and Medicare Services

While having no authority to regulate ART procedures, CMS can regulate the quality of genetic tests performed for PGS. Congress granted this authority to CMS through the Clinical Laboratory Improvement Act (CLIA), which regulates diagnostic tests performed in clinical laboratories.[264] By establishing standards for laboratory testing, Congress acknowledged the importance of accurate testing to maintaining the integrity of health care. For specific areas of testing expertise, like microbiology and diagnostic immunology, CLIA grants CMS the authority to create a specialty certification. Any laboratory that performs tests in an area of specialty must become certified in that specialty by receiving a minimum score on proficiency tests and meeting specific requirements for quality assurance, quality control, and personnel.[265] CMS has not created a specialty certification governing genetic testing laboratories.[266] As a result, the laboratories that perform

259. *Id.* § 263a-5.

260. Adamson, *supra* note 213, at 933.

261. 42 U.S.C. § 263a-2(i)(1) (2000).

262. *Id.* § 263a-4.

263. Adamson, *supra* note 213, at 933 (stating that 30 out of 370 clinics had received on-site inspections as of 1997).

264. 42 U.S.C. § 263a(b) (2000) (requiring all laboratories that solicit or accept materials derived from the human body for laboratory examination to be certified); *see also* H. COMM. ON ENERGY AND COMMERCE, H.R. REP. NO. 100-899, *as reprinted in* 1988 U.S.C.C.A.N. 3828.

265. 42 C.F.R. §§ 493.801 to .807.

266. GAIL H. JAVITT & KATHY HUDSON, GENETICS & PUB. POLICY CTR., PUBLIC HEALTH AT

the genetic tests for PGS are not required to meet proficiency standards to ensure the accuracy of their results, nor are they required to maintain specific quality assurance and control standards specific to genetic tests. Numerous entities, including patients, directors of clinical laboratories, government advisory bodies, and non-profit organizations focused on genetics, have called for the creation of a specialty for genetic tests and heavily criticized CMS's lack of action.[267]

A specialty certification to ensure the accuracy of genetic tests is especially important for PGS. Laboratories that conduct PGS testing have extremely limited amounts of sample DNA and time to examine it. Testing protocols must be performed with speed and precision, and errors in procedure or testing reliability have dire consequences. Requiring minimum scores on proficiency tests and quality assurance measures in genetic testing laboratories will greatly improve the reliability of PGS.

iii) The Food and Drug Administration

The FDA's authority over PGS is limited because the FDA does not regulate medical procedures or drugs used in an off-label manner. The FDA does, however, have the authority to regulate any genetic test used in PGS that would qualify as a medical device.[268] Section 201(h) of the Food, Drug and Cosmetic Act defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals."[269] The FDA therefore has the

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RISK: FAILURES IN OVERSIGHT OF GENETIC TESTING LABORATORIES 4 (2006), *available at* http://www.dnapolicy.org/images/reportpdfs/PublicHealthAtRiskFinalWithCover.pdf.

267. *Id.* at 18 (reporting that in a poll 73% of clinical laboratory directors agreed that the creation of a genetic specialty should be created); INST. OF MED., ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY (Lori B. Andrews et al. eds., 1994), *available at* http://www.nap.edu/catalog.php?record_id=2057; NAT'L INSTS. OF HEALTH, ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT (2000), *available at* http://www4.od.nih.gov/oba/sacgt/reports/oversight_report.pdf; SUBCOMM. MEETING ON GENETICS, CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE, SUMMARY REPORT, September 10, 1997, *available at* http://wwwn.cdc.gov/cliac/pdf/gsc997.pdf; TASK FORCE ON GENETIC TESTING, NAT'L INSTS. OF HEALTH, PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE UNITED STATES: FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING (Neil Holtzman & Michael Watson eds., 1997), *available at* http://www.genome.gov/10001733.

268. 21 U.S.C. § 321(h) (2000).

269. *Id.*; *see also* FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, CLINICAL LABORATORIES, AND FDA STAFF: IN VITRO DIAGNOSTIC MULTIVARIATE INDEX ASSAYS 3 (2007), *available at* http://www.fda.gov/cdrh/oivd/guidance/1610.pdf.

ability to regulate the commercial use of any genetic test used to diagnose a preimplantation embryo with a specific genetic disease or chromosomal abnormality based on its safety and efficacy.[270] The direct safety of genetic tests is not in question, as they are performed on cells that have already been removed from the embryo and that will be discarded.[271] However, the efficacy of the genetic tests used for PGS is indirectly linked to the safety of the test, as an inaccurate genetic test may cause parents to discard a healthy embryo or transfer an affected one. If the FDA were to regulate, the efficacy of genetic tests could be demonstrated in two ways: 1) the test must correctly and reliably identify the desired gene; and 2) the presence of that gene should reliably predict the development of the disorder.

However, the FDA has not exercised its authority to regulate the efficacy of the majority of genetic tests offered in practice.[272] This "hands off" approach relies heavily on voluntary laboratory compliance with current Good Manufacturing Practices, medical device reporting requirements, labeling requirements, and on CMS regulation of genetic tests through the CLIA.[273] Since laboratories often create their own genetic tests rather than purchasing commercial genetic testing kits, the FDA's reliance on CMS initially was appropriate. However, there is a need for more substantial regulation of the genetic tests used for PGS now that genetic tests are entering commercial markets in increasing numbers, microarrays can be sold to test for a panel of genetic conditions, and such tests are often accompanied by complex statistical algorithms to diagnose multiple genetic conditions.[274]

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270. Interestingly, under this definition, the FDA may not have the ability to regulate the use of genetic tests to diagnose non-health related conditions. While any genetic test could be said to diagnose some form of "condition," the context of the statute seems to suggest that the device must be used for disease or health related purposes.

271. Whether the removal of a cell from the blastocyst for genetic testing is harmful to the embryo or future offspring is a different issue than the safety of the test.

272. BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 7. The FDA does regulate certain components used in in-house laboratory tests, known as analyte specific reagents (ASRs), so that healthcare providers would know how the tests were being validated. *See* FOOD & DRUG ADMIN., *supra* note 269, at. 4 (citing 21 C.F.R. §§ 809.10(e), 809.30, 864.4020 (2007)).

273. *See* Sales Restriction to CLIA Regulated Laboratories that Perform High Complexity Testing, 62 Fed. Reg. 62,252 (Nov. 21, 1997) (codified at 21 C.F.R. pts. 809, 864); FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF, COMMERCIALLY DISTRIBUTED ANALYTE SPECIFIC REAGENTS (ASRS): FREQUENTLY ASKED QUESTIONS 5 (2007), *available at* http://www.fda.gov/cdrh/oivd/guidance/1590.pdf.

274. Press Release, Genetics & Pub. Policy Ctr., Center Sees "New Era in Oversight" in Two New FDA Draft Guidances, Sept. 7, 2006, http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=56.

b) New Regulatory Body

While the CDC, FDA, and CMS all have some regulatory authority over ART that could be expanded to include PGS, the range of oversight required exceeds each of their mandates.[275] The President's Council on Bioethics stated that "the choice between delegating power to a new federal agency or to an existing agency or agencies should come down to the question of whether this arena of technology and activity raises (or is likely to raise) fundamentally new and different sorts of questions and challenges from those that have been dealt with by existing federal agencies in the past."[276] Many of the issues associated with assisted reproduction and genetic testing raise new challenges that do not fall under the expertise of existing governmental bodies.[277] For instance, should parents have the right to engage in non-medical sex selection? Should they be able to screen for genes associated with behavioral conditions such as shyness? What are the limits of parental discretion? What are the social implications of screening for multiple conditions? The CDC, CMS, and FDA were not designed to assess the intricate social and ethical implications of ART and genetic screening practices.[278] Rather than straining existing agencies to expand their resources and expertise, as Michael Malinowski suggests, the government should design a new regulatory body specifically to address the scientific, legal, ethical and social challenges associated with the ever-changing world of ART.[279]

An administrative agency created to oversee the practice of ART, if designed correctly, could be centralized, flexible, and backed with legal force. Each of these factors will be important to the ability to respond adequately to the challenges of PGS and other developments in ART. Since the risks associated with PGS also include the risks associated with many of the other activities of ART practice, including IVF, ICSI, extraction and handling of gametes, and embryo creation and storage, creating an agency to regulate PGS would also provide the infrastructure necessary to oversee the entire practice of ART within one federal body. When multiple agencies have jurisdiction over an area of practice, the oversight can be disjointed. Given the uncertainty of risk associated with PGS use, the centralization of information, expertise, and regulatory authority would produce more complete oversight and improve efficiency in communication and coordination.

Centralizing information and decision-making power would also give a single regulatory body more flexibility. The flexibility to respond quickly to new

275. *See* PRESIDENT'S COUNCIL, *supra* note 112, at 76-78.

276. *Id.* at 189.

277. *Id.* at 187.

278. *See id.*

279. Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 566.

information would enable the policy response to evolve alongside the technology. A centralized agency could quickly enjoin harmful practices or issue regulatory guidance without needing to coordinate with other federal entities.

To maintain policy continuity in an area staunchly divided by religious and political forces, the agency should be independent of the executive branch, similar to the Securities Exchange Commission.[280] As expounded upon in greater detail by Frances Fukuyama and Franco Furger, in today's fractured political landscape, only an independent agency would have a chance of being supported by special interest groups and a majority in Congress.[281] The U.S. should not let the politics of abortion prevent it from passing important measures to regulate the future of other reproductive activities. Both sides have a great deal to gain from creating some oversight for PGS practice.[282] An independent agency could evaluate the benefits and risks to both individuals and society of different uses of PGS from a neutral position and establish regulations to curb unwarranted risks and promote benefits.

The creation of an independent body to monitor and regulate PGS will provide the best assurance that the risks of PGS are being considered, while the benefits of PGS continue to remain accessible.

IV. HOW SHOULD THE UNITED STATES OVERSEE THE USE OF PGS?

Designing the mandate of a new regulatory entity to oversee the use of assisted reproductive technologies, including IVF and PGS, will be challenging because of the competing interests and ethical issues involved. Instead of trying to resolve the differences between stakeholders, the government should pursue a political solution that addresses areas of overlapping stakeholder interests and balances the conflicting interests.[283]

The remainder of this Article argues for the creation of a new regulatory entity to oversee the practice of ART in the United States. Section IV.A identifies the major stakeholders and the factors the government should consider in policy development. Section IV.B outlines the development of policy objectives for the agency and examines possible regulatory approaches. Section IV.C proposes the creation of the Assisted Reproductive Technology Authority and outlines its initial responsibilities.

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280. *See* FUKUYAMA & FURGER, *supra* note 20, at 293-300.

281. *See id.* at 293.

282. *See id.*

283. *See* Charo, *supra* note 190, at 20-23 (advocating a similar approach to addressing the conflicting interests associated with embryo research).

A. Factors To Consider

The relevant factors in developing PGS policy should reflect the interests of all stakeholders involved in the procedure or impacted by it. ART stakeholders include the individuals who want to use ART, offspring born via ART, members of society affected by its use, and ART practitioners. Their interests fall into four categories that can be used to define the mandate of a new regulatory body. The government should strive to preserve these stakeholders' interests by developing a regulatory approach that accomplishes the following goals: 1) protecting the health and well-being of individuals; 2) protecting members of society from harms caused by ART; 3) protecting individual autonomy to make reproductive decisions; and 4) protecting the interests of the medical profession. To develop a regulatory strategy, the government should rank these goals and establish an infrastructure to balance the competing interests when the goals conflict.

1. Protecting Individual Health and Well-Being

The government's highest priority should be to protect the women who undergo ART and their children, as they represent the most vulnerable entities involved in the procedure. Couples who undertake ART procedures are often willing to take disproportionate personal risks to improve their chances of having a healthy child. The children born via ART are subjected to additional risks, but they cannot consent or participate in discussions regarding the use of the procedure.

The government can protect women by improving their access to information and monitoring the clinics that provide ART services. While women should always retain the autonomy to determine what risks to accept with respect to reproductive procedures, the government can play an important role in informing their decision. Promoting or requiring genetic counseling to explain the risks of ART and PGS misdiagnosis to parents would assist them in making decisions regarding embryo selection. Efforts to fund research on women's health outcomes, ensure access to the most up-to-date health information, and provide information on other viable treatment alternatives will improve women's ability to make an informed reproductive decision.[284] Likewise, by licensing all ART clinics and requiring them to meet minimum quality standards, the government can better assure women undergoing ART procedures of their safety.

The government can also take several actions to reduce the potential harm to

284. Women should be told that alternatives to IVF and PGD exist. For instance, they could obtain a donor egg or a surrogate carrier. AM. SOC'Y REPROD. MED., THIRD PARTY REPRODUCTION: A GUIDE FOR PATIENTS (SPERM, EGG AND EMBRYO DONATION AND SURROGACY) 3 (2006), *available at* http://www.asrm.org/Patients/patientbooklets/thirdparty.pdf.

children born through ART. Increasing research funding to monitor the health and well-being of children born through the procedures would greatly improve our understanding of the extent and magnitude of the health risks. This research would also shed light on practices within clinics, such as multiple embryo transfers, that negatively impact the overall health of ART children.

In addition to funding research, the government could seek to develop practice guidelines for assessing the risk/benefit ratio of engaging in PGS for a certain condition. Physicians should examine the benefits and the risks in a systematic manner. Numerous factors contribute to the benefit provided by the genetic selection, including 1) gene penetrance; 2) availability of treatment for the condition; 3) tolerability of the treatment; 4) efficacy of treatment; 5) impact of the disorder or characteristic on the individual; 6) the known genetic contribution to the development of the disorder; and 7) age of onset. These factors should be weighed against the known risks to children associated with IVF and PGS. Practice guidelines, while not mandated, can provide significant assistance to physicians attempting to determine which genetic selections provide sufficient benefit to outweigh the risks of PGS. Couples could also use the guidelines to make their own decisions about what types of genetic tests they should pursue.

2. Protecting Society

The government has an interest in protecting society from the potential negative effects of PGS. The collective use of PGS may result in increased health disparities and discrimination against individuals with the diseases and characteristics commonly selected against. The government also maintains an interest in demonstrating respect for potential human life.[285]

PGS impacts society less directly than the individuals engaged in the procedure; therefore, the government's interests in protecting society are less immediately relevant. However, if data begin to substantiate that PGS use will significantly increase health disparities or discrimination against disadvantaged groups, these risks should be given significant weight that in some instances could outweigh individual autonomy to use PGS. The government's interest in demonstrating respect for unborn human life should also be weighed against individual interests in using PGS in light of significant public discussion and consultation on the issue.

In order to protect society, the government should seek a regulatory strategy that enables it to identify social risks as they arise both in attitude and in practice. This will entail promoting extensive public discourse and monitoring discriminatory practices. These goals could be accomplished through notice and

285. *See* Gonzales v. Carhart, 127 S. Ct. 1610 (2007).

comment proceedings and public hearings, monitoring the use of PGS for certain conditions, predicting future demand, and employing a diverse staff of experts to identify and raise pertinent issues. Each of these features will be especially important as the government determines whether and under what conditions parents can screen for moderate medical and non-medical conditions.

3. Protecting Reproductive Autonomy

Any government policy regulating ART should start from the foundation of protecting the ability of American citizens to make choices about whether to have a child through assisted reproduction and whether to implant an embryo with certain genetic characteristics. However, as noted above, constitutional protection for reproductive autonomy is not boundless.[286] Reproductive autonomy should be granted less priority than individual and social harm because in some instances, those interests will trump an individual's right to make reproductive decisions. The government can intervene in the practice of ART and PGS without infringing on the Constitution in two instances. First, if the intervention restricts a fundamental right, it must be supported by "sufficiently important state interests and . . . closely tailored to effectuate only those interests."[287] Second, in cases where the intervention does not restrain a fundamental right, the government may regulate so long as a rational basis exists for the regulation.[288] If the governmental interest is important enough to outweigh an individual's privacy rights, presumably the government should act. In the absence of a fundamental right and a substantial state interest, the government should critically examine whether intervention provides the best course of action.

Decisions regarding reproduction and child-rearing remain extremely personal, even if not constitutionally protected. Parents bear responsibility for raising their children and may have a wide range of reasons for wanting to select for specific traits. In these instances, Mill's principle again becomes salient[289] – the government should restrain itself from intervening in the decisions of citizens regarding PGS unless those decisions cause direct harm or pose a substantiated threat to others. The agency should develop a framework to balance parental interests against the individual and societal risks associated with some uses of

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286. *See supra* Section III.B.

287. Zablocki v. Redhail, 434 U.S. 374, 388 (1978); *see also* Planned Parenthood of Se. Pa. v. Casey, 550 U.S. 832, 878 (1992) (striking a balance between the state and individual interests in reproductive decision-making as opposed to applying strict scrutiny analysis); *Carhart*, 127 S. Ct. at 1627 (affirming the balancing approach taken in *Casey*). No court has addressed whether individuals possess a constitutionally protected, fundamental right to make decisions regarding embryo selection via PGS.

288. Cleburne v. Cleburne Living Ctr., Inc., 473 U.S. 432, 440 (1985).

289. MILL, *supra* note 81, at 73-74.

PGS. This framework should reflect the relative priority of interests and the amount of evidence supporting each interest. Maintaining this level of regulatory restraint provides credibility to the regulations that the government does institute, especially if the regulations are established in a transparent way.

4. Practitioners' Interests

In developing a regulatory strategy for PGS, the government should also consider and protect the interests of practitioners, but they should receive the lowest priority of the four stakeholder groups. Practitioners have a strong interest in enabling their patients to have healthy children and in protecting the integrity of the physician-patient relationship. Government efforts to improve access to information and ensure the quality of laboratory procedures would help promote these interests. However, practitioners are likely to view substantive regulations aimed at restricting the professional decision-making as unjust interference in the physician-patient relationship.

Practitioners are also wary of well-meaning but poorly crafted legislation that will restrict the use of PGS or result in additional burdens for the ART patient population.[290] For instance, ART practitioners heavily criticize FCSRCA's ART registry for its unintended consequences. First, they view the registry as an unfunded mandate that pushes reporting costs on to patients or providers.[291] Second, by publishing the success rates of clinics that do report, they argue that FCSRCA might encourage clinics with low success rates to avoid reporting or to begin selectively accepting those patients most likely to become pregnant.[292] Patients with poorer prognoses may have difficulty accessing care. Both increases in cost and provider unwillingness to treat certain patients could further limit the population that can access ART treatment.

Many practitioners believe that legislative or governmental regulation in general will have a "chilling effect" on PGS practice as a whole in the United States.[293] Since insurance carriers often do not cover PGS, couples are not financially bound to physicians or facilities. Many couples will travel to different countries in order to obtain access to the reproductive treatments they desire.[294]

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290. Simpson, Rebar & Carson, *supra* note 203, at 1656-59.

291. *Id.* at 1658. While it may seem fair that those who provide and use ART pay for reporting, the providers argue that these extra costs prevent others from accessing ART.

292. *Id.* Simpson and colleagues provide a number of examples of how clinics might select healthier patients.

293. *Id.*

294. Guido Pennings, *Legal Harmonization and Reproductive Tourism in Europe*, 19 HUM. REPROD. 2689, 2690-91 (2004); Press Release, European Soc'y of Human Reprod. & Embryology, Europe Struggles To Meet the Legal, Ethical and Regulatory Challenges Posed by More Patients Traveling Abroad for PGD, July 2, 2007, http://www.eshre.com/emc.asp?pageId=936.

As a result, countries with more relaxed regulations on PGS will capture more of the market, not only for patients and consumers,[295] but also for the development of new genetic tests for predictive genomics.[296]

Not all practitioners are opposed to governmental oversight. Although some members of SART have argued that self-regulation is the "most appropriate policy in the United States,"[297] others support the development of an independent oversight authority derived from a partnership between patients, providers, and the public.[298] Those members supporting an independent authority advocate regulatory initiatives that include the following: "mandatory compliance, meaningful sanctions, uniformity in reporting, on-site inspection and validation, and development of practice standards, research standards, education standards, and counseling standards, as well as access to insurance coverage and research funding, and a limitation of regulation."[299] The backing and continued participation of ART practitioners is invaluable to any oversight proposal. Their desire for more stringent enforcement mechanisms and uniform practice standards should form the foundation of any regulatory policy.

Balancing these conflicting interests and concerns in one political initiative will be extremely challenging. However, it is imperative to establish infrastructure to address these questions as PGS technology develops.

B. Policy Development

PGS policy should develop in two steps. The agency should first examine the four policy goals described above to identify areas of overlapping interest among the potential stakeholders – what policy goals would benefit all or most of them? Addressing those needs should be the initial mission of the regulatory entity. Next, the agency should consider the areas where the policy goals conflict with one another. It should develop a regulatory framework that balances the interests in accordance with their level of priority.

1. Aligning Similar Interests

Governmental initiatives that benefit all or most stakeholders should form the fundamental features of a new regulatory policy. Achieving the following goals would improve the practice of ART for everyone: 1) ensuring the safety and efficacy of all services provided; 2) improving access to information regarding the risks and benefits of ART; and 3) providing increased analysis of

295. *See, e.g.*, Spar, *supra* note 57, at 214-16.

296. *See, e.g.*, Simpson, Rebar & Carson, *supra* note 203, at 1658-59.

297. *See Id.* at 1656.

298. *See* Adamson, *supra* note 213, at 941.

299. *Id.*

the impact of ART, and especially PGS, on both individuals and society.

The agency's first objective should be to develop procedural regulations to ensure the safety and efficacy of all procedures performed in ART clinics, as well as the reliability of the genetic tests used in conjunction with PGS. The United Kingdom's Human Fertilisation and Embryology Authority (HFEA) provides an excellent licensing model that could be modified for implementation in the United States to ensure the quality of both ART procedures and genetic tests.[300] Under the U.K. licensing approach, clinics must be licensed to engage in any activity that involves the ex vivo creation of a human embryo, the storage of embryos and gametes, or research involving embryos.[301]

By requiring each clinic that offers ART services to obtain and maintain a license to practice, the agency could require all clinics to have appropriately trained staff and maintain quality assurance standards. In addition, by licensing the clinics, the agency could ensure that all clinics reported practice and outcome information to a central database for analysis of child and maternal health risks. The licensing approach would also grant the agency the ability to sanction clinics that do not comply by suspension or revocation of their license.

This licensing approach can be broadened to include laboratories that provide genetic tests for PGS. PGS procedures require a degree of expertise and skill beyond that of a typical diagnostic testing laboratory,[302] given that it requires testing on a single biopsied cell within a short window of time. Laboratories that provide these services should also receive licenses that demonstrate staff qualifications, procedures to avoid misdiagnoses or embryo mix-ups, and the reliability of their tests. In addition, the agency should create procedural standards for gene variations that may be identified through PGS, based on the reliability of available genetic tests, the variation's contribution to the particular disorder (alone or in combination with other identifiable genes), and each variation's penetrance.

The agency's second objective should be to increase understanding of PGS practice. Any policy approach should include provisions to sponsor additional research on ART, create an ART central database to gather and analyze information, and disseminate information to patients, physicians, and the public regarding the uses of PGS.

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300. *See also* FUKUYAMA, *supra* note 198, at 203-04; Fahrenkrog, *supra* note 20, at 779; Parens & Knowles, *supra* note 20, at S18-21; *cf.* PRESIDENT'S COUNCIL, *supra* note 112, at 220-24.

301. Human Fertilisation and Embryology Act. 1990, c. 37, § 5 (U.K.); *see also* Margaret Foster Riley with Richard A. Merrill, *Regulating Reproductive Genetics: A Review of American Bioethics Commissions and Comparison to the British Human Ferilisation and Embryology Authority*, 6 COLUM. SCI. & TECH. L. REV. 1 *passim* (2005) (providing a detailed description of the licensing process).

302. GENETICS & PUB. POLICY CTR., *supra* note 127.

The agency should establish key research objectives and provide funding to address the unanswered questions regarding PGS use. For instance, studies should be done to determine whether embryo biopsy harms embryo development or affects the long-term health of children.[303] The government should also sponsor research on public sentiment regarding the appropriate uses of PGS and the likely demand for genetic tests.

Since PGS practice will continue while this research is being performed, the government should create a central database of information on IVF and PGS procedures. ART clinics should be required to submit information on all IVF and PGS procedures performed, including the following: the medical history of the couple; the procedures used to create the embryo; the number of embryos created and transferred; the implantation, pregnancy, and live birth success rates; the health outcomes of all women; the immediate health outcomes of all babies born via the procedure; all genetic tests performed; and embryo selections made. ART clinicians should ask all parents at the time of ART treatment initiation to consent for this information to be reported to the federal government and used for research. In addition, parents and children born through ART procedures, upon reaching the age of assent, should be asked to consent to having the child's health status reported to the federal database on an annual basis for monitoring and research. Pediatricians could simply forward check-up information to the database stripped of all identifying information and in compliance with all federal privacy requirements.[304] The database could expedite identification of risks to children and women and could ensure that physicians and patients make reproductive decisions on the best information available.

Although additional information on the outcomes of ART and PGS procedures will provide benefit, ART providers are likely to resist the imposition of a mandatory reporting requirement in addition to FSCRCA. FSCRCA's reporting requirements should form the foundation of the central database and be broadened to include additional information related to PGS. Maintenance of FSCRCA's reporting requirements should be transferred from the CDC to the new regulatory body. Providing proper funding to establish the database and assist practitioners in meeting the reporting requirements should also alleviate some of their resistance.[305]

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303. Federally sponsored research on whether embryo biopsy impedes embryo development will most likely violate the Dickey-Wicker Amendment. *See* Balanced Budget Repayment Act of 1996, Pub. L. No. 104-99 § 128, 110 Stat. 26, 34. This amendment should be repealed to permit research on the effectiveness of ART to proceed. Research on the long-term health outcomes of children born via PGS will be less likely to violate the amendment, as the research could start from their birth.

304. *See* 45 C.F.R. § 164.501 (2007).

305. *See* Simpson, Rebar & Carson, *supra* note 203, at 1658.

The government should also create educational materials detailing the risks, benefits and alternatives to IVF and PGS for distribution to physicians, patients and the public. Stimulating public debate will be essential to creating effective policy regulations for PGS use.

The third policy goal should be to improve analysis of PGS's effect on both individuals and society. Monitoring the demand for certain genetic tests reported in the PGS central database will be essential for understanding the potential social risks associated with PGS use. Policymakers should combine this data with information from public discussion and surveys to determine whether access barriers to PGS affect health disparities or whether individuals use PGS in ways that reinforce discrimination.

2. Balancing Conflicting Interests

The most significant challenges of regulating PGS will arise when the interests of the various stakeholders conflict. Conflicts are most likely to occur when prospective parents want to use PGS in ways that threaten harm to a child or society. The government must develop a strategy for handling these conflicts. Examining policy approaches taken by other countries provides insight for developing U.S. policy.

Other countries have taken a range of approaches to minimize the risk of harm from PGS. Banning the procedure altogether, as Germany, Austria, Switzerland, and, more recently, Italy have done, is overly restrictive given the speculative nature of social harms arising from PGS.[306] However, other approaches warrant further consideration. Countries in which PGS occurs have generally selected two regulatory features: a serious impairment requirement and an indication analysis. The severe impairment requirement restricts the use of PGD to testing only those genetic or chromosomal disorders that would cause severe impairment. Under the indications analysis approach, an agency reviews each indication on a case-by-case basis and determines which uses are appropriate.

While both of these approaches offer improvements over the United States' current laissez faire system of ART regulation, neither approach is well suited to our political system or to address recent advances in PGS technology. The severe impairment requirement, a highly precautionary approach, impinges significantly upon reproductive liberty in the absence of substantiated risk. The indications analysis approach requires an excessive amount of oversight and monitoring and favors precaution over reproductive freedom. In the absence of substantiated risk of harm, restricting the use of reproductive technologies may run afoul of constitutionally protected reproductive liberties. Likewise, such an approach will

306. *See supra* notes 171-174 and accompanying text.

likely receive significant resistance from both physicians and patients. A more politically feasible and less-disruptive regulatory model would establish safety and efficacy regulations, monitor the use of ART practice, and then be prepared to intervene if and when risks appear on the horizon. This approach offers significantly more protection than the current lack of regulation, without unnecessarily stifling the development and use of recent advances in ART.

a. Severe Impairment Requirement

Nearly all forms of regulation regarding PGS require that the risk of the condition or disorder tested for be sufficiently grave.[307] Most countries and professional societies that allow PGS limit genetic testing of embryos to only those conditions that will result in serious or severe impairment. For instance, the Netherlands restricts PGS use to "serious conditions."[308] In such countries, the only goal of PGS is to bring about the birth of a healthy child.[309] Some regulatory bodies have gone further to restrict PGS to only those conditions for which medicine cannot provide a remedy; for example, the Australian Medical Association recommends PGD testing only when the disease is permanent.[310] For the most part, governments and professional societies have left the decision of what qualifies as a "serious" or "severe" condition to the patient and the physician.[311]

The definition of "severe impairment" largely determines the scope of the

307. Knoppers & Isasi, *supra* note 172, at 2696. Examples of countries with a severe or serious impairment requirement include the United Kingdom, Japan, India, France, and the Netherlands. *Id.* at 2697.

308. *See* Health Council of the Neth. *Pre-implantation Genetic Diagnosis*, *in* REPORTS 2006: EXECUTIVE SUMMARIES 9, 9 (2006), *available at* http://www.gezondheidsraad.nl/pdf.php?ID=1646&p=1.

309. *See* Knoppers & Isasi, *supra* note 172, at 2696-97 (describing policies in the Netherlands, France, Japan, the United Kingdom, and Australia) (citing Law No. 94-654, art. R2131-7 (1994) (Fr.); HUM. FERTILISATION & EMBRYOLOGY AUTH., CODE OF PRACTICE (5th ed. 2001); Act Containing Rules Relating to the Use of Gametes and Embryos [The Embryos Act], Stb. 2002, 338 (Neth.), *available at* http://www.minvws.nl/includes/dl/openbestand.asp?File=/images/engembryowettekst_tcm20-107819.pdf; JAPAN SOC'Y FOR HUMAN GENETICS ET AL., GUIDELINES FOR GENETIC TESTING (English ed. 2004), *available at* http://jshg.jp/pdf/10academies_e.pdf). Permitted indications tends to include the screening for X-linked disorders, autosomal recessive disorders (such as cystic fibrosis, Tay-Sachs, and spinal muscular atrophy), autosomal dominant disorders (such as myotonic dystrophy and achondroplasia), and chromosomal abnormalities. *See, e.g.*, JAPAN SOC'Y FOR HUM. GENETICS ET AL., *supra*, at 7.

310. AUSTRALIAN MED. ASS'N, HUMAN GENETIC ISSUES 3 (2002), *available at* http://www.ama.com.au/web.nsf/doc/SHED5G7DBE/$file/healths_gd_ps_human%20genetics%20issues.pdf.

311. *See* Knoppers & Isasi, *supra* note 172, at 2699.

regulation, but identifying those disorders that cause a "severe impairment" is extremely difficult. In fact, ART practitioners Joe Leigh Simpson and colleagues have argued that "[c]odifying diseases for which PG[S] should or should not be allowed is hopelessly naïve . . . ."[312] Does severe impairment imply that a disorder shortens the life span of the individual? Must the disorder be incurable? What if the gene only confers a small probability of a very severe disorder? Should the disorder qualify the individual for disability benefits, such that one or more major life activities are limited? What if it does not present until later in life, but has very severe symptoms, like Huntington's disease or Alzheimer's disease?

If defined narrowly to only include those disorders that result in severe suffering and death at an early age, PGS use will continue to have a minimal impact. This approach would permit physicians to provide PGS only in cases where the benefit obtained by parents in selecting against a disease or disorder substantially outweighs any risks. As a result, fewer offspring would be born from the procedure.

Under this narrow definition, the social impacts of PGS would be limited as well. PGS for serious disorders would most likely be covered by insurance, such that lack of financial access to care will not significantly exacerbate health inequities, except between the insured and uninsured. A narrowly defined severe impairment requirement would also limit discrimination, as only a small population would have access to the procedure and a smaller population would be living with the disorders.

A more broadly defined severe impairment requirement that included, for example, disabilities such as blindness and deafness, might expand the potential for certain social harms associated with PGS. Compared to the narrow serious impairment approach, increased numbers of individuals would already live with disorders identifiable by PGS. This could increase discrimination against individuals living with the disorders and create greater disparities in use.[313]

The severe impairment requirement is under-inclusive. Preventing individuals from selecting for traits that do not confer a severe impairment is not warranted by risks to either the offspring or society. While being born through IVF and PGS increases the risk that a child will have a serious health complication, the overall risk remains relatively low.[314] While these risks should be significant enough to outweigh the benefit of selecting for many non-medical

312. Simpson, Rebar & Carson, *supra* note 203, at 1658.

313. Discrimination could increase in two ways. First, by offering a way for parents to avoid having a child with a specific disorder, PGS serves to increase discrimination against those with the disorder, especially if only wealthier people have access. Secondly, by screening for a wider range of conditions, more people will be exposed to discrimination.

314. *See generally supra* note 15.

traits, there is not sufficient evidence of harm to offspring or society at this time to warrant restriction of PGS use to only the most severe disorders.

The ability to select for non-severe traits in addition to a severe trait will further undermine the logic of the severe impairment requirement. For couples who have met the initial clinical indication requirement to undergo PGS, such that the benefits of screening for a certain condition already outweigh the risks, screening their embryos for additional genetic variations presents no additional risk to the offspring or the mother. As a result, a severe impairment requirement would prevent parents from accessing additional information, medical or non-medical, about their embryos for non-serious conditions. In this scenario, the only justifiable arguments against permitting the parents from screening for additional conditions are that such screening will result in social harm.

Social concerns that may justify the severe impairment requirement approach arise largely from the potential for discrimination and respect for the embryo. As noted above, many countries limit PGS use to only severe conditions to limit the extent of eugenic practices and discrimination.[315] However, this approach is overly broad as an effort to protect society from discriminatory practices. Many alleles that are not associated with serious impairment do not raise concerns about discrimination. For instance, parents selecting an embryo that is a tissue match to a sick sibling, an entirely non-disease related trait, would not constitute discrimination against individuals with other tissue types. Consider also screening against alleles associated with a common but not severe allergy, such as an allergy to cats. Permitting parents to select embryos on this basis would benefit cat-loving parents, while not harming other members of society. In this regard, the severe impairment approach appears overly rigid without being substantiated by viable risks.

In sum, the severe impairment requirement has numerous drawbacks. By restricting the conditions for which PGS can be used, the severe impairment requirement unnecessarily constrains parental autonomy in light of the known individual and social risks. The policy would require the government to define those disorders that qualify as "severe," which would be extremely challenging. Such a policy approach also has the potential to increase discrimination against individuals with the listed disorders. To avoid these concerns, the government should err on the side of granting parents expansive autonomy to make choices, which should only be limited in cases of substantiated harms to others.

b. Indications Analysis Approach

Another possible approach would be to examine each indication, or specific reason for conducting PGS, on a case-by-case basis to determine the risks to

315. Knoppers & Isasi, *supra* note 172, at 2697.

individuals and society.[316] A few legal and ethical scholars have suggested that the United States model its ART regulations after the indications approach taken by the United Kingdom's HFEA.[317] Most notably, Lori Knowles and Erik Parens suggest the creation of a Federal Reprogenetics Technologies Board,[318] and Frances Fukuyama and Franco Furger recommend the creation of an independent federal agency to address human biotechnologies and ART.[319] While the creation of an independent federal agency to regulate the practice of ART is the best strategy, the HFEA indications approach has significant flaws that leave it unprepared for the future challenges of PGS.

Under the U.K. indications approach, clinics are prohibited from engaging in any activity that involves the ex vivo creation of a human embryo, the storage of embryos and gametes, or research involving embryos, except as permitted by an HFEA license.[320] ART clinics must receive a license approving the use of IVF and PGS as "treatment services."[321] Licenses are narrowly tailored to specific indications. In order to provide PGD, the HFEA Code of Practice requires clinics to submit a new application for every new PGD indication it wishes to provide and for every new genetic test or combination of tests they want to use.[322]

The indications approach has significant benefits. The HFEA is dexterous at responding to scientific developments that affect ART research and practice.[323] The regulatory infrastructure enables the authority not only to evaluate the social, ethical, and scientific implications of a particular indication, but it also allows the authority to react quickly and effectively to changes in information by issuing licenses or suspending them. The indications approach also permits clinics to evaluate couples on the full extent of their personal situation, rather than evaluating uses only.[324]

By combining comprehensive monitoring and indication licensing, the indications-based approach offers a complete examination of all of the risks to offspring. By keeping records of each child born via PGS, the HFEA can rapidly identify any adverse health outcomes associated with the procedure. The agency can easily incorporate new risk information into existing practice by initiating

316. For instance, sex selection for family balancing and sex selection to avoid an X-linked disorder would use the same test for different indications.

317. FUKUYAMA & FURGER, *supra* note 20, at 14-23; Fahrenkrog, *supra* note 20, at 779; Parens & Knowles, *supra* note 20, at S18-21. The HFEA examines each indication for conducting PGS.

318. Parens & Knowles, *supra* note 20, at S18-21.

319. FUKUYAMA & FURGER, *supra* note 20, at 14-23.

320. Human Fertilisation and Embryology Act, 1990, c. 37, § 5 (U.K.).

321. *Id.* at § 3.

322. HUMAN FERTILISATION & EMBRYOLOGY AUTH., CODE OF PRACTICE pt. A.13.8-9 (7th ed. 2007), *available at* http://cop.hfea.gov.uk/cop/pdf/COPv2.pdf.

323. Riley & Merrill, *supra* note 301, at 58.

324. *See Id.* at 57-58.

investigations,[325] considering new data during the licensing process or modifying existing licenses. Because the HFEA examines each PGS indication, the risks and benefits can be weighed in the most accurate manner possible. Overall, a licensing approach permits PGS use to expand as genetic testing and reproductive technology improves, but in a controlled manner.

Examining PGS uses on a case-by-case basis also provides a thorough method for identifying and considering social impact. An independent regulatory body like the HFEA would have the ability to consider the social impact of permitting an individual indication of PGS, while monitoring the numbers of individuals undergoing PGS for a specific purpose to determine if a broader social effect may occur. Only by overseeing usage and keeping in touch with public sentiment could a society adequately attempt to weigh important social interests, minimize health disparities, eliminate discrimination, and define the appropriate treatment of embryos.

However, as practiced by the HFEA, the indications approach also requires more government intervention than the risks of PGS practice currently warrant. Requiring a committee to evaluate and license each clinic for each potential use or combination of uses is overly burdensome, expensive, and time-consuming. As the number of genetic tests expands and PGS testing for multiple traits becomes available, licensing each clinic to use each specific indication will be impossible. UK clinicians have argued that licensing each use interferes with the doctor-patient relationship and patient privacy.[326] Others complain that the licensing system creates unnecessary delays for time-sensitive treatments and further delays the already limited access to treatments available to underserved populations.[327]

The United States could choose a modified approach that requires agency approval each time a new genetic test was provided for PGS. While this would greatly reduce the time and expense required for PGS licensing, microarray PGS testing would quickly negate the efficacy of such an approach. For instance, the agency might prohibit PGS solely for non-medical sex selection on the basis that the benefit of selecting for a girl does not outweigh the risks that the child will incur during the procedure. For a couple undergoing PGS to screen for a severe disorder, denying the license for broad non-medical sex selection would eliminate the opportunity to select girls from the remaining healthy embryos, even though this selection would pose no risk to the offspring. Any use of PGS that the agency could deny solely based on risk to the children from the PGS procedure could become permissible if paired with screening for a more severe genetic condition that would outweigh this risk.

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325. *Id.* at 58.

326. *Id.* at 24.

327. *Id.*

The government could attempt to license those uses that qualify as "clinically indicated," such that the benefits of engaging in PGS outweigh the risks, so that other tests, like non-medical sex selection, could be licensed for use only in combination with a clinically indicated use. Advances in PGS could also confound this approach, as the benefit of screening for numerous genetic conditions at once may outweigh the risks to the offspring of conducting PGS, even if no singular test on its own would warrant the use of PGS. In the absence of demonstrated individual or social risk from sex selection, prohibiting it in all cases would fail to give sufficient weight to parental autonomy.

In light of these challenges, the government should not seek to evaluate each individual use or combination of uses, as this approach would be extremely burdensome and unlikely to produce the desired effect. Instead, the government should attempt to establish an infrastructure that enables it to monitor PGS use for potential risks to offspring and society, provide guidance on appropriate uses, and place restrictions on uses only when their harms clearly outweigh their benefits.

c. Balancing Framework

Given the political climate and constitutional freedoms in the United States, neither the indications framework nor the severe impairment requirement offers a viable policy option. To resolve conflicts of interest between protecting reproductive autonomy and protecting individuals and society from unjust harms associated with ART use, the United States should adopt a decisional framework based on the interests at stake and their relative importance. Following current practice and Mill's principle the regulation of ART practice should originate from a position of parental autonomy and sanctity of the medical profession. Under this approach, individuals and their physicians would be able to decide whether to use ART procedures, including PGS, to screen for any condition without governmental approval. However, this right would not be absolute: their autonomy must be balanced against the government's interest in protecting individuals and society.

Such a balancing approach would suggest the need for immediate governmental action, as well as monitoring to determine when future action is required. Currently, the agency should restrict those medical practices in which the clinical benefit is outweighed by the risk to the child. For instance, parents and physicians often opt to transfer more than one embryo to the uterus to improve the odds of pregnancy, but this practice also increases the health risk to each embryo transferred.[328] In order to diminish the number of multiple births,

328. *See* Bonduelle et al., *supra* note 15, at 418; Hansen et al., *supra* note 97, at 729; Klemetti et al., *supra* note 14, at 1822; Soini et al., *supra* note 93, at 605-07.

the agency could decide to restrict the number of embryos transferred.[329] The agency should also require clinics to maintain a strict code of medical ethics, such that PGS will only be provided when clinically indicated. The agency should provide practice guidelines to assist physicians in determining whether a specific procedure is clinically indicated, but the ultimate decision in any individual case should belong to both the physician and parents. Physicians are trained to make decisions regarding the risk-benefit ratio of a specific procedure and are better suited to make those decisions in individual circumstances. However, the government should require the clinics to report their use patterns, disclose success rates, and monitor clinic use patterns for repeat or egregious inappropriate uses. The government should also perform on-site inspections to ensure the accuracy of the reporting. In cases of abuse, the agency could suspend or revoke the license of the clinic.

In the future, the government should also reserve the right to restrict PGS use to select for certain alleles that would risk significant harm to society. For instance, if the practice of sex selection, on its own or as part of multi-use PGS, began to demonstrate significantly uneven selection patterns between males and females, as has occurred in China and India,[330] the agency should prohibit PGS for non-medical sex selection. The agency might also have the ability to limit PGS use to demonstrate its respect for unborn human life even in the absence of individual or social risk.[331] The government's interest in protecting unborn life, which grows as the embryo matures,[332] would be quite limited at the preimplantation stage. But in some instances, the countervailing parental interest in selecting a specific gene variant may be minimal as well. The parental interest in selecting embryos based on non-medical characteristics of scant importance, such as eye color, may not outweigh the government's interest in demonstrating respect for the human embryo by not discarding it for a trivial purpose. In these situations, the government may wish to restrict certain uses of PGS in the absence of individual risk.

As genetic testing capabilities improve and the understanding of PGS risks develops, the challenges of balancing the respective interests will increase in size and magnitude. To mitigate the potential harms associated with unrestricted PGS use, Congress should develop the infrastructure necessary to address the current risks of PGS use as well as those visible on the horizon.

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329. *See* Practice Comm., *supra* note 100, at S51-52.

330. *See, e.g.*, Parliamentary Office of Sci. & Tech., *Sex Selection*, POSTNOTE 198, Aug. 2003, at 4, *available at* http://www.parliament.uk/post/pn198.pdf.

331. Gonzales v. Carhart, 127 S. Ct. 1610 (2007).

332. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 869 (1992).

C. Assisted Reproductive Technology Authority

The preceding arguments suggest that Congress should create a national independent regulatory body, the Assisted Reproductive Technology Agency (ARTA), to perform five main functions: 1) establish a licensing system for ART clinics; 2) establish procedural guidelines and regulations for ART practice; 3) gather data on ART procedures, including PGS, long-term offspring and maternal health outcomes, and public sentiment; 4) monitor that data for individual and social risks; and 5) in the case that proven risks outweigh the benefits for certain procedures, regulate the use of PGS for certain indications using the novel balancing framework proposed above.

1. Procedural Regulations

ARTA's first responsibility will be to establish procedural requirements for ART clinics. All ART clinics should be required to obtain a license from ARTA. Licensing will signify that the clinic has met and continues to maintain certain minimum standards of safety, quality of care, and expertise. ARTA should require a license for clinicians who seek to perform highly technical procedures such as egg retrieval and embryo biopsy. Clinics should offer patients genetic counseling services by licensed genetic counselors. ARTA should also work with ASRM and SART to establish best practices guidelines for ART procedures. In addition to the laboratory regulations established by CLIA, ARTA should license genetic testing laboratories that perform tests for PGS.[333] These laboratories should meet standards of accuracy, quality control, and quality assurance set by ARTA in order to obtain and maintain a license.

ARTA should then begin more long-term projects. First, the agency should create a database of information on all ART procedures occurring in licensed clinics. The CDC's requirements under FCSRCA should be turned over to ARTA and expanded to include additional information, including the number of embryos created, screened and transferred; the genetic and chromosomal analysis performed; implantation and pregnancy rates; multiple gestations, including information on reductions and live births; and infant health status. Parents should be asked to consent to providing their child's annual health status report to obtain health information from a representative sample of children born via PGS.[334]

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333. If CMS eventually develops a genetic testing specialty and proficiency requirements that specifically address the quality of genetic tests for PGS, then ARTA could relinquish this responsibility to CMS.

334. Some parents may want to avoid having their children become permanent research subjects; however, since PGS has never been vetted through a randomized control trial for health outcomes, monitoring the children's health status is incredibly important. These health reports can be provided without significant burden to the parents or child via annual physician check-up reports

Women who undergo ART procedures should also be asked to provide updated reports of their health status at regular intervals. Due to the uncertainties associated with the current and future uses of PGS, more information is greatly needed to adequately regulate the procedure. By encouraging those who engage in PGS to provide information on their health outcomes, success rates, and reasons for using the technology, ARTA can effectively determine where government intervention is required. This would also enable ARTA to regulate without resorting to a precautionary approach that would require the agency to act before evidence of clear need. The license and monitoring approach of ARTA could provide a policy solution that lies between the United States' current laissez-faire approach and the precautionary tactics seen in many other nations that have either banned or heavily regulated PGS.[335]

ARTA should monitor the database to identify adverse health outcomes, the most common uses of PGS, possible discriminatory uses, and other issues of individual or social concern, including socio-economic and demographic use patterns. To maintain individual confidentiality, clinicians should remove all identifying data. As more non-disease-related genetic screening becomes available, ARTA should monitor the volume and popularity of such practices to determine if more rigorous standards of regulation are necessary.[336] For non-disease related indications, ARTA should examine closely whether the risks and burdens of undergoing PGS to screen out the trait outweigh the potential benefit of selection.

ARTA should provide information to enhance the understanding of issues associated with reproductive genetics and PGS. It could work in collaboration with genetic counselors and clinic providers to develop educational tools to improve comprehension of the risks and benefits of PGS, as well as the alternatives available to prospective parents. ARTA should conduct research on the data collected in the database and make the data available to the public for independent research. In addition to promoting scholarly publications and research, ARTA should provide materials and programs to help laypersons understand the issues surrounding assisted reproduction and genetics. Efforts to educate and engage the public in conversation about ART and PGS will help ensure that policies created in this area reflect the needs and concerns of society as a whole, not just those with immediate financial or personal interests.

To determine the impact of certain indications, ARTA should work with a diverse array of individuals, including geneticists, pediatricians, members from the disability community, prospective parents, religious leaders, and others, to

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until the child is eighteen, and then with the adult child's permission, on an every five-year basis after that. *See* Soini et al., *supra* note 93, at 611.

335. I am indebted to Amitai Aviram for this helpful description of the ARTA proposal.

336. PRESIDENT'S COUNCIL, *supra* note 112, at 197-98.

create PGS selection guidelines and decision analysis algorithms. This should be an ongoing project with public opportunities for input and transparency. These guidelines would be non-binding, but meant to assist clinicians and parents in determining whether undergoing PGS for a particular purpose or discarding embryos due to the presence of a specific allele is appropriate. ARTA's main role in establishing PGS selection guidelines would be to determine the social impact of various uses of PGS.

2. Substantive Regulations

In addition to creating and monitoring a database, establishing a licensing system, and developing practice and PGS selection guidelines, ARTA should establish a system for regulating the appropriate and inappropriate uses of PGS as they arise, as well as mechanisms to identify and address many of the social risks associated with PGS.

Initially, ARTA should permit parents and physicians to use PGS for any purpose for which they believe the benefits of the selection outweigh the risks to the offspring, mother, and society. The agency should create PGS selection guidelines to assist physicians in accounting for the benefit of selecting a child with a certain trait, the scientific accuracy of the genetic tests, the potential individual risks to the mother and offspring, the overall demand for the procedure, and the likely harm to others that might arise from its widespread use.

The first substantive standards ARTA should establish are those targeting the accuracy and reliability of genetic tests that may be used in PGS. Genetic tests for genes with low penetrance or low predictive value may be inappropriate for PGS. Likewise, the agency should establish minimum levels of association between the genetic loci tested for and the specific phenotype or physical characteristic of interest, and then require all genetic associations to be replicated with high reliability and without refutation before permitting the testing to be used in PGS.

To address potential social harms, ARTA should take steps to reduce the barriers to access for clinically indicated uses of ART for all members of society. ARTA should use information from the database to identify disparities in access as they arise and to determine factors contributing to the cause. The government could also seek to engage and inform the public about the available treatment choices and the risks and benefits that accompany them. If the barriers are financial, the governmental efforts could improve access to insurance coverage or provide subsidies for low-income families.[337] In addition, any attempt to encourage individuals to select for or against any specific conditions may be

337. However, any attempts to do so should be weighed against other health priorities. Subsidies for ART may not become a priority for some time, if ever.

viewed as discriminatory or eugenic. With respect to PGS, efforts to reduce health disparities both in use of PGS itself or through selection for or against genetic conditions should be made solely with the goal of helping individuals obtain the necessary information and services to fulfill their health care goals. The government should neither encourage nor discourage the use of PGS in any particular group.

To address harms associated with discrimination, ARTA should examine whether the screening results in balanced or one-sided selection patterns, and whether those patterns reflect possible discrimination. For instance, concerns about sex selection in the United States have been tempered by the fact that prospective parents tend to select for boys and girls at similar rates. If parents began systematically selecting boys for non-medical reasons, especially if based upon discriminatory beliefs about the value of women, the government could pass regulation prohibiting this practice. Determining whether collective choices reflect discriminatory practices and at what point those choices create social harm will be one of ARTA's main tasks. Only through expert analysis of PGS use patterns and public sentiment could ARTA determine if such stigma and discrimination rose to the level of generating a social risk.

By putting a regulatory system in place to ensure the safety and efficacy of clinical practice and monitoring the use of PGS in the United States, we can gain many of the benefits associated with PGS, while preparing to identify and respond in a fast and efficient manner to any harms as they develop.

CONCLUSION

With little consideration for American preparedness, a technological revolution in reproduction is coming. Recent advances in DNA microarrays and bioinformatics will enable parents to select embryos based on a broad range of genetic information. While this information will offer prospective parents unprecedented decision-making capabilities regarding their future children, unregulated use of the technology poses significant risk to women, children, and society as a whole. To address these concerns, this Article advocates the creation of a novel regulatory system that establishes the middle ground between the current laissez faire approach and the precautionary approach taken in other countries. Under this system, the ARTA will provide both procedural and substantive regulation over the practice of assisted reproduction. Procedurally, ARTA should license all ART clinics and genetics laboratories that provide services for PGS, create a database of information on ART health outcomes and practice patterns, and monitor the database for risks to individuals and society. Substantively, the ARTA should establish a balancing framework that weighs various interests based on the priority and strength of the interest to determine whether certain ART practices should be regulated. Creating this infrastructure now will promote the safety of those individuals currently engaged in ART

practices, the informed choice of those seeking to use IVF and PGS in the future, and the ability of the United States to adapt appropriately as new challenges emerge.

Without question, passing any substantial legislation to establish a new regulatory entity will prove extremely challenging, especially laws that regulate reproductive practices. However, America's current lack of oversight and regulation over ART, and especially PGS, invites significant social change without pausing to consider what is at stake. While the proposal put forth in this Article may change during the regulatory process, I hope that it will contribute to the body of literature on the regulation of ART, stimulate further discussion of the implications of PGS, and serve as a sound beginning to the establishment of a regulatory framework for PGS.

One of the most challenging questions we face is how PGS use will impact the everyday lives of Americans. If widely used, PGS has the potential to dramatically change the way we reproduce, think about and relate to our children, perceive other members of society, and value pre-nascent human life. Without monitoring the use patterns of PGS and the public sentiment regarding current and future capabilities of the procedure, we have no way to predict the potential social impact of PGS. By pausing now to consider the future society we hope to create for our children, we will have a better chance of making it a reality.

Non-Beneficial Pediatric Research and the Best Interests Standard: A Legal and Ethical Reconciliation

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INTRODUCTION

In 1966, Henry Beecher, a professor at Harvard Medical School, published an article in the *New England Journal of Medicine* describing twenty-two cases of unethical medical research, some of which involved children.[1] In the infamous Willowbrook study, for example, researchers deliberately exposed children who were wards in a state facility to hepatitis to study preventive measures.[2] Public attention to research tragedies led to the passage of federal regulations governing human subjects research, including special protections for children.[3] The regulations restricted the participation of children in research, and, in that sense, they have protected children. However, this effort to protect children "may partly explain the underfunding and understudy of . . . health issues unique to children" that followed.[4] Consequently, the vast majority of medications prescribed to children today have not been adequately studied in pediatric populations.[5]

Since the late 1990s, deploying an array of carrots and sticks, the federal government has sought to increase pediatric research, particularly with respect to pharmaceuticals, to address our lack of knowledge regarding the safety and efficacy of pediatric therapies.[6] Its efforts have worked. Between 1990 and 1997, researchers completed eleven pediatric studies of marketed drugs; since 1997, the Food and Drug Administration (FDA) has requested approximately 800 studies involving 45,000 children in clinical trials.[7] Pediatric research will continue to expand as the President recently signed into law measures to encourage pediatric

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1. Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966).

2. *Id.*; Ezekiel J. Emanuel et al., *Scandals and Tragedies of Research with Human Participants: Nuremberg, the Jewish Chronic Disease Hospital, Beecher, and Tuskegee*, *in* ETHICAL AND REGULATORY ASPECTS OF CLINICAL RESEARCH: READINGS AND COMMENTARY 1, 3-4 (Ezekiel J. Emanuel et al. eds., 2003). As two commentators have described it, the history of pediatric experimentation at the time of Beecher's article was "largely one of child abuse." Susan E. Lederer & Michael A. Grodin, *Historical Overview: Pediatric Experimentation*, *in* CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 3, 19 (Michael A. Grodin & Leonard H. Glantz eds., 1994) [hereinafter CHILDREN AS RESEARCH SUBJECTS].

3. LAINIE FRIEDMAN ROSS, CHILDREN IN MEDICAL RESEARCH 12 (2006) [hereinafter ROSS, CHILDREN IN MEDICAL RESEARCH]. The federal regulations governing human subjects research are codified at 45 C.F.R. § 46 (2007); the regulations pertaining to pediatric research are found within Subpart D.

4. ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 24.

5. *See infra* notes 42-46 and accompanying text.

6. *See* ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 24-28; *see also infra* note 60 and accompanying text.

7. SENATE DEMOCRATIC POLICY COMM., LEGISLATIVE NOTICE: S. 1082 – THE FOOD AND DRUG ADMINISTRATION REVITALIZATION ACT (2007), http://www.democrats.senate.gov/dpc/dpc-new.cfm?doc_name=lb-110-1-68.

research regarding medical devices.[8]

Any assessment of this expansion in pediatric research must carefully distinguish the purpose of research from the purpose of medical care. Medical care aims to promote an individual patient's well-being.[9] Research aims to produce generalizable knowledge.[10] Though the medical benefits of research participation sometimes outweigh its risks, much research inevitably exposes subjects to risks that are uncompensated by health benefits to the individual subjects; for such research to be worthwhile, the potential benefits to society must outweigh the risks to subjects.

Non-beneficial pediatric research aims to improve the general health and well-being of all children by exposing individual pediatric subjects to risks uncompensated by any health benefit to the subjects derived from participating in the study. For example, researchers often expose children to medical procedures, such as blood draws, biopsies, and x-rays, that carry some risk of pain and more serious harm—even though these procedures provide no potential benefit to the pediatric subjects.[11] They are performed only to learn more about a particular disease or to discover possible therapies. Research subjects do not include only ill children; researchers also enroll healthy children in protocols, exposing them to the risks of non-beneficial procedures, as a comparison group. Essentially, a non-beneficial pediatric protocol places some children at risk (very low risk, but nonetheless risk) purely for the good of children in the future. Is it ethical—and should it be legal—to conduct such research?

These issues have received scholarly attention over the past forty years, even before the passage of our current federal regulations, which permit some non-beneficial pediatric research.[12] This increased attention is due to 1) the exponential increase in pediatric research, and 2) the 2001 *Grimes* decision of the Maryland Court of Appeals (the state's highest court), which declared that parents have no legal authority to consent to enroll their children in non-

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8. Pediatric Medical Device Safety and Improvement Act of 2007, Pub. L. No. 110-85, 121 Stat. 824. See *infra* note 64 for further discussion.

9. Franklin G. Miller & Howard Brody, *What Makes Placebo-Controlled Trials Unethical?*, 2 AM. J. BIOETHICS 3, 4 (2002); *accord* Trudo Lemmens & Paul B. Miller, *Avoiding a Jekyll-and-Hyde Approach to the Ethics of Clinical Research and Practice*, 2 AM. J. BIOETHICS 14 (2002) (agreeing that the aim of clinical care is to optimize a patient's welfare while the purpose of research is to produce generalizable knowledge).

10. 45 C.F.R. § 46.102(d) (2007) (stating that goal of research is to "develop or contribute to generalizable knowledge"); Emanuel et al., *supra* note 2, at 1.

11. David Wendler, The Personal Significance of Helping Others: Implications for Non-Beneficial Pediatric Research 5 (unpublished manuscript, on file with author) [hereinafter Wendler, Significance].

12. The federal regulations governing human subjects research with children, codified at 45 C.F.R. § 46.406 (2007), were enacted in 1983.

beneficial pediatric research.[13] The court based its conclusion on the "best interests of the child" standard,[14] concurring with both then-Judge Warren E. Burger's view that experimentation on a child, unless for her benefit, is simply "indefensible,"[15] and with Justice Wiley Rutledge's famous sentiment in *Prince*:[16] "Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."[17]

Most commentators on pediatric research, however, disagree with *Grimes* and maintain that at least some non-beneficial pediatric research is ethically justifiable.[18] A legal ban on all non-beneficial pediatric research would prove costly to the overall welfare of children, prohibiting pursuit of important medical knowledge and greatly slowing improvement of pediatric care.[19]

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13. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 852-58 (Md. 2001).

14. For a discussion of the history of the best interests standard, see MARY ANN MASON, FROM FATHER'S PROPERTY TO CHILDREN'S RIGHTS: THE HISTORY OF CHILD CUSTODY IN THE UNITED STATES 121-60 (1994).

15. Warren E. Burger, *Reflections on Law and Experimental Medicine*, 15 UCLA L. REV. 436, 438 (1968).

16. Prince v. Massachusetts, 321 U.S. 158, 170 (1944). The petitioner in *Prince* had been convicted for violating state child labor laws after she had provided her nine-year-old niece, to whom she was guardian, with religious literature to distribute on public streets while preaching. She challenged the constitutionality of her convictions, arguing that they violated her First Amendment right to free exercise, her parental rights under the Fourteenth Amendment's Due Process Clause, and her right to equal protection under the Fourteenth Amendment. The Court, however, upheld her convictions, affirming that "[t]he state's authority over children's activities is broader than over like actions of adults." *Id.* at 168.

17. *Id.* at 170; *see also Grimes*, 782 A.2d at 856 (quoting T.D. v. N.Y. State Office of Mental Health, 626 N.Y.S.2d 1015, 1020-21 (App. Div. 1996) (quoting *Prince*, 321 U.S. at 170)).

18. *E.g.*, NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, RESEARCH INVOLVING CHILDREN: REPORT AND RECOMMENDATIONS (1977) [hereinafter NAT'L COMM'N]; LAINIE FRIEDMAN ROSS, CHILDREN, FAMILIES, AND HEALTH CARE DECISION MAKING (1998) [hereinafter ROSS, CHILDREN, FAMILIES]; Wendler, Significance, *supra* note 11; Dan W. Brock, *Ethical Issues in Exposing Children to Risks in Research*, *in* CHILDREN AS RESEARCH SUBJECTS, *supra* note 2, at 81, 91-92; Loretta Kopelman, *What Conditions Justify Risky Non-therapeutic or "No Benefit" Pediatric Studies: A Sliding Scale Analysis*, 32 J.L. MED. & ETHICS 749 (2004) [hereinafter Kopelman, *Conditions*]; Richard A. McCormick, *Experimentation in Children: Sharing in Sociality*, 6 HASTINGS CENTER REP. 41 (1976) [hereinafter McCormick, *Experimentation*]; Lainie Friedman Ross, *In Defense of the Hopkins Lead Abatement Studies*, 30 J.L. MED. & ETHICS 50 (2002); Jack Schwartz, *The Kennedy Krieger Case: Judicial Anger and the Research Enterprise*, 6 J. HEALTH CARE L. & POL'Y 148 (2002).

19. NAT'L COMM'N, *supra* note 18, at 23-26; ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 19.

Because of the overall benefits to children provided by pediatric research, its practice appears clearly justified on consequentialist grounds. Consequentialism represents a family of views within moral theory that maintains that the right action or policy in a given context is that which produces the best consequences, the most overall net good.[20] Consequentialist theories can differ in how they define the good (i.e., what is to count as a good and bad consequence), but all have the same structure in advocating that morality requires us to maximize good consequences. Utilitarianism, for example, is a form of consequentialism that equates the good with pleasure and the absence of pain, and thus maintains that morality requires us to maximize overall net pleasure. In contrast, non-consequentialist (or deontological) accounts of morality maintain that "there are right- and wrong-making considerations other than good and bad effects."[21] To illustrate, a non-consequentialist would maintain that punishing innocent persons wrongs them, and is thereby wrong, even if punishing them would optimize good consequences.[22] There are different versions of non-consequentialism, but the non-consequentialist idea that is most relevant for our purposes at this point is Kant's famous conclusion that we must never treat any person merely as a means to an end, but always as an end-in-herself.[23] Others may serve as means to our ends, as I might hire an electrician to fix a faulty circuit. But I do not thereby use the electrician *merely* as a means to my ends, given that he has freely agreed to fix my circuit. To punish an innocent person to deter crime, on the other hand, treats that person merely as an instrument and not as a person.

We can now see why the justification for pediatric research, if one exists, has been described as "frankly and inevitably utilitarian."[24] We conduct pediatric research because of the good consequences it produces for the health of children as a group; yet pediatric research often requires exposing children to risks contrary to their best interests, though children cannot provide binding consent. It appears, on its face, that pediatric research treats pediatric subjects merely as a means to an end when it exposes them to risk for the good of others without their informed consent.

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20. STEPHEN DARWALL, PHILOSOPHICAL ETHICS 81 (1998). More specifically, an *act*-consequentialist takes right action to be that which maximizes good consequences in the particular circumstances. *Id.* A *rule*-consequentialist takes right action to be determined by *rules* which, if followed, would produce the best consequences (compared to other possible rules). *Id.*

21. *Id.* at 82.

22. *Id.*

23. IMMANUEL KANT, GROUNDING FOR THE METAPHYSICS OF MORALS 36 (James W. Ellington trans., Hackett Publ'g Co. 1993) (1785) ("Act in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end and never simply as a means.").

24. Randall Baldwin Clark, *Speed, Safety, and Dignity: Pediatric Pharmaceutical Development in an Age of Optimism*, 9 U. CHI. L. SCH. ROUNDTABLE 1, 3 (2002).

An amicus brief submitted by research universities to the Maryland high court, asking it to reconsider its virtual ban on non-beneficial pediatric research, reflects the idea that this research is based on utilitarian considerations and conflicts with non-consequentialist moral principles: "The overall cost of [prohibiting non-beneficial pediatric research] in terms of lost advances in medical and health knowledge (and ultimately lost opportunities to cure diseases and prevent suffering and the loss of life) will far outweigh the asserted advantage of protecting individual rights."[25]

Though most commentators conclude that at least some non-beneficial pediatric research is morally permissible, they are unwilling to condone its practice on utilitarian or other consequentialist grounds, uncomfortable endorsing the use of children to improve others' health when those children cannot provide binding consent. Thus, the fundamental ethical question raised by the pediatric ethics literature is whether a non-consequentialist justification exists for exposing pediatric subjects to research risks compensated only by the potential benefits to others. Alternatively, in Kantian terms, can we treat a pediatric subject, incapable of providing informed consent, as an end-in-herself and not merely as a means when we expose her to risks that are not in her best interests to face? Although these questions have received attention, a persuasive account has yet to appear.

The legal question addressed in this Article regarding the *Grimes* court's reliance on the best interests standard in the research context has not received adequate attention. In determining researchers' duties to children and parents' legal authority to enroll their sons and daughters in research, should courts be guided by the best interests standard?[26] Are there legal grounds to which courts may turn to avoid invoking that standard? And if courts should, in fact, rely on the best interests standard, how should they interpret and apply that standard to research? Does the best interests standard preclude non-beneficial pediatric

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25. Brief for Ass'n of Am. Med. Colls., Ass'n of Am. Univs., Johns Hopkins Univ. & Univ. of Md. Med. Sys. Corp. as Amici Curiae Supporting Appellee's Motion for Reconsideration, Grimes v. Kennedy Krieger Inst. Inc., 782 A.2d 808 (2001) (No. 128), *available at* http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/briefs.htm [hereinafter Amici].

26. Bioethics scholar Loretta Kopelman commented:

> This [best interests] standard is so engrained in the law that the *Grimes* court made it clear that if the "best interests of the child" standard is incompatible with the federal pediatric regulations and practices, then the pediatric regulations and practices would have to change, and if federal agencies do not clarify the regulations, the courts will.

Loretta Kopelman, *Children As Research Subjects: Moral Disputes, Regulatory Guidance, and Recent Court Decisions*, 73 MT. SINAI J. MED. 596, 603 (2006). Kopelman is mistaken in implying that any state court could require a change in, or announce a clarification of, federal regulations. And the *Grimes* court did not make any such statement. But the *Grimes* decision and Kopelman's commentary evidence a need to discuss the relationship between the law's best interests standard and non-beneficial pediatric research, particularly for non-legal bioethics commentators.

research which seems, by definition, to be contrary to the best interests of each pediatric subject?

The legal questions are important for Maryland and for other states. First, even though the Maryland legislature passed a statute specifying standards for research that accord with the federal regulations, the *Grimes* ruling on parental authority remains law. It remains unclear whether *Grimes* prohibits minimal risk, non-beneficial pediatric research. If researchers in Maryland continue conducting minimal risk, non-beneficial pediatric research and a child is injured or dies, as may be inevitable, litigants will dispute whether the best interests standard prohibits even minimal risk, non-beneficial pediatric research in Maryland. Second, the number of research-related lawsuits filed in other states has increased over the past few years,[27] making it "likely that the courts will play a growing role in the future evolution of the law relating to research,"[28] and forcing these courts to consider non-beneficial pediatric research in light of the best interests standard. Third, discussion of the legal questions helps shed light on a persuasive non-consequentialist justification for non-beneficial pediatric research.

This Article answers two related questions: 1) What is the appropriate legal relationship between non-beneficial pediatric research and the best interests standard?; and 2) What is the fundamental ethical justification for this research, if not utilitarian or otherwise consequentialist? With regard to the legal question, this Article considers two possible approaches not taken by the *Grimes* court: first, that the best interests standard should not solely determine whether non-beneficial pediatric research should be legally permissible, but rather that the standard should be weighed against the overall good consequences produced by such research. Upon rejecting this approach, this Article advocates a second legal avenue: *Grimes* correctly invoked the best interests standard as controlling whether parents should have legal authority to enroll their children, but the court misapplied that standard. *Grimes* limited the relevant facts to the potential burdens and benefits to individual pediatric subjects presented by a non-beneficial protocol. As described below, in thinking about the best interests of each child, a court (or legislator or regulator) must also consider that from the perspective of each child (including each child enrolled in non-beneficial research), it is in her best interests for the state to permit such research where there is an appropriately low ceiling on the acceptable level of risk.

The second approach illuminates one compelling non-consequentialist justification for non-beneficial pediatric research. The justification for a child's

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27. *See, e.g.*, Michelle M. Mello et al., *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40 (2003); E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1 (2003).

28. CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 106 (2005).

participation does not rest on the greater good, but rather appeals to the benefits of the practice *for each child*. For each child, including those exposed to risk in a non-beneficial protocol, the benefits of such a policy outweigh the risks of being harmed in research.[29]

Though I argue for that empirical claim, it may turn out to be false, in which case the research would require a different justification. This Article articulates an additional, potentially more controversial justification, appealing to the reason each person, including each child, has to help others when one can do so at little to no cost to oneself. The argument presented attempts to interpret and vindicate the work of Richard McCormick, whose debates in the scholarly literature with Paul Ramsey represent the classic departure for the pediatric research ethics literature.

In this Article, Part I presents background on the importance of pediatric research and recent federal attempts to expand it. Part II describes the tension between the federal regulations and *Grimes*. Part III defends *Grimes* against accusations that it failed to respect parental rights or failed to appreciate non-medical benefits that might accompany a child's research participation. Part IV considers, but ultimately rejects, the argument that *Grimes* should have treated the best interests of pediatric subjects as one consideration to be weighed against others, such as the benefits of research to future children. Part V presents both the proper best interests legal analysis of the issue and a non-consequentialist ethical justification. Finally, Part VI discusses a second non-consequentialist justification, attempting to revive McCormick's arguments.

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29. One might ask whether the arguments presented are applicable to all phases of research or only to Phase II and later stages. The arguments do not presume any particular phase of research. I presume that the ethical standard and justification for non-beneficial pediatric research is the same regardless of the phase. As any commentator on pediatric research ethics would agree, ethically justifiable pediatric research places a very low ceiling on acceptable risk, whether that low ceiling is defined as "minimal risk" or "a minor increase over minimal risk," or by some other standard. A separate question—one that requires separate treatment—is how the fact of unknown risks, including the unknown risks of Phase I trials, should be considered when assessing protocols under the proper standard defining that ceiling on acceptable risk.

However, it is important to note that non-beneficial research on children is ethically justifiable only when it is scientifically necessary to conduct research on children. If it is not scientifically necessary to include children in safety tests because reliable results can be achieved through research on adults, then children should not be used as research subjects. *See* Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, 283 JAMA 2701, 2705 (2000) (noting that fair subject selection is an ethical requirement in research, which implies that "it may be appropriate to include [children in research testing a therapy] only after the safety of the drug has been assessed in adults[,]" given that it is "not necessary to include children in all phases of research").

I. BACKGROUND

A. Importance of Pediatric Research

According to the Institute of Medicine,[30] biomedical research conducted over the past few decades has "helped change medical care and public health practices in ways that, each year, save or lengthen the lives of tens of thousands of children around the world, prevent or reduce illness or disability in many more, and improve the quality of life for countless others."[31] New vaccines, therapies, and discoveries regarding unexpected risks of accepted therapies have contributed to great improvements in children's welfare.[32]

It would be ethically preferable if this kind of medical progress could result from research on adults only, with findings then extrapolated to apply in the pediatric setting. Competent adults can provide informed consent, while young children cannot. However, research on adults cannot improve children's lives nearly as much as pediatric research.[33]

The Institute of Medicine discusses at least five reasons "why medicines must be studied in research with children to ensure their safe and effective use."[34] First, some diseases and conditions affect children only (such as premature birth and phenylketonuria[35]) or affect children differently than adults (such as arthritis and some forms of cancer).[36] Second, children often require forms of oral medicines, such as good-tasting liquids or chewable tablets, different than what is appropriate for adults. It is crucial to test the substances in which the active medication is dissolved or otherwise administered. Third, the ways in which medicines are absorbed, distributed to organs, and excreted depend on an

30. The Institute of Medicine is a private, non-governmental organization and component of the National Academies of Science. It was created by the federal government to provide "science-based advice on matters of biomedical science, medicine, and health." About the Institute of Medicine, http://www.iom.edu/CMS/AboutIOM.aspx (last visited Sept. 7, 2007).

31. INST. OF MED., ETHICAL CONDUCT OF CLINICAL RESEARCH INVOLVING CHILDREN 25-26 (2004).

32. *Id.* at 26.

33. *See id.* at 66-72.

34. *Id.* at 66-67. For a similar discussion of the reasons to conduct research on children, highlighting the differences between children and adults, see Ralph E. Kauffman, *Scientific Issues in Biomedical Research with Children*, *in* CHILDREN AS RESEARCH SUBJECTS, *supra* note 3, at 29.

35. Phenylketonuria (PKU) is a genetic disorder that causes a buildup of a particular amino acid in the blood due to the lack of a specific enzyme, which causes mental retardation and other neurologic and psychiatric problems. Newborns are screened for the disorder and its effects can be controlled with diet. THE MERCK MANUAL OF MEDICAL INFORMATION 1618-19 (Mark H. Beers et al. eds., 2d Home ed. 2003).

36. *See* INST. OF MED., *supra* note 31, at 58-59.

individual's stage of development.[37] Because absorption depends on development, and because the relative size of children's organs does not match the relative size of adults', danger of over- or under-dosing arises when calculating a pediatric dose by extrapolating from adult studies. A trial and error approach to dosing based on adult studies sometimes works, but has also led to tragedy.[38] Fourth, we know that some medicines act differently in children (e.g., antihistamines may make an adult sleepy but a child hyperactive) or do not act at all because the necessary receptor has not yet developed in children.[39] Finally, some adverse effects of medicines are relevant only to children. For example, corticosteroids, inhaled to control asthma, can affect a child's growth.[40] Thus, pediatric studies, even more than similar adult studies, may require long-term tracking of outcomes.

Despite its importance, pediatric research has constituted an extremely small portion of medical research. The lack of knowledge regarding the safety and efficacy of therapies for children led Harry Shirkey in 1968 famously to describe children as "therapeutic orphans."[41] Most medications prescribed for children have not actually been tested in children,[42] and many labels for drugs used in children provide little information specific to pediatric patients.[43] Even some of the most-widely used drugs for children have labels that state explicitly that

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37. *Id.* at 67-70; Margaret P. Sullivan, *Children as Therapeutic Orphans*, *in* RESEARCH ON CHILDREN: MEDICAL IMPERATIVES, ETHICAL QUANDARIES, AND LEGAL CONSTRAINTS 27 (Jan van Eys ed., 1978).

38. Michelle Meadows, *Drug Research and Children*, FDA CONSUMER MAG., Jan.-Feb. 2003, at 13, *available at* http://www.fda.gov/fdac/features/2003/103_drugs.html (discussing infant deaths caused by chloramphenical, used in adults to treat penicillin-resistant infections).

39. INST. OF MED., *supra* note 31, at 71.

40. *Id.* at 71; Alessandro Salvatoni et al., *Inhaled Corticosteroids in Childhood Asthma: Long-Term Effects on Growth and Adrenocortical Function*, 5 PEDIATRIC DRUGS 351 (2003).

41. Harry Shirkey, *Therapeutic Orphans*, 72 J. PEDIATRICS 119 (1968), *reprinted in* 104 PEDIATRICS 583 (1999).

42. Meadows, *supra* note 38, at 13.

43. Jane E. Henney, Comm'r, Food & Drug Admin., Increasing Pediatric Access to Medical Therapies, Talk Given to Joint Meeting of Pediatric Academic Societies and American Academy of Pediatrics: Pediatrics in the New Millennium: Compelling Issues in Public Policy, May 15, 2000, *available at* http://www.fda.gov/oc/speeches/2000/pediatricacademic.html (stating that "for far too long, we haven't had enough scientific data to support [using therapies off-label] in the pediatric population[,] . . . a population made up of distinct subgroups, from infants to teenagers, each with its own biological and physiological characteristics"); *see also* Regulations Requiring Manufactures To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998) (codified as amended in scattered sections of 21 C.F.R.) ("[P]roduct labeling frequently fails to provide directions for safe and effective use in pediatric patients.").

"safety and effectiveness in pediatric patients have not been established."[44] In 2001, Congress noted that "only 20 percent of prescription medications on the market have been tested and approved for use in children."[45]

B. Federal Efforts to Increase Pediatric Research

In recent years the federal government has responded to this lack of pediatric information with multiple initiatives designed to increase pediatric research.[46] In the FDA Modernization Act of 1997 (FDAMA),[47] Congress enticed pharmaceutical companies with the promise to extend the patent life on specified drugs for six months in exchange for conducting clinical trials to determine appropriate pediatric dosing and safety information.[48] Concerned that this incentive would not adequately increase pediatric research,[49] the FDA promulgated what is known as the "Pediatric Rule." It required pediatric safety and effectiveness data in applications for new drugs and biologic licenses,[50] barring exceptional circumstances,[51] and it asserted the FDA's authority to

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44. FOOD & DRUG ADMIN., THE PEDIATRIC EXCLUSIVITY PROVISION, JANUARY 2001 REPORT TO CONGRESS 2 (citing C.J. Cote et al., *Is the Therapeutic Orphan About To Be Adopted?*, 98 PEDIATRICS 118, 118, 119 tbl. (1996)).

45. S. REP. NO. 107-838, at 1 (2001).

46. For discussions of the federal government's efforts to promote pediatric therapies and drug safety prior to the most recent years, see I. Glenn Cohen, *Therapeutic Orphans, Pediatric Victims? The Best Pharmaceuticals for Children Act and Existing Pediatric Human Subject Protection*, 58 FOOD & DRUG L.J. 661, 661-63 (2003); Holly Lynch Fernandez, *Give Them What They Want? The Permissibility of Pediatric Placebo-Controlled Trials Under the Best Pharmaceuticals for Children Act*, 16 ANNALS HEALTH L. 79, 91-97 (2007).

47. Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified as 21 U.S.C. § 355a.).

48. The financial incentive of another six months of market exclusivity is significant. Schering-Plough, for instance, had an additional $975 million in sales from Claritin during this bonus period. COLEMAN ET AL., *supra* note 28, at 531 (2005) (discussing *User Fees, Pediatric Exclusivity Keys in FDAMA Reauthorization*, FOOD & DRUG LETTER, June 22, 2001). For a more detailed account of how the incentive program functioned, see Cohen, *supra* note 46, at 663-67.

49. Regulations Requiring Manufactures To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998) (codified as amended in scattered sections of 21 C.F.R.); *id.* at 66,639. In *Association of American Physicians and Surgeons v. FDA*, 226 F. Supp. 2d 204, 207 (D.D.C. 2002), the District Court for the District of Columbia struck down the rule as exceeding the FDA's statutory authority. In 2003, Congress provided the agency with the necessary authority. 21 U.S.C.A. § 355c (Supp. 2006). *See infra* notes 57-58 and accompanying text.

50. Regulations Requiring Manufactures To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. at 66,632.

51. An applicant was able to request a waiver by certifying that 1) the drug did not present a "meaningful therapeutic benefit over existing treatments" and was not likely to be given to a

require manufacturers of already-marketed drugs and biologics to conduct pediatric studies.[52]

FDAMA and the Pediatric Rule stimulated pediatric research[53] but also reflected shortcomings. Drug companies continued to lack an incentive to study 1) off-patent drugs, which was significant because "six of the ten drugs most widely prescribed to children were older antibiotics";[54] and 2) drugs commanding a small market, especially drugs intended for newborns.[55]

To address these concerns, as well as to renew FDAMA's expiring market exclusivity provision, Congress passed the Best Pharmaceuticals for Children Act of 2002 (BPCA).[56] For high-priority drugs that lacked pediatric testing and that were no longer under patent, BPCA directed the National Institutes of Health to fund the needed research. Finally, because a federal district court struck down the FDA's Pediatric Rule as exceeding the FDA's authority,[57] Congress passed the Pediatric Research Equity Act (PREA) in 2003 to grant the FDA authority to require manufacturers to conduct pediatric studies.[58]

The federal government's efforts have significantly increased the amount of pediatric research. Since 1997, the FDA has requested approximately 800 studies, resulting in pediatric labeling for 119 drugs, whereas only eleven such studies had been completed in the previous seven years.[59] The medical research director at one children's hospital estimated that "more studies [were] conducted

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substantial number of children, 2) necessary studies would be "impossible or highly impractical," or 3) strong evidence showed the drug would be "ineffective or unsafe in all pediatric groups." *Id.* at 66,634. An applicant could also obtain a partial waiver by showing that "reasonable attempts to produce a pediatric formulation" necessary for that age group had failed. *Id.* at 66,634.

52. *Id.* at 66,632.

53. A status report to Congress prepared by the FDA in January 2001 conveyed that "[a]s a result of [FDAMA's exclusivity provision], the FDA ha[d] issued over 157 Written Requests, asking for 332 studies that would potentially involve well over 20,000 pediatric patients. In less than three years [since FDAMA's passage], over 58 pediatric studies ha[d] been conducted, study reports submitted, and exclusivity granted to 25 drugs." FOOD & DRUG ADMIN., *supra* note 44, at ii.

54. COLEMAN ET AL., *supra* note 28, at 532; *see also* S. REP. NO. 107-79, at 2 (2001) (reporting FDA analysis of 1994 data finding that "6 of 10 drugs most commonly prescribed for children were off-patent"); FOOD & DRUG ADMIN., *supra* note 44, at iii

55. COLEMAN ET AL., *supra* note 28, at 532; FOOD & DRUG ADMIN., *supra* note 44, at iii.

56. Best Pharmaceuticals for Children Act of 2002, Pub. L. No. 107-109, 115 Stat. 1408 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.). Due to a concern for the welfare of children enrolled in research, as part of this Act Congress commissioned the Institute of Medicine to review the federal regulations and to make "recommendations about desirable practices in clinical research involving children." INST. OF MED., *supra* note 31, at 2.

57. Ass'n of Am., Physicians & Surgeons v. FDA, 226 F. Supp. 2d 204 (D.D.C. 2002).

58. Pub. L. No. 108-155, 117 Stat. 1936 (2003) (codified as amended at 21 U.S.C. § 355c).

59. SENATE DEMOCRATIC POLICY COMM., *supra* note 7.

in children [between 1998 and 2003] than in the previous 30 years combined."[60] As a result, many more children are participating in research.[61] The 800 FDA-requested studies would potentially enroll 45,000 children.[62]

The amount of pediatric research, and consequently the number of children involved in research, may increase beyond these numbers in the near future. President Bush recently signed into law a bill that, in addition to renewing both BPCA and PREA,[63] aims to increase pediatric research on medical devices.[64] With tens of thousands more children involved in research than when the federal regulations were passed, the time is ripe to revisit whether it is respectful of a child to enroll her in a protocol that is intended only to benefit children in the future.

C. Non-Beneficial Pediatric Research

The discussion above reviewed mostly familiar territory regarding the importance of, and efforts to increase, pediatric research generally. Much of this research exposes pediatric subjects to risks uncompensated by potential medical benefit to them individually. To produce reliable, generalizable data, researchers often perform medical procedures on pediatric subjects that carry some risk but do not benefit the participants in any way.[65]

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60. Meadows, *supra* note 38, at 13-14 (quoting Ralph Kauffman, M.D., Dir. of Med. Res. at Children's Mercy Hosp., Kansas City, Mo.). Philip Walson, then-Professor of Pharmacology and Pharmacy at The Ohio State University, made a similar statement: "I have been doing pediatric research for twenty-five years . . . [a]nd I can honestly say that there has been more research done in the past three years than in all the others combined." Stacey Schultz, *Drug Trials Are Clamoring for Kids, But Scrutinize the Study Before Signing Up*, U.S. NEWS & WORLD REP., Apr. 9, 2000, at 62. The FDA also provided a report to Congress in January 2001, as required by FDAMA, stating that the Act was "highly effective in generating pediatric studies of many drugs and in providing useful new information in product labeling." FOOD & DRUG ADMIN., *supra* note 44, at i (2001).

61. INST. OF MED., *supra* note 31, at 92.

62. SENATE DEMOCRATIC POLICY COMM., *supra* note 7.

63. Pediatric Research Equity Act of 2007, Pub. L. No. 110-85, § 402, 121 Stat. 866; Best Pharmaceuticals for Children Act of 2007, Pub. L. No. 110-85, § 502, 121 Stat. 876 (to be codified at 21 U.S.C. § 355 *et seq.*).

64. Pediatric Medical Device Safety and Improvement Act of 2007, Pub. L. No. 110-85, 121 Stat. 824. For example, this law requires the Director of the National Institutes of Health to designate an office as a contact point to help researchers "identify sources of funding available for pediatric medical device development." *Id.* § 304(a)(3). The Act also directs the Secretary of Health and Human Services, relying on the National Institutes of Health, Food and Drug Administration, and the Agency for Healthcare Research and Quality, to submit to Congress within six months of enactment a "plan for expanding pediatric medical device research development." *Id.* § 304(b)(1).

65. Many Phase I pharmacokinetic pediatric studies test drugs that will hopefully one day

As we will see below, some courts and commentators have posed the relevant ethical and legal questions at hand with respect to *non-therapeutic*, as opposed to *non-beneficial*, pediatric research. *Therapeutic* research usually refers to research intended or designed to benefit the enrolled subjects; *non-therapeutic* research aims primarily to produce generalizable knowledge.[66] This terminology has been persuasively criticized elsewhere, and I will not rehearse all the arguments.[67] Briefly, much research is intended to benefit enrolled subjects *and* produce generalizable knowledge, making the terminology difficult to apply.[68]

But more importantly, labeling some research as "therapeutic" obfuscates the important, ethically-relevant distinctions between research (including "therapeutic" research) and actual therapy.[69] Therapy aims to optimize the well-being of each patient. A medical care physician owes primary loyalty to her patient: the potential benefits *to the patient* must outweigh the risks from any

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provide treatment for a childhood cancer that has no present treatment. For many of these studies it is debatable whether they should be classified as non-beneficial or not. Many physicians see themselves as trying to treat pediatric oncology patients by recommending enrollment in such protocols. On the other hand, the odds that enrolling in a Phase I pharmockinetic study will prove beneficial to a pediatric oncology patient are so small that it is difficult to understand such research participation as beneficial, given that participation comes with great opportunity costs regarding other ways in which a child might live out the rest of his or her life. For a very helpful discussion on this topic and for other examples of non-beneficial pediatric research, I thank Benjamin Wilfond, M.D., Chief of the Division of Pediatric Bioethics in the University of Washington's Department of Pediatrics.

66. *See* ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 8-9 (2d ed. 1988).

67. *See, e.g., id.*

68. *Id.*

69. As Franklin Miller and others have argued, it is morally worrisome if all parties to research—both researchers and the subjects—do not grasp the essential difference between research and therapy. Subjects are prone to believe that procedures are administered to them for their benefit when, in reality, they are for purely research purposes. Franklin G. Miller et al., *Professional Integrity in Clinical Research*, 280 JAMA 1449, 1450 (1998) (citing Paul S. Appelbaum et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 17 HASTINGS CENTER REP. 20 (1987) (discussing the "therapeutic misconception")). For example:

> Insofar as investigators conflate the context and language of medical care with that of research, they not only reinforce the therapeutic misconception for patient volunteers, they also fall prey themselves to the seduction of the therapeutic misconception. In doing so, they can undermine informed consent and contribute to the potential for patient volunteers to be exploited for the sake of science and the benefit of future patients and present researchers.

Id. at 1451; *see also* Franklin G. Miller & Howard Brody, *A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials*, 33 HASTINGS CENTER REP. 19, 25-26 (2003) (arguing similar points); Franklin G. Miller & Donald L. Rosenstein, *The Therapeutic Orientation to Clinical Trials*, 348 NEW ENG. J. MED. 1383, 1384-85 (2003) (same).

prescribed diagnostic and therapeutic interventions.[70] However, the purpose of research is fundamentally different—to produce generalizable knowledge that will contribute to the welfare of future patients.[71] Research subjects often face risks that are outweighed by potential benefit *to future patients*, not by potential benefits to the subjects.

Research methods used to produce such generalizable knowledge, even in many "therapeutic" protocols, are inconsistent with the best interests of individual research subjects. Researchers "seek[] to learn about disease and its treatment in *groups* of patients, with the ultimate aim of improving medical care";[72] thus, in contrast to the medical setting, "dosages and timing of drugs and other interventions"[73] are determined by the protocol, not based on or amended to suit individual characteristics of subjects.[74]

Moreover, even research intended to provide a direct benefit to subjects may involve interventions—which carry risk—solely to produce generalizable knowledge without in any way benefiting the subjects.[75] For example, researchers are currently trying to find a treatment for a serious renal disease affecting children by giving some subjects a standard (though not adequately effective) therapy and other subjects an experimental therapy thought to be at least as effective as the standard one.[76] Thus, the group receiving the experimental intervention is put at no more risk than the children receiving

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70. *See* National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23,192 (Apr. 18, 1979), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm; Paul Litton & Franklin G. Miller, *A Normative Justification for Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care*, 33 J.L. MED. & ETHICS 566, 566 (2005).

71. *See supra* note 10 and accompanying text.

72. Miller & Brody, *supra* note 69, at 21.

73. Carl H. Coleman, *Shifting the Debate on Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment*, 83 IND. L.J. (forthcoming 2008) [hereinafter Coleman, *Decisionally Incapacitated*].

74. Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 VAND. L. REV. 387, 398 (2005) (citing JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 282 (2d ed. 2001)).

75. *Id.* at 399; Benjamin Freedman et al., In Loco Parentis*: Minimal Risk As an Ethical Threshold for Research upon Children*, 23 HASTINGS CENTER REP. 13 (1993); Miller & Rosenstein, *supra* note 69, at 1383.

76. *See* FSGS Clinical Trial, FAQs for Potential Patients, http://www.fsgstrial.org/faqspatients.html (last visited Apr. 1, 2008) (discussing Focal Segmental Glomerulosclerosis (FSGS)); Interview with Ted Groshong, M.D., Chairman, Dep't of Child Health, Univ. of Mo. Sch. of Med., in Columbia, Mo. (Aug. 15, 2007). I thank Dr. Groshong for taking the time to explain and discuss this and other pediatric trials with me.

standard therapy. However, all pediatric participants will be subject to a regimen of blood draws that are not clinically-indicated; these blood draws are for research purposes only, conducted to monitor changes in the chemical values within the participants' blood, as well as to monitor their compliance with the protocol. Though associated risks may be minimal,[77] they are risks of harm nonetheless[78] and do not medically benefit the subjects.

Ethically, then, there is no relevant difference between non-therapeutic protocols and non-therapeutic interventions used within the context of a protocol that might, overall, be described as therapeutic.[79] Both need ethical justification, especially with regard to children. Thus, I focus on the ethical and legal acceptability of non-beneficial, not non-therapeutic, pediatric research.

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77. *See* Seema Shah et al., *How Do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research?* 291 JAMA 476 (2004) (finding that a single blood draw was the only research procedure that a majority of IRB chairpersons deemed to be minimal risk for pediatric subjects).

78. At the least there is risk of pain, and it cannot always be eliminated. *See* Susan Jane Fetzer, *Reducing Venipuncture and Intravenous Insertion Pain with Eutectic Mixture of Local Anesthetic: A Meta-Analysis*, 51 NURSING RES. 119 (2002) (finding that popular topical anesthetic does not significantly decrease pain during venipuncture and intravenous insertion for 15% of the population); Brigitte Lemyre, *How Effective Is Tetracaine 4% Gel, Before a Venipuncture, in Reducing Procedural Pain in Infants: A Randomized Double-Blind Placebo Controlled Trial*, 7 BMC PEDIATRICS 27 (2007), *available at* http://www.biomedcentral.com/1471-2431/7/7 (noting that pain relief from venipuncture is "sub-optimal in neonates" and that the topical gel under study failed to significantly decrease pain). There are now topical anesthetics to reduce the risk of pain for older children, but some children still experience pain and anxiety due to venipuncture. Kim Cavender et al., *Parents' Positioning and Distracting Children During Venipuncture: Effects on Children's Pain, Fear, and Distress*, 22 J. HOLISTIC NURSING 32 (2004). Moreover, these anesthetics come with at least some risk of adverse effect. Janice Lander et al., *EMLA and Amethocaine for Reduction of Children's Pain Associated with Needle Insertion*, COCHRANE DATABASE OF SYSTEMATIC REVS., July 19, 2006, http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004236/pdf_fs.html.

79. It is also commonly thought that the technique of randomization in clinical trials—in which some subjects receive the experimental intervention while others receive another therapy or placebo—has the potential to compromise the welfare of patients, given that treatment decisions are based on random chance instead of any reasons related to each patient's needs or characteristics. However, a recent study concluded that "randomized treatment assignment as part of a clinical trial does not harm research participants." Cary P. Gross, *Does Random Treatment Assignment Cause Harm to Research Participants?*, 3 PLOS MED. 800, 800 (2006), http://medicine.plosjournals.org/archive/1549-1676/3/6/pdf/10.1371_journal.pmed.0030188-S.pdf.

II. LEGAL TENSION BETWEEN THE FEDERAL REGULATIONS AND EXISTING CASE LAW

A. Federal Regulations

Federal regulations govern all medical research conducted or supported by the federal government, conducted by institutions that have agreed to comply with the regulations, or conducted on any product intended to obtain FDA approval.[80] Subpart A of the regulation requires institutions to assure that their research is reviewed and approved by institutional review boards (IRBs) composed of persons with requisite knowledge to assess the ethical acceptability of proposed protocols.[81] Subpart D specifies criteria that IRBs must use to evaluate pediatric protocols, depending upon their assessment of the protocol's risk/benefit profile.[82]

According to these criteria,[83] a pediatric protocol must satisfy one of four sets of criteria regarding the potential risks and benefits of research participation before the protocol may be conducted.[84] First, under § 404, an IRB may approve "minimal risk research;" that is, § 404 authorizes IRB approval of protocols that pose "no greater than minimal risk" to the pediatric subjects, even if they do not stand to benefit from research participation.[85] The regulations define "minimal risk" as equivalent to or less than the risks "ordinarily encountered in daily life" or during routine health exams.[86] This standard is notoriously difficult to apply in

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80. 45 C.F.R. § 46.101 (2007).

81. *Id.* §§ 46.103(b), 46.107. According to the regulations' criteria for assessing research, IRB approval requires first that "[r]isks to subjects are minimized," *id.* § 46.111(a)(1); second that such risks 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.* § 46.111(a)(2); third that subjects are selected on a fair basis, *id.* § 46.111(a)(3); and finally that researchers will obtain informed consent from each research subject or legally authorized representative according to the specifications for informed consent established by the regulations, *id.* §§ 46.111(a)(4), 46.116.

82. *Id.* §§ 46.401 to 46.409.

83. The FDA has also adopted these protections, with some changes. 21 C.F.R. §§ 50.51 to 50.56, 56.102, 56.107, 56.109, 56.111 (2007).

84. In addition to the provisions described above, regarding level of risk and potential benefits, Subpart D also prescribes that IRBs must "determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent." 45 C.F.R. § 46.408(a) (2007). IRBs must also determine that adequate provisions are made for obtaining the informed consent of one or both parents, depending on the circumstances, unless there is good reason to waive that consent requirement. *Id.* § 46.408(b)-(c). In this Article I will not address issues relating to the consent or assent of children in research.

85. *Id.* § 46.404.

86. *Id.* § 46.102(i).

practice and leads to varied judgments among IRB members;[87] nonetheless, it is the regulatory standard.

Second, § 405 permits "direct benefit" research. An IRB may approve a protocol that presents greater than minimal risk if it "present[s] the prospect of direct benefit to the individual subjects."[88] The risks of an approved protocol must be "justified by the anticipated benefit" to the pediatric subjects, and "the relation of the anticipated benefit to the risk [must be] at least as favorable to the subjects as that presented by available alternative approaches."[89] Research approvable under § 405 is most analogous, ethically, to clinical care, in that the direct benefits of research participation must counterbalance the risks for IRB approval.

Third, under § 406, an IRB may approve a protocol presenting up to a "minor increase over minimal risk" if the protocol is likely to yield vitally important knowledge about the subjects' disorder or condition, even if the risks are not compensated by any potential benefit to the subjects.[90] The regulations do not define a "minor increase over minimal," but the Institute of Medicine, commissioned by Congress to review the regulations, recently recommended interpreting the phrase as "a slight increase in the potential for harms or discomfort beyond minimal risk."[91]

Finally, § 407 is a "catch-all" provision. If an IRB finds that a protocol fails to satisfy one of the first three sets of criteria but represents "an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children," the Secretary of the Department of Health and Human Services may approve the protocol after consulting with a "panel of experts in pertinent disciplines" and providing "an opportunity for public review and comment."[92] However, § 407 does not provide any criteria to guide the panel of experts or the Secretary in assessing a proposed protocol. The regulations provide only the vague requirement that "the research will be conducted in accordance with sound

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87. *See* Shah et al., *supra* note 77, at 476; *see also* INST. OF MED., *supra* note 31, at 5, 113 (noting that one of the tasks requested of authoring committee, writing for the Institute of Medicine and commissioned by Congress to review regulations regarding pediatric research, was to consider the "regulatory definition of 'minimal risk'"). For an intriguing proposal for using empirical data to help interpret "minimal risk," see David Wendler et al., *Quantifying the Federal Minimal Risk Standard: Implications for Pediatric Research Without a Prospect of Direct Benefit*, 294 JAMA 826 (2005).

88. 45 C.F.R. § 46.405 (2007).

89. *Id.* Note that IRBs do not consider financial payment as a benefit of research participation. Alex Rajczi, *Making Risk Benefit Assessments of Medical Research Protocols*, 32 J.L. MED. & ETHICS 338, 344 (2004).

90. 45 C.F.R. § 46.406 (2007).

91. INST. OF MED., *supra* note 31, at 128.

92. 45 C.F.R. § 46.407 (2007).

ethical principles."[93]

Evidently, the regulations permit non-beneficial pediatric research. Sections 404 ("minimal risk" research), 406 ("minor increase over minimal risk" research), and 407 ("catch-all" provision) clearly allow pediatric subjects in regulated research to be exposed to risks uncompensated by any benefit. Indeed, § 407 does not place any explicit ceiling on the level of risk to which a child may be exposed.

B. Existing State Case Law: Grimes

Very little state case law deals with pediatric research or even human subjects research more broadly. In 1996, an intermediate New York appellate court invalidated regulations promulgated by the state's Office of Mental Health (OMH) which sanctioned the exposure of minor and incapacitated research subjects to "more than minimal risk" without compensating benefit.[94] The court cited two grounds: 1) OMH lacked authority under state law to publish these regulations;[95] and 2) the regulations violated the constitutional due process rights and common-law right to personal autonomy of subjects and potential subjects of OMH research.[96] The court found that by permitting greater than minimal risk, the regulations struck an improper balance between the "interests of researchers and the rights of the subjects."[97] However, the New York Court of Appeals vacated that latter holding as an "inappropriate advisory opinion" once the lower court found OMH to lack the requisite authority.[98]

The Maryland Court of Appeals' 2001 *Grimes* opinion remains the sole major opinion addressing the propriety of pediatric research. The controversial research under scrutiny aimed to assess different methods of partial lead abatement in low-income housing in order to find an economically feasible means for landlords to make their units safe for rental.[99] Many landlords were choosing to abandon their units because the lead levels were not legally compliant and the cost of complete lead abatement exceeded the worth of many of the properties.[100] The ultimate purpose of the study, conducted by the Kennedy Krieger Institute (KKI), was to help increase the supply of housing for low-income Baltimore families.[101]

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93. *Id.* § 46.407(b)(2)(ii).

94. T.D. v. N.Y. State Office of Mental Health, 650 N.Y.S.2d 175, 194 (App. Div. 1996).

95. *Id.* at 182.

96. *Id.* at 177.

97. *Id.*

98. T.D. v. N.Y. State Office of Mental Health, 690 N.E.2d 1259, 1260 (N.Y. 1997).

99. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 808 (Md. 2001).

100. *Id.* at 815 n.6.

101. *Id.*

The study involved over one hundred homes, divided into five groups: three groups of homes, which had significant lead dust levels, received varying degrees of lead abatement; a fourth group received complete lead abatement; and a fifth group of homes, built more recently, never had lead paint at all.[102] Children lived in many of these homes, and landlords agreed to rent unoccupied units to families with at least one young child;[103] in exchange, at least in some cases, KKI helped landlords obtain public grants or loans to pay for the abatement procedures.[104] Investigators tested the lead levels in both the houses and the children's blood over a two-year period to determine whether any partial lead abatement method proved adequately safe.[105]

Before the research concluded, two parents, on behalf of their respective children, sued KKI for breaching duties owed to the children to protect them from foreseeable harms inherent in the research.[106] Plaintiffs argued that KKI neglected to obtain the parents' truly informed consent by failing to disclose the dangers of lead poisoning, the fact that their homes contained high levels of lead dust, the particularly hazardous areas of the homes, the purpose of the study, and other pertinent facts.[107] Plaintiffs also charged that KKI failed to fulfill its duties under the signed consent; namely, that KKI broke its promise to inform plaintiffs of any new findings during the research that could impact plaintiffs' willingness to continue participation.[108] According to plaintiffs, KKI was unreasonably slow to inform them that the lead dust levels in their homes remained high even after intervention, and that the lead levels in their children's blood were elevated.[109]

The trial court granted KKI's motion for summary judgment on the grounds that it owed no duty to the minor research subjects on which to base any civil liability.[110] The children were living in their homes with elevated dust levels, and KKI was, in the trial court's view, an "institutional volunteer" trying to improve conditions for the community.[111] Accordingly, the trial court found neither a contract nor special relationship between KKI and the children that gave rise to any duty to protect the children from harm.[112]

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102. *Id.* at 820.

103. *Id.* at 812. Researchers were interested in families with at least one child between five and forty-eight months old. *Id.* at 823.

104. *Id.* at 812, 821.

105. *Id.* at 812.

106. *Id.* at 818.

107. Brief for Appellant at 8-9, Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807 (Md. 2001) (No. 1177), 2001 WL 34552913.

108. *Id.* at 11-13.

109. *Id.* at 14-15; *Grimes*, 782 A.2d at 843.

110. *Grimes*, 782 A.2d at 832.

111. *Id.*

112. *Id.*

The court of appeals vacated the trial court's grant of summary judgment and remanded for trial.[113] It held on a number of grounds that the relationship between KKI and the minor subjects could give rise to a duty to protect them from harm. Briefly, that duty could be based on the informed consent document (representing a contract),[114] on KKI's act of recruiting the children to participate in non-therapeutic research,[115] on the federal regulations governing human subjects research,[116] and/or on the Nuremberg Code.[117]

Although the court remanded for trial, it addressed an issue that was neither essential to its reversal nor briefed by the parties:[118] namely, the more general question of whether parents should have legal authority to consent to enroll their children in "non-therapeutic research."[119] The court acknowledged that the federal regulations bound KKI because it received federal funding,[120] and that the regulations permit parents to enroll their children in some non-therapeutic research. However, the court held that it could bind researchers to more stringent standards in order to provide protections to human subjects greater than those provided by the regulations.[121]

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113. *Id.* at 858.

114. *Id.* at 843. But as Jack Schwartz points out, the court "did not elaborate on how the existence of this contract gives rise to a duty enforceable in tort, as distinct from a cause of action for breach of contract." Schwartz, *supra* note 18, at 153.

115. *Grimes*, 782 A.2d at 845-46. The court stated:

> [T]he trial courts appear to have held that special relationships out of which duties arise cannot be created by the relationship between researchers and the subjects of the research. While in some rare cases that may be correct, it is not correct when researchers recruit people, especially children whose consent is furnished indirectly . . . .

Id.

116. *Id.* at 846-49 (citing 45 C.F.R. §§ 46.101, 46.116, 46.407 (2007)).

117. *Id.* at 849. The Court also discusses and quotes the Nuremberg Code at length earlier in the opinion. *Id.* at 835-37.

118. *Id.* at 852.

119. *Id.* at 852-58. The court discussed *non-therapeutic*, as opposed to *non-beneficial*, research. For the difference between these terms, see *supra* notes 66-79 and accompanying text. That the court used "non-therapeutic" is not important, though, as it clearly had in mind pediatric research that poses risks uncompensated by benefit to the individual subjects.

120. The research was funded by the Environmental Protection Agency and Maryland's Department of Housing and Community Development. *Grimes*, 782 A.2d at 820.

121. The court noted that the regulation, 45 C.F.R. § 46.116(e) (2007), specifically states that the federal regulations' informed consent requirements "are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective." *Grimes*, 782 A.2d at 820. Subpart A of the regulations, though, contains even greater support for the court's position. It specifically states: "This policy does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects." 45 C.F.R. § 46.101(f) (2007). Subpart D does

And the court did, declaring that Maryland parents lack legal authority to enroll their children in research that would expose them to risk without potential benefit.[122] Thus, even if the informed consent was adequate and KKI had lived up to its terms, the court condemned the research insofar as it exposed children to risks for the good of others.[123] It based its decision on the best interests standard:

> We have long stressed that the "best interests of the child" is the overriding concern of this Court in matters relating to children. Whatever the interests of a parent, and whatever the interests of the general public in fostering research that might, according to a researcher's hypothesis, be for the good of all children, this Court's concern for the particular child and particular case, overarches all other interests. It is, simply, and we hope, succinctly put, not in the best interest of any healthy child to be intentionally put in a non-therapeutic situation where his or her health may be impaired, in order to test methods that may ultimately benefit all children.[124]

Concluding that participation in non-beneficial pediatric research is not in the best interests of any child, the court effectively prohibited all pediatric research exposing a pediatric subject to "any risk" uncompensated by potential benefit to him or her.[125]

The court's ruling greatly distressed the research community as it prohibited a vast amount of critically important research. The Association of American Medical Colleges, along with the Association of American Universities, Johns Hopkins University, and the University of Maryland, filed an amicus brief in support of KKI's motion for reconsideration, urging the court to rescind its

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not contain any such proviso, but it also "does not purport to preempt any state laws." Jack Schwartz, *Oversight of Human Subjects Research: The Role of the States*, *in* NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS M-1, M-6 (2001).

122. *Grimes*, 782 A.2d at 858.

123. *Id.* at 849-58.

124. *Id.* at 853. Earlier in the opinion, the court stated: "[I]n our view, parents, whether improperly enticed by trinkets, food stamps, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous non-therapeutic research surroundings, than do researchers. In such cases, parental consent, no matter how informed, is insufficient." *Id.* at 814. This pronouncement is not contrary to the law and ethics of pediatric research, which agree with the court that "parental consent, no matter how informed," can never be *sufficient* to justify enrolling a child in research. Parental consent would not be sufficient to justify exposing a child to unreasonable risks, for example. But the court later clarified its view, demonstrating its break with the federal regulations and commentators who support some non-beneficial pediatric research. The court described parental consent as never sufficient because it declared that *no conditions* could justify non-beneficial pediatric research.

125. *Id.* at 858.

prohibition of non-therapeutic pediatric research.[126] The court's standard disallows the use of placebos—given their non-therapeutic nature—in any trial carrying any risk whatsoever. Without placebo controls, amici argued that Maryland researchers would no longer be able to find cures or treatments for childhood illnesses for which there is no effective treatment, and would be unable to test new important vaccines for safety and efficacy.[127] The court's prohibition of non-therapeutic research carrying *any* risk would even rule out critically important research that exposes children only to minimal risks.[128] For example, under the ruling, "the ability to do skin biopsies . . . of disease-affected children and their non-affected siblings is necessary to determine the association of abnormal genes with disease."[129] Skin biopsies represent very minimal risk to children, but nevertheless *some* risk, and thus would be prohibited under the *Grimes* ruling.[130]

The court denied KKI's motion to reconsider,[131] but did attempt to clarify its ruling on research that carries "*any* risk" without compensating benefit, stating: "As we think is clear from . . . the Opinion, by 'any risk,' we meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor."[132] We will discuss this "clarification" below.

C. Incompatibility of Grimes *and the Regulations*

After *Grimes*, the Maryland legislature enacted a statute requiring all research conducted in the state, regardless of funding or institution, to conform to "the federal regulations on the protection of human subjects."[133] Nevertheless, *Grimes* remains law. Is *Grimes* inconsistent with the federal regulations and, if so, to what extent? Of course, this question is important to Maryland researchers, who must know what standards govern their practice. Looking beyond Maryland to possible future litigation, it is important to ask whether the best interests standard necessarily conflicts with federal regulations.

Most plainly, §§ 406 ("minor increase over minimal risk" research) and 407 (the catch-all provision) are inconsistent with *Grimes*. Section 406 allows "risk beyond the minimal kind . . . that is inherent in any endeavor," as it authorizes IRB approval of research presenting a minor increase over minimal risk.[134]

126. Amici, *supra* note 25.

127. *Id.* at 5-6.

128. *Id.*

129. *Id.* at 6.

130. *Id.*

131. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 861 (Md. 2001).

132. *Id.* at 862.

133. MD. CODE ANN., HEALTH-GEN. § 13-2002 (West 2005).

134. Some commentators disagree, maintaining that § 406 *is* consistent with *Grimes*. *See, e.g.*,

Section 407 is unmistakably inconsistent with *Grimes*, placing no ceiling at all on the level of risk to which children may be exposed. The only remaining question is whether *Grimes*, by forbidding "any articulable risk beyond the minimal kind that is inherent in any endeavor," permits non-beneficial, *minimal risk* research

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Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny: Grimes Narrows Their Interpretation*, 30 J.L. MED. & ETHICS 38, 43 (2002) [hereinafter Kopelman, *Pediatric Reseach Regulations*]; Kopelman, *Conditions*, *supra* note 18, at 755-56 (2004); John D. Lantos, Editorial, *Pediatric Research: What Is Broken and What Needs To Be Fixed?*, 144 J. PEDIATRICS 147, 148 (2004) (stating that the *Grimes* clarification "makes clear that investigators should not be held liable if they did, in fact, abide by federal regulatory standards. . . . In short, the decision strengthens, rather than undermines, the authority of the current federal regulations."). Loretta Kopelman begins by highlighting that a protocol presenting a minor increase over minimal risk is approvable only if its interventions expose subjects to experiences "reasonably commensurate" with what the subjects normally experience due to their particular disorder or condition. Kopelman, *Pediatric Research Regulations*, *supra*, at 38; Kopelman, *Conditions*, *supra* note 18, at 755-56. This commensurability requirement is related to the rationale for § 406. The National Commission, on whose recommendations the regulations are based, stated that "commensurability is intended to assure that participation in research will be closer to the ordinary experience of the subjects." NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, DEP'T OF HEALTH, EDUC. & WELFARE, PUB NO. (OS) 77-0004, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN 9 (1977).

Given the commensurability requirement, Kopelman argues that § 406 authorizes studies whose interventions present no more than minimal risk to the pediatric subjects (who have the disorder or condition under study), though the interventions *would* present a minor increase over minimal risk for healthy children (who, as such, would not be enrolled in the study). Kopelman, *Pediatric Research Regulations, supra*, at 47; Kopelman, *Conditions, supra* note 18, at 755-56. Because the everyday experiences of the ill children under study may include exposure to interventions similar to those involved in the protocol, a study itself might represent only minimal risk to these children. Thus, on Kopelman's account, § 406 could be construed to permit only research that exposes pediatric subjects to minimal risk and thus could be consistent with *Grimes* (on the assumption that *Grimes* would permit minimal risk, non-beneficial research). Kopelman, *Pediatric Research Regulations*, *supra*, at 47; Kopelman, *Conditions*, *supra* note 18, at 755-56.

Kopelman's argument lacks merit, though. The fact that *some* studies would present a minor increase over minimal risk to a healthy child, but only minimal risk to children with a particular condition, does not imply that *all* or even most studies representing a minor increase over minimal risk to healthy children would expose sick children to only minimal risk. Some interventions may expose sick children to only minimal risk given their everyday experiences, but other interventions that would expose healthy children to a minor increase over minimal risk may expose sick children to a risk *greater* than a minor increase over minimal risk, precisely because of their weakened or otherwise highly vulnerable condition. Kopelman might argue, as the title of her article suggests, that *Grimes* "narrows" what the federal regulations mean; perhaps *Grimes* implies that § 406 should be read to authorize research on sick children only when the risks are no greater than minimal. But, *Grimes* in no way interprets the regulations, and, of course, it is not within the authority of state courts to determine the ultimate meaning of the federal regulations.

approvable under § 404. Generally commentators have maintained that it does.[135]

However, neither the reasoning of the opinion nor the plain language of the court's subsequent clarification supports such a reading. *Grimes* places a risk ceiling at the level of risk inherent in *any* endeavor, suggesting, on its face, endeavors carrying the very lowest levels of risk. The level of risk inherent in all endeavors is the level of risk we cannot escape. But § 404 of the regulations does *not* restrict non-beneficial research to risks that low, but rather to the levels of risk associated with children's common, everyday activities. And as Dave Wendler points out,[136] the risks associated with children's everyday activities are greater than the risk inherent in all endeavors. The risks of riding in a car, of playing contact sports, or even of walking on a sidewalk are necessarily greater than, say, the risks of listening to a parent read a children's story.[137] Non-beneficial pediatric protocols that carry risks equivalent to those associated with riding in a car would be approvable under § 404 (as posing minimal risk), but not under the plain language of *Grimes*. The risks of riding in a car are "ordinarily encountered in daily life," and thus acceptable for research under the federal regulations, but they certainly are greater than the level of risk that is inescapable. Perhaps the court was not sufficiently careful and did not intend its

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135. *See* Coleman, *Decisionally Incapacitated*, *supra* note 73, at 23 (characterizing *Grimes* as precluding parents from enrolling children in studies "involving more than minimal risk[,]" implying the permissibility of non-beneficial, minimal risk studies); Rupali Gandhi, *Research Involving Children: Regulations, Review Boards, and Reform*, 8 J. HEALTH CARE L. & POL'Y 264, 288 (2005); Kopelman, *Pediatric Research Regulations*, *supra* note 134, at 47; Anna C. Mastroianni & Jeffrey P. Kahn, *Risk and Responsibility: Ethics,* Grimes v. Kennedy Krieger, *and Public Health Research Involving Children*, 92 AM. J. PUB. HEALTH 1073, 1073-74 (2002); David M. Smolin, *Non-therapeutic Research with Children: The Virtues and Vices of Legal Uncertainty*, 33 CUMB. L. REV. 621, 641 (2003).

136. David Wendler, *Risk Standards for Pediatric Research: Rethinking the* Grimes *Ruling*, 14 KENNEDY INST. ETHICS J. 187, 190-91 (2004). I follow Dave Wendler in arguing that *Grimes* is inconsistent with § 404.

137. Riding in a car is certainly an activity "ordinarily encountered in daily life," and carries a risk of dying at "approximately 0.06 per million trips for children aged 0 to 14 years and approximately 0.4 per million trips for children aged 15 to 19 years." Wendler et al., *supra* note 87, at 828 (conveying data adapted from U.S. DEP'T OF TRANSP., NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., TRAFFIC SAFETY FACTS: 2003 DATA (2004), *available at* http://www-nrd.nhtsa.dot.gov/pdf/nrd-30/ncsa/tsf2003/809774.pdf, and U.S. DEP'T OF TRANSP., NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., TRAFFIC SAFETY FACTS 2002 (2004), *available at* http://www-nrd.nhtsa.dot.gov/pdf/nrd-30/ncsa/tsfann/tsf2002final.pdf).

That statistic just quantifies the risk of dying. The risk of visiting an emergency room from car riding is about 3 per million trips for children younger than one; 8 per million trips for children between 1 and 4 years old; 13 per million trips for children 5 to 9; 18 per million trips for minors between 10 and 14; and 32 per million trips for those between 15 and 19. *Id.* We can confidently say that the risks of reading or being read to, or even of taking a family stroll, are not as great.

decision to have such implications, but the decision by its plain language has them nonetheless.

Furthermore, even if the court's plain language were ambiguous, its reasoning speaks against an interpretation consistent with § 404. As mentioned, the court stated that the best interests of the child are its overriding concern, and it took that standard to imply that no child should be used in research "where his or her health *may be impaired*" or "which *might possibly be*, or which proves to be, hazardous to [the child's] health," in a protocol aimed to "benefit all children."[138] The court's reasoning implies that no child should be exposed to any intervention that is not clinically indicated and poses some risk beyond what is inescapable.

It is worth noting *how* the court applied the best interests standard. Its analysis was based solely on the potential risks and benefits to a child of participating in a particular non-therapeutic protocol.[139] The court did not deem relevant any risks or benefits to a child that result from the ongoing practice of non-beneficial (or non-therapeutic) research. In that sense, it construed the relevant facts quite narrowly in applying the best interests standard. The court thereby assumed that non-beneficial protocols could be justified only by their benefits to the greater good, on a utilitarian basis which it ruled inconsistent with the law. The remainder of this Article explains that, while the court was right to reject a utilitarian justification, it erred in concluding that no other valid justification could be offered.

III. PEDIATRIC RESEARCH AND THE PARENT-CHILD RELATIONSHIP

In *Grimes*, neither party briefed, and the plaintiffs did not even raise, the issue of whether parents should have legal authority to enroll their children in non-therapeutic research.[140] There was no dispute to settle. Implicitly, and in quite an unusual way, the Maryland Court of Appeals invoked the state's *parens patriae* authority to limit the scope of parental authority. Under the Fourteenth Amendment, parents have the substantive due process right to direct the upbringing of their children and make decisions for them. However, Maryland and other states have received the English common law,[141] which grants the state *parens patriae* authority to protect children in appropriate cases.[142]

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138. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 853 (Md. 2001) (emphasis added).

139. Coleman, *Decisionally Incapacitated*, *supra* note 73, at 48 (explaining two levels at which to assess best interests, in context of discussing research on incompetent adults).

140. *Grimes*, 782 A.2d at 852.

141. *See, e.g.*, MD. CODE. ANN., CONST., art. 5 (West 2007) (receiving the common law unless in conflict with constitutional or statutory law).

142. *In re* Adoption/Guardianship of Victor A., 872 A.2d 662, 669 (Md. 2005) ("[The] fundamental interest [in raising a child] . . . is not absolute and does not exclude other important

The Maryland court's implicit invocation of the state's *parens patriae* authority was unusual because it was not stepping into a specific parent-child relationship to protect the interests of a child, as courts do when, for example, they are asked to approve a blood transfusion over a parent's objection. Rather, the court announced an absolute rule limiting the scope of parental authority in Maryland.

This Section highlights some legal support for the court's implicit invocation of the state's *parens patriae* powers in stripping parents of the power to enroll their children in non-beneficial research. I discuss two possible rationales for parents' presumptive legal authority to make decisions for their children, and argue that they are inapplicable to non-beneficial research; thus, the court's intrusion into the parent-child relationship, limiting the power of parents, is unproblematic on these grounds. Some commentators disagree, however; their views entail that the court failed to properly respect parental authority and, specifically, the interests that parents have in teaching their children altruism through research participation. I argue that the court was right not to grant weight to such views.

A. Parental Rights Protecting Parental Interests

First, one might argue that parental rights are based on the interests of *parents*, in light of the importance that parents attach to raising their children. This argument finds considerable support in judicial opinions. For example, in the well-known line of constitutional cases including *Meyer*,[143] *Pierce*,[144] *Yoder*,[145] and more recently *Troxel*,[146] the U.S. Supreme Court has affirmed that

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considerations. Pursuant to the doctrine of *parens patriae,* the State of Maryland has an interest in caring for those, such as minors, who cannot care for themselves."); *see also* Koshko v. Haining, 921 A.2d 171, 191 (Md. 2007) (citing the state's compelling interest as *parens patriae* "to ensure the well-being of Maryland's children"). An Illinois appellate court explained:

> The [court], through the doctrine of *parens patriae*, has an inherent plenary power, independent of any authority given to it by the legislature, to act solely in the best interests of the child and for his own protection. It is not a justiciable matter because the authority does not derive from statute. The court's power to interfere with and control the persons and custody of all minors within its jurisdiction existed in the common law, prior to and independent of the Juvenile Court Act, by inheritance from the English courts of chancery.

In re O.H., 768 N.E.2d 799, 804 (Ill. App. 3d 2002) (citations omitted). For a discussion of the history of the *parens patriae* doctrine, see John Seymour, *Parens Patriae and Wardship Powers: Their Nature and Origins*, 14 OXFORD J. LEGAL STUD. 159 (1994).

143. Meyer v. Nebraska, 262 U.S. 390 (1923).

144. Pierce v. Soc'y of Sisters, 268 U.S. 510 (1925).

145. Wisconsin v. Yoder, 406 U.S. 205 (1972).

146. Troxel v. Granville, 530 U.S. 57 (2000).

parents have a fundamental liberty interest, protected by the Fourteenth Amendment, "in the care, custody, and control of their children."[147]

One prominent pediatric ethics commentator, Lainie Friedman Ross, attempts to provide a non-consequentialist defense of non-beneficial pediatric research in part by arguing that parents have a right to make decisions for their children, where that right is protective of the parents' own interests. Her view is rooted in the idea that under a liberal political constitution, a primary function of government is to protect the freedom of competent adults to live according to their own conception of the good life; and a person's conception of the good life may include "the freedom to form and raise a family" according to that conception.[148] Thus, according to Ross, parental rights are fundamental to parents, protective of their interests. Parent rights are not, in her view, derivative of children's interests or justified as a means to protecting the interests of children.

Despite the support from case law and some commentators, the very idea that parents have rights over their children to protect *parents'* interests, and not to promote *children's* interests, should have no role in showing how a child's participation in non-beneficial pediatric research is consistent with treating her as an end-in-herself. The notion that parental rights are justified as protective of parents' interests (and not derivative from children's interests) quintessentially depicts children as a means and not as ends-in-themselves. It is the view that children are like property, the object of others' rights. As Professor James Dwyer argues, parental rights are necessary only to allow a parent to treat his children in ways that he wants but are in serious conflict with the children's interests.[149]

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147. *Id.* at 65. I am not suggesting that there is a plausible constitutional argument against the *Grimes* ruling; only that the idea that parents have rights that are protective of their own interests has support in the Court's language.

148. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 3. At one point she does seem to suggest that parental rights are grounded at least in part by the welfare interests of children: "Parents [should be] given wide latitude in balancing the risks and benefits among family members because of the importance to a family's well-being to the parents' and the child(ren)'s well-being." *Id.* at 95. But nevertheless, even in making that suggestion, she makes clear that on her view, parental rights are justified, in part, as protective of interests inherent to the parent.

149. *See* James G. Dwyer, *Parents' Religion and Children's Welfare: Debunking the Doctrine of Parents' Rights*, 82 CAL. L. REV. 1371, 1439-40 (1994). Dwyer continues, explaining why a denial of parental rights does not imply unacceptably low barriers for justified state intervention into the family:

> Given the costs of state intervention to the child, the child's negative claim-rights would preclude state intervention where parents' actions are in the child's interests, have no clear effect on the child's interests, or negative affect the child's interests to a lesser extent than would the intervention. Given this assumption, parental rights would be necessary only to raise the threshold of harm to children that must be reached before the State may intervene.

Though court decisions, especially those interpreting the Free Exercise Clause,[150] endorse the idea that parents have rights to control their children, that fact implies neither that those decisions are morally justified nor that they are consistent with "a proper understanding of the limited purpose of rights in our legal system."[151] Invoking parental autonomy to show how exposing a child to non-beneficial research is respectful of that child's moral status is, indeed, a strange way to argue that enrolling the child does not treat her merely as a means.

B. Parental Rights as Protection for Children's Interests

Thus, we conceive of parental rights more plausibly as derivative and protective of children's interests.[152] That is, we should ascribe rights of control and custody to parents if that ascription is generally in the best interests of children. Children require the care, direction, and protection of adults, and "[c]onventional wisdom . . . holds that parents are in the best position to know what is best for their children and are likely to care more than any other adult about their children's well-being."[153]

1. Case Law: Parents Act in Their Children's Interests

This justification for ascribing parental rights also finds support in judicial

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Id. at 1440 n.284. Ross reaches a somewhat similar conclusion in arguing that the state should not hold parents to the best interests standard in determining when state intervention is appropriate, but rather should interfere with the family only when children are being deprived of their basic needs. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 24, 90-93. The bases for their respective conclusions differ, as explained above.

150. These decisions are discussed in Dwyer, *supra* note 149, at 1379-1405.

151. *Id.*

152. In addition, in ascribing rights or interests to parents in controlling the lives of their children, courts, including the U.S. Supreme Court, have appealed to tradition, or historical practices. For example, to support the proposition that parents have a substantive due process liberty interest, the Supreme Court recently cited with approval its prior claim in *Yoder*: "The history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. This primary role of parents in the upbringing of their children is now established beyond debate as an enduring American tradition." Troxel v. Granville, 530 U.S. 57, 66 (2000) (citing Wisconsin v. Yoder, 406 U.S. 205, 232 (1972)); *see also* Moore v. City of E. Cleveland, 431 U.S. 494, 503 (1977) ("Our decisions establish that the Constitution protects the sanctity of the family *precisely because* the institution of the family is deeply rooted in this Nation's history and tradition.") (emphasis added). However, as James Dwyer rightly argues, the fact that a practice or rule has long been observed and part of tradition cannot serve, by itself, as a justification for the ascription of a right. Dwyer, *supra* note 149, at 1424. A longstanding tradition can be, of course, unjust. *Id.*

153. Dwyer, *supra* note 149, at 1427.

language, including the Supreme Court's. In describing its past recognition of "the family as a unit with broad parental authority over minor children," the Court in *Parham* elaborated:

> The law's concept of the family rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions. More important, historically it has recognized that natural bonds of affection lead parents to act in the best interests of their children.[154]

Accordingly, the Supreme Court and other courts presume that:

> [F]it parents act in the best interests of their children. . . . [S]o long as a parent adequately cares for his or her children (i.e., is fit), there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children.[155]

The Maryland Court of Appeals follows this line of reasoning, recently stating that in the context of parental disputes between a parent and a third party, the best interests standard does not govern the matter unless the parent is deemed unfit.[156]

In the medical research context, a parent's decision to expose a child to, say, a venipuncture or other minimal risk procedure for the good of others would not provide reason to deem that parent unfit to care for her child. Thus, there would seem to be no reason for a state agent, such as a court, to intervene in the parent-child relationship by limiting parental authority regarding pediatric research. Nevertheless, one sympathetic to *Grimes* could respond persuasively that the "presumption that parents act in their children's best interests, while applicable to most child-rearing decisions, is not applicable in the [non-beneficial research] context."[157] The risks presented by a non-beneficial protocol are, by definition, not in the best interests of the children enrolled. Therefore we do not even need to ask whether a parent who enrolls a child in non-beneficial pediatric research is unfit; the decision to enroll is not within parental authority from the outset because the presumption that parents act in their children's best interests is

154. Troxel, 530 U.S. at 68 (quoting Parham v. J.R., 442 U.S. 584, 602 (1979)).

155. *Id.* at 68-69.

156. *In re* Roberto d.B., 923 A.2d 115, 128-29 (Md. 2007) (discussing McDermott v. Dougherty, 869 A.2d 751 (Md. 2005)).

157. *Parham*, 442 U.S. at 632 (Brennan, J., concurring in part and dissenting in part). The context of this quote was not a discussion of medical research, but of parental decisions to commit their children to mental hospitals.

inapplicable.

The argument in support of *Grimes* is not that any parental decision contrary to a child's best interests is outside the scope of parental authority; we do not require parents to sacrifice all their own interests to promote constantly the best interests of a child every hour of the day. Moreover, it is impossible to promote the best interests of each child in every situation when there are siblings who have competing interests. Parents must have authority to make many decisions (that do not constitute neglect or abuse) that are not in a child's best interests. However, we generally take this *policy* of permitting a wide scope of parental decision-making to be in the best interests of children. It is in the best interests of children to have parents who are able to pursue their own interests: to have content parents and to see their adult role models pursuing worthwhile activities. But the interests of children served by this general policy are irrelevant to a parental decision to enroll a child in non-beneficial research. Parents do not have a strong interest in exposing their children to non-beneficial risk, and a policy prohibiting non-beneficial pediatric research appears to be a negligible intrusion into the parent-child relationship.

2. Moral Education and Research Participation

Some commentators,[158]—most notably, Ross—disagree, and would argue that the *Grimes* court failed to appreciate both the interests of parents in inculcating their children with their values and the interests of children in learning altruism through research participation. In Ross' view, the presumption that parents act in their children's best interest should be applicable in the research context because even if non-beneficial research is not in a child's best *medical* interests, research participation can be in the child's best *overall* interests by morally educating a child.[159] Because it "is likely that [a] child will come to share in some, if not most, of [her parent's] values,"[160] like altruism, Ross argues

158. *See, e.g.*, HENRY K. BEECHER, RESEARCH AND THE INDIVIDUAL: HUMAN STUDIES 63 (1970); William G. Bartholome, *Parents, Children, and the Moral Benefits of Research*, 6 HASTINGS CENTER REP. 44 (1976).

159. With regard to the law, Ross might draw on a famous passage from *Pierce* for support: "The child is not the mere creature of the State; those who nurture him and direct his destiny have the right, coupled with the high duty, to recognize and *prepare him for additional obligations*." Pierce v. Soc'y of Sisters, 268 U.S. 510, 535 (1925) (emphasis added). The context of the statement, in that case, might imply religious obligations, but it is reasonable to suppose that it also includes moral obligations more generally. *See, e.g.*, Michael H. v. Gerald D., 491 U.S. 110, 118-19 (1989) (citing California family law statute using similar language, stating that legal status of parenthood implies duty "to prepare the child for additional obligations, which includes the teaching of moral standards").

160. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 92.

that enrolling a child in non-beneficial research (at least with a minimal risk ceiling)[161] can be consistent with treating the child as an end-in-herself and not merely a means.[162] Even if the child does not adopt altruistic goals, Ross argues that parents respect children by teaching them the value of altruism.[163]

The problem with Ross' argument, though, is that it is completely inapposite to research on children who are too young to learn any lesson of altruism.[164] An infant's or toddler's future moral character will not be affected by being told that she is helping others by taking a needle.[165]

But even with regard to children who are somewhat older, Ross does not provide support for the conclusion that participating in medical research is an effective way to engrain altruistic dispositions. Generally, research participation is a passive activity and not something that a child will regularly engage in. We might question the judgment of a parent who regularly enrolls her child in research in order to teach altruism. But regardless, we are not concerned with justifying the regular enrollment of a child in non-beneficial pediatric research. We need to know whether any justification exists for enrolling a child even once in a non-beneficial protocol, and it seems doubtful that a one-time enrollment, perhaps in a protocol that involves one venipuncture or allergy skin testing, will have any importance for a child's long-term moral development. Furthermore, one should wonder whether any anxiety and fear that children experience when enduring physical discomfort or brief pain in a medical setting are conducive to learning moral lessons. Perhaps the anxiety and fear do not interfere with moral education; but if moral education is the justification for research, then we need some reason to believe participation effectively teaches altruism.

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161. Ross asserts that children incapable of assenting should not be enrolled in any non-beneficial pediatric research that carries more than minimal risk, but that children who can assent may be enrolled if the risk is no "more than a minor increase over minimal." *Id.* at 98.

162. *Id.* at 90-93.

163. *Id.*

164. *Cf.* Jennifer K. Robbennolt et al., *Advancing the Rights of Children and Adolescents To Be Altruistic: Bone Marrow Donation by Minors*, 9 J.L. & HEALTH 213, 225 (1994-1995) (arguing that the mature minor doctrine is insufficient as a justification for most organ donation procedures involving young family members).

165. Perhaps if there is any benefit to the child from giving blood for research purposes it is that the experience may be helpful the next time she has to give blood or see a doctor or dentist in the future. *See* Y-L Lau & C-Y Yeung, *Parental Perception of the Effect of Venepuncture in Preschool Children in Non-Therapeutic Research*, 28 J. PAEDIATRICS & CHILD HEALTH 294 (78% of parents felt experience would benefit their child for future blood draws; 40% felt their child would be more confident for their next doctor or dentist visit).

3. Interests of Children in New Experiences

Benjamin Freedman and colleagues also defend non-beneficial pediatric research by appealing to the interests of parents and children in allowing parents to expose their children to a low level of risk.[166] They begin by arguing that the purpose of the IRB in protecting pediatric subjects is to "backup" parental decisions "by filtering out those studies that would impose an unacceptable level of risk."[167] That is, on the authors' view, the IRB is supposed to permit only those studies that an "informed and scrupulous parent[]" could consent to.[168] As research would normally present a "new" experience for a child, a scrupulous parent would ask, "Is [my] child ready for this? . . . Are the risks sufficiently similar to those in my child's everyday life that I should allow this experience at this time?"[169] In answering those questions, parental decisions about new risks are anchored to the risks of everyday life, and the regulations reflect that fact.[170] Thus, the authors contend that the "risks of everyday life" standard has normative force, "reflecting a level of risk that is not simply accepted but is deemed socially acceptable."[171]

The problem with this view, though, is that it ignores one crucial fact about the risks that parents generally allow their children to face: Parents usually understand those risks as outweighed by the potential benefits to their children.[172] Playing organized sports presents risks to children, but parents allow and frequently encourage or even cajole their children to play, not because the risks of injury are "deemed socially acceptable" in the abstract, but because the parents think the risks are outweighed by the benefits of participation to the child's physical and emotional development. Even attending school carries risks of harm (e.g., children can be cruel to one another, traveling to school may carry risks); but we still send our children because it serves their best overall interests. The risks of these activities are justified by the benefits to the individuals incurring the risk. However, with non-beneficial pediatric research, we must ask what justifies exposure to the risk of research interventions when they offer *no* benefit to the individual child.

Freedman and colleagues suggest another role for the minimal risk standard in a justification for non-beneficial pediatric research, but it, too, suffers from the

166. Freedman et al., *supra* note 75, at 16-17.

167. *Id.* at 16.

168. *Id.*

169. *Id.*

170. *Id.* at 17.

171. *Id.*

172. For a thorough discussion of why we accept or ignore some risks and not others (and our irrationality with regard to the judgments implicit in our actions and beliefs), see Wendler, Significance, *supra* note 11, at 45-47, 80-81.

same shortcoming. They write: "[t]he risks of research are to a degree substitutive, rather than additive: research risks are undergone, but the risks of alternative activities are forgone."[173] The problem is that the risks of forgone activities are most likely accompanied by benefits to the child, unlike non-beneficial pediatric research.

The authors helpfully stress that defining "minimal risk" without any reference to the ethical rationale behind it "is incapable of capturing anything significant by the term."[174] But what they miss is that the ethical rationale behind any definition must be based on the ethical justification for exposing children to research risks. The purpose of exposing children to the risks of everyday life is very different from the purpose of exposing them to the risks of non-beneficial research, and thus, the minimal risk standard cannot justify non-beneficial pediatric research.

IV. "BEST INTERESTS" AS ONE FACTOR AMONG OTHERS

Our discussion thus far supports *Grimes'* implicit invocation of the state's *parens patriae* power and its limitation of parental authority based on the best interests standard. The court's decision, however, is arguably vulnerable to the charge that it unwisely treated the best interests standard as an absolute bar to weighing other important considerations. This section first discusses legal support for treating the best interests standard as one factor among many. However, I then defend the court's decision to determine the parental consent issue in light of the best interests standard. The court's error was in how it *applied* the best interests standard to the issue at hand.

One tactic to take against *Grimes* is to argue that the best interests standard should not be dispositive in the research context. In many legal contexts the best interest of the relevant child is one consideration to be weighed among many.[175] One can then argue that with respect to research, the overall welfare of children must be considered along with the best interests of individual children who could be enrolled in research. This particular legal avenue is not optimal for reasons presented below, but it is still preferable to the *Grimes* ruling and is supportable by legal precedent.

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173. Freedman et al., *supra* note 75, at 17.

174. *Id.* at 15. The authors point out that some procedures, like a splenectomy, are described in some contexts as "minimal risk" because of their necessity in the circumstances in which they are performed. Thus, what is to count as "minimal risk" is context-dependent. *Id.*

175. For an excellent and comprehensive assessment of the extent to which children possess legal rights with regard to their personal relationships, noting when state decision-makers do and do not appeal to a child's best interests, see James G. Dwyer, *A Taxonomy of Children's Existing Rights in State Decision Making About Their Relationships*, 11 WM. & MARY BILL RTS. J. 845 (2002-2003) [hereinafter Dwyer, *A Taxonomy*].

Recall that the *Grimes* court justified its reliance on the best interests standard by stating that it has "long stressed that the 'best interests of the child' is [its] overriding concern . . . in matters relating to children."[176] As illustrated below, that statement is far-fetched, even as a description of the court's own jurisprudence. No court, including the Maryland high court, settles *all* matters relating to children by a best interests analysis.[177] The Maryland Court of Appeals, in fact, recently acknowledged that context matters in determining whether the best interests standard is applicable: Though "the controlling factor in adoption and custody cases is . . . what serves the interest of the child, . . . it is clear that the context in which [an] issue arises is significant in determining the standard by which to evaluate the situation."[178]

Making the same point, the Supreme Court characterized the role of the best interests consideration within legal precedent:

> "The best interests of the child," a venerable phrase familiar from divorce proceedings, is a proper and feasible criterion for making the decision as to which of two parents will be accorded custody. But it is not traditionally the sole criterion . . . for other, less narrowly channeled judgments involving children, where their interests conflict in varying degrees with the interests of others.[179]

In fact, the reason that the best interests standard is generally dispositive in custody disputes is because other legally relevant interests neutralize each other.[180] When two legal parents compete for custody of a child, each comes to court with a fundamental, constitutionally protected liberty interest "in the care, custody, and control of their child[]."[181] With their interests in equipoise, the child's is supposed to prevail. But in custody disputes between a legal parent and a third party, the best interests standard does not govern because of parental rights. Even where a third party (e.g., a grandparent) has raised a child for considerable time while a parent was "off pursuing other interests or wallowing in addiction,"[182] most jurisdictions grant the parent a legal right to resume

176. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 853 (Md. 2001).

177. As an obvious example, see earlier portions of the *Grimes* opinion itself. The court had to decide whether any evidence supported the claim that KKI owed a duty to the plaintiffs, and the court did not decide *that particular* children-relating matter according to a best interest analysis. Other considerations were relevant, such as whether the consent form created a contract between KKI and the parents. *Grimes*, 782 A.2d at 843.

178. *In re* Roberto d.B, 923 A.2d 115, 126 (Md. 2007).

179. Reno v. Flores, 507 U.S. 292, 303-04 (1993).

180. McDermott v. Dougherty, 869 A.2d 751, 770 (Md. 2005).

181. Troxel v. Granville, 530 U.S. 57, 65 (2000).

182. Dwyer, *A Taxonomy*, *supra* note 175, at 942.

custody "absent proof of willful abandonment or present unfitness."[183] Under law, an adult's interest in raising his or her child may trump the child's best interests.[184]

But sometimes the best interests of a child must compete with other societal interests even in the context of a custody dispute between two fit legal parents. Consider the Supreme Court's decision in *Palmore v. Sidotti*.[185] In that case, a Caucasian father petitioned in state court to modify a prior judgment granting custody of his son to the child's mother, also a Caucasian, on grounds that the mother had begun cohabitating with an African-American man, whom she later married. The Florida state court awarded custody to the father, stating that the child, upon reaching school age, will be "more vulnerable to peer pressures [and] suffer from . . . social stigmatization" because of her mother's interracial relationship.[186] The U.S. Supreme Court reversed, holding that state courts may not consider that the child may eventually suffer from existing racial prejudice: the law cannot control such prejudice, but it must not give it effect.[187] Regardless of whether the Florida court accurately assessed the child's best interests, the point should be clear: although the fact that a child will eventually suffer from such racist bias is relevant to assessing her best interests, that consideration shall not control because of other important societal interests.

The Maryland Court of Appeals, which decided *Grimes*, handed down a similar opinion in *Griffin v. Crane* in 1998.[188] In that case, the trial court modified a prior judgment of custody for a father, awarding custody of two girls to their mother on grounds that the older girl had "reach[ed] an age where [she] at the very least exemplifies a need for a female hand."[189] The state's highest court reversed, holding that the Maryland Equal Rights Amendment to its state

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183. *Id.*

184. *Id.* at 943. The Maryland Court of Appeals has stated:

> [T]he non-constitutional best interests of the child standard, absent extraordinary (i.e., exceptional) circumstances, does not override a parent's fundamental constitutional right to raise his or her child when the case is between a fit parent . . . and a third party who does not possess such constitutionally-protected parental rights. . . . In the balancing of court-created or statutorily-created 'standards,' such as 'the best interest of the child' test, with fundamental constitutional rights, in private custody actions involving private third parties where the parents are fit, absent extraordinary . . . circumstances, the constitutional right is the ultimate determinative factor; and only if the parents are unfit or extraordinary circumstances exist is the 'best interest of the child' test to be considered, any contrary comment in . . . our cases notwithstanding.

In re Roberto d.B, 923 A.2d 115, 130 (Md. 2007) (quoting *McDermott*, 869 A.2d at 808-09).

185. 466 U.S. 429 (1984).

186. *Id.* at 431.

187. *Id.*

188. 716 A.2d 1029 (Md. 1998).

189. *Id.* at 1033.

constitution forbids consideration of a parent's sex in determining parental rights.[190] Like the U.S. Supreme Court, this Maryland decision maintains that even if in reality the sex of a parent were relevant to discerning the best interests of a child in a custody dispute, a distinct societal interest, protected by law, prohibits consideration of that fact.

More recently, the Maryland high court had to decide whether a gestational mother, who was not genetically related to the fetuses she carried, had to be listed as the mother of the children when born on the birth certificate, even where the gestational mother had no intention of raising the twins. To the dismay of the dissent,[191] the majority held that the best interests of the children were irrelevant.[192] The court deemed dispositive that a state statute grants a man the opportunity to avoid legal parentage by demonstrating a lack of genetic link to a child, and, under the state's Equal Rights Amendment, concluded that a woman must have that same opportunity.

Maryland courts recognize and give weight to other interests—including interests not protected by the state constitution—that compete with the best interests of individual children in other contexts. For example, in cases in which parents disagree about a child's surname, "best interests" govern only sometimes, according to Maryland courts. In cases in which a child has "no initial surname"—in which the parents disagree at birth and continue to do so—courts should apply a "pure best interests" analysis.[193] However, if a father delays in seeking a paternity determination or objecting to the name given by the mother, the best interests standard does *not* govern. Rather, the father must demonstrate "extreme circumstances" that justify the name change because, in this "matter of . . . equity, . . . the doctrine of laches applies."[194]

In other matters faced by courts, the interests of some child or children conflict with the interests of other children. For example, the Supreme Judicial Court of Massachusetts had to decide whether posthumously conceived children—conceived by a woman whose husband's sperm had been frozen before he died—should enjoy inheritance rights under its state intestacy statute.[195] That statute provided that posthumous children could inherit from a deceased parent, but it did not define "posthumous children."[196] The court stated that it should interpret the statute in light of "three powerful State interests: the best interests of

190. *Id.* at 1037.

191. *In re* Roberto d.B, 923 A.2d 115, 142 (Md. 2007) (Harrell, J., dissenting).

192. *Id.* at 130.

193. *Id.* at 127.

194. *Id.* (quoting, with approval, Schroeder v. Broadfoot, 790 A.2d 773, 784-85 (Md. Ct. Spec. App. 2002)).

195. Woodward v. Comm'r of Soc. Sec., 760 N.E.2d 257 (Mass. 2002).

196. *Id.* at 264.

children, the State's interest in the orderly administration of estates, and the reproductive rights of the genetic parent."[197] Notably, the court recognized that in considering the best interests of children, it could not focus solely on the best interests of posthumously conceived children: Granting "succession rights . . . to posthumously conceived children may, in a given case, have the potential to pit child against child" because that could "reduce the intestate share available to children born prior to the decedent's death."[198] Thus, in addition to the interests of genetic parents and other state interests, the court recognized that the best interests of some children had to be weighed against the interests of other children.

Arguably, a similar line of reasoning is applicable to research: A court or other agent of the state, in addition to focusing on the best interests of those children enrolled or to be enrolled in research, must also weigh the best interests of all children, generally. And a prohibition on all non-beneficial research is not in the best interests of children.

Given that the *Grimes* court's intervention into the family-child relationship was based on its *parens patriae* powers, it only makes sense that the court (or any other agent of the state) should consider the best interests of all children. The state, as *parens patriae* to all children, has a duty to "guard the general interest in youth's well-being,"[199] and thus must consider the implications of any policy or court holding on all children. As any parent of multiple children knows, it is not always possible to do what is in the best interests of one child in a particular situation without impacting the other children. It might be in the best interests of one child to be driven one hour away to play in some sporting event, though that might require exposing a sibling to the risks of highway driving without any compensating benefits awaiting at the end of the drive.

Nonetheless, case law exists supporting the court's heavy emphasis on the best interests standard in a context in which children are intentionally exposed to medical risks. Organ and bone marrow donation from a child or other incompetent person presents a similar ethical and legal issue: whether it is justified to perform an invasive medical procedure on a child or other person who cannot give binding consent where that procedure's sole medical purpose is to benefit a different person.[200] Generally, when courts have been asked to authorize

197. *Id.* at 264-65.

198. *Id.* at 266.

199. Prince v. Massachusetts, 321 U.S. 158, 166 (1944).

200. The *Grimes* court also discussed organ donation in a section denying the legal authority of parents to enroll their children in non-therapeutic research. However, the court discussed these cases to the extent that they support the view that judicial permission should be sought before non-therapeutic procedures are performed upon a child. The court was strongly dissatisfied with the IRB review of KKI's protocol and emphatically stated that Maryland courts "will not defer to

such procedures upon a guardian's request, they have not treated the best interests of the donor child as merely one factor among many.[201] They do not weigh the donor's interests against the interests of the recipient and of the parents who petitioned for court approval. Courts basically ask whether undergoing the procedure, with its attendant risks, is in the best interests of the donor child. Because donating confers no *medical* benefit to donors, courts look principally to the relationship between donor and donee, assessing the benefit to the donor of a

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science to be the sole determinant of the ethicality or legality of such experiments." Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 855 (Md. 2001).

201. *See, e.g.*, Curran v. Bosze, 566 N.E.2d 1319, 1331 (Ill. 1990) (holding that a parent "may give consent on behalf of a minor [child] for the child to donate bone marrow to a sibling, only when to do so would be in the minor's best interest"); Little v. Little, 576 S.W.2d 493, 500 (Tex. Civ. App. 1979) (upholding the trial court's decision to authorize the donation of a kidney by a fourteen-year-old sibling with mental retardation to her brother because of "strong evidence . . . that she will receive substantial psychological benefits" from the donation); *see also In re* Doe, 481 N.Y.S.2d 932 (N.Y. App. Div. 1984) (stating that a court's power to authorize a surgical intervention for an incompetent person to help a third party is confined by its *parens patriae* power, permitting authorization only where it is in the incompetent person's best interests); Robbennolt et al., *supra* note 164, at 214 (reporting that most courts deciding whether to authorize bone marrow donation from minor child have relied on "best interests" standard); Lisa K. Gregory, Annotation, *Propriety of Surgically Invading Incompetent or Minor for Benefit of Third Party*, 4 A.L.R.5th 1000 (2006) ("When considering whether an incompetent should undergo a surgical invasion for the benefit of a sibling, the cases [discussed herein] indicate an attempt by the courts to determine from an objective point of view what . . . will confer the incompetent the greatest net benefit, that is, what will be in the 'best interests' of the incompetent.").

In a widely cited Connecticut case, *Hart v. Brown*, the court declared that the parents of seven-year-old twins had the right to consent for one twin to donate a kidney to her sibling, holding that "natural parents . . . should have the right to . . . consent to an isograft kidney transplantation procedure when their motivation and reasoning are favorably reviewed by a community representation which includes a court of equity." 289 A.2d 386, 391 (Conn. Super. Ct. 1972). When will a court favorably review parents' reasoning? Here the court emphasized that the risks to the donor were very low and that the expected success of the surgery would be "of immense benefit to the donor" given that it would relieve stress on her family and prevent her from losing her sister. *Id.* at 389.

Some courts have appealed to the doctrine of substituted judgment—asking what the incompetent would choose to do if competent—instead of the best interests standard. However, putting aside whether it is appropriate to appeal to substituted judgment with persons who have never been competent, these courts basically engage in the substituted judgment analysis by examining what would be in the best interests of the incompetent. *See, e.g.*, Strunk v. Strunk, 445 S.W.2d 145 (Ky. Ct. App. 1969) (authorizing a kidney donation from an incompetent person to his brother based on the importance of the donee to the donor's well-being); *see also Little*, 576 S.W.2d at 498 ("It is clear in transplant cases that courts, whether they use the term 'substituted judgment' or not, will consider the benefits to the donor as a basis for permitting an incompetent to donate an organ.").

continued relationship with the donee, as well as to any psychological benefit derived from helping to save the donee's life.[202]

Furthermore, ethically, concluding that the health benefits to all children should be weighed against the health risks imposed on some children does not explain how intentionally risking pediatric subjects avoids treating them merely as a means to an end. Weighing different interests and values along with the interests of individual children does not, in itself, imply consequentialist moral reasoning. However, if we take the consequences to children's health as the only relevant metric for assessing non-beneficial pediatric research, then we are essentially engaged in consequentialist reasoning without explaining how non-beneficial protocols respect the worth of their subjects. Indeed, if our only concern is health outcomes for all children, then, in principle, we cannot rule out the possibility that good consequences could justify exposing some small subset of children to significant risk for the good of others. Dave Wendler raises the example of testing vaccines: Perhaps that best way to maximize health benefits for all children would be to give, say, an experimental HIV vaccine to a small set of children and then test it by deliberately exposing them to HIV.[203] But that, of course, would be unacceptable.

One might respond by arguing that, in reality, a policy permitting such high risk would not actually maximize good consequences, perhaps because of the outrage many would experience or a lack of trust the public would have in the ethics of research. But even if that response has the empirical facts correct, and even if a policy seeking to maximize health benefits to children should place an extremely low ceiling of acceptable risk on non-beneficial pediatric research, a consequentialist approach is inadequate. A consequentialist justification for any practice of human subjects research is unpersuasive because it cannot capture what would be wrong with a system that does unjustifiably expose some people to risks. If a researcher knowingly exposes a child to very serious risk without compensating benefit to her, we take the researcher's action to be wrong precisely because it *wronged the child.* The child's inherent value was disregarded. But on consequentialist diagnoses of what, if anything, would be wrong with such action, no sense can be made of the idea that the child was wronged. The action would be wrong on consequentialist grounds if a different course of action would have maximized overall welfare (act-consequentialism) or if the act contravened a rule which, if followed, would maximize overall welfare (rule-consequentialism). Neither consequentialist diagnosis makes reference to the value of the individual child or to the idea of wronging the child.

Thomas Nagel helpfully explicates this aspect of consequentialist moral reasoning. Consequentialist justifications are directed toward the "world at

202. Gregory, *supra* note 201, at 1000.

203. Wendler, Significance, *supra* note 11, at 97.

large,"[204] meaning that the "object of justification . . . is everyone taken together"[205] and not any particular individual. The interests of individuals matter to the consequentialist, but only as components of the overall state of the world, and are to be summed together to discern what act or policy is morally justified. Our researcher's action might be unjustifiable to the child, but that moral fact would be an afterthought: It would be unjustifiable to the child—and to anyone else—primarily because it would not be justifiable to the world at large by failing to maximize overall welfare.[206] Consequentialist moral reasoning cannot account for our firm commitment that some actions are wrong because the value of an individual has not been properly respected.

V. NON-CONSEQUENTIALISM, THE BEST INTERESTS STANDARD, AND PEDIATRIC RESEARCH

Nagel contrasts consequentialism with a non-consequentialist form of justification that is directed towards an individual person *as a distinct individual.*[207] The essential idea in a non-consequentialist account is that an action or policy that affects a person in some way must be justifiable to her in light of reasons related to the "importance *for [that] individual*"[208] of being related to in the way proposed by the considered act or policy. The justification for any act or policy must be assessed by comparing the reasons of *each individual, taken separately* (and not aggregated), for endorsing or rejecting that act or policy. This notion that acts (or omissions) or government policies must be justified to each individual *as an individual* conveys our common sense idea that we must treat and relate to each person in a way that expresses a respectful attitude toward *her* and not just to the overall state of the world. That our conduct

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204. Thomas Nagel, *War and Massacre*, 1 PHIL. & PUB. AFF. 123, 137 (1972), *reprinted in* THOMAS NAGEL, MORTAL QUESTIONS 53, 68 (1979).

205. John Oberdiek, The Morality of Risking: On the Normative Foundations of Risk Regulation (2003) (unpublished Ph.D. dissertation, University of Pennsylvania) (manuscript at 93, on file with Van Pelt Library, University of Pennsylvania).

206. Oberdiek helpfully clarifies the distinction:

> Under justification to the world at large, behavior is justified to persons *via* the world at large, or only after first being justified to the world at large; under justification to [an individual person], behavior is justified to the world at large *via* persons, or only after being justified to every individual taken separately.

Id. at 95.

207. Nagel, *supra* note 204, at 135.

208. Rahul Kumar, *Defending the Moral Moderate: Contractualism and Common Sense*, 28 PHIL. & PUB. AFF. 275, 281 (1999) [hereinafter Kumar, *Defending*]; *see also* T.M. SCANLON, WHAT WE OWE TO EACH OTHER 229 (1998) (stating that "the justifiability of a moral principle depends only on various *individuals'* reasons for objecting to that principle and alternatives to it").

and policies must be justifiable to each individual, taken separately, characterizes a specific form of relationship among persons: that of mutual recognition of each individual's status as a person.[209]

To see the difference between consequentialist accounts and this non-consequentialist account of moral reasoning, consider a policy that seriously burdens some individuals, without their consent, to bring about slight benefit to many, such that the policy maximizes overall welfare.[210] A consequentialist would maintain that the burdened individuals have reason to endorse the policy because it maximizes welfare. But on the non-consequentialist account described, the slight benefits accrued to the many are not aggregated and offered to the burdened individuals as justification. Rather, the reasons that each individual has, *taken separately,* to endorse or reject the proposed policy are compared with one another, on a one-on-one basis. That is, what matters morally on this non-consequentialist view is whether any individuals "have personal reasons to reject this [policy] which are stronger than anyone's reasons to reject some alternative."[211]

We have discussed so far a non-consequentialist moral framework that expresses a commitment to the intrinsic worth of each individual person, requiring actions and policies to be justifiable to each person, not as a mere component in the general welfare of the world, but as an individual. In this sense

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209. SCANLON, *supra* note 208, at 162; *see also* Kumar, *Defending*, *supra* note 208, at 284 ("[T]he aim [of moral reasoning] is to find principles that can serve as the basis for a shared understanding of the kind of consideration, in a person's practical deliberations, that persons may legitimately expect of one another, as a matter of mutual respect for one another as persons.").

210. *See* Derek Parfit, *Justification to Each Person*, 16 RATIO 368, 372 (2003).

211. *Id.* T.M. Scanlon provides a compelling example that illustrates the intuitive appeal of this account of moral reasoning. SCANLON, *supra* note 208, at 235. Imagine that Jones works in the transmitter room of a television station that is broadcasting a World Cup match being watched by millions of soccer fans. Electrical equipment falls on Jones' arm, crushing it and continually sending painful electric shocks through him, though his life is not endangered. Rescuing Jones from the pain would require shutting down the equipment—stopping the broadcast—for fifteen minutes, causing a great deal of displeasure to millions. Scanlon asks whether we should save him now or wait an hour until the game is over, and whether our answer depends on how many people's lives would be made slightly worse off should the broadcast be interrupted. Intuitively, it seems that Jones' co-workers should save him regardless of how many people's lives would be made slightly worse off by stopping the broadcast. Even if the displeasure aggregated across the entire world would be greater than the pain Jones was suffering, it seems clear that there is more reason to save Jones than to avoid interrupting the broadcast. That conclusion makes sense in light of a commitment to justification to each individual based on a comparison of the reasons that each affected person, taken individually, has to support or reject a principle requiring Jones to be saved. As Scanlon remarks, no individual in the class of persons watching the game could offer reasons regarding his own life that are as strong as the reasons Jones could provide to argue in favor of rescuing him. *Id.*

it is Kantian, though it does not follow the details of Kant's own theory. But it represents a way to understand Kant's Formula of Humanity, to treat each person as an end-in-herself and never merely as a means to an end.[212] Demonstrating to an individual that she is treated in a manner justifiable to her on grounds she has reason to accept "is like reminding [her] that she was consulted before hand on what the appropriate course of action [or policy] would be."[213] She is treated as an end-in-herself, and not merely as a means, because she has reason to perceive the way in which she is treated by others or a government's policy as not merely something that has happened to her, but as what she has authorized herself.[214]

Some commentators have assumed that non-consequentialist moral principles require the *actual* consent of research subjects in order for such research to be ethically justifiable. Critics have tended to assume that unconsented experimentation (including experimentation on young children) necessarily fails to treat research subjects as ends-in-themselves. Unsurprisingly, then, *Grimes* assumes that the central justification for non-beneficial pediatric research must be utilitarian. I will argue that this assumption is incorrect and that there is both a non-consequentialist ethical justification and a corresponding legal argument, invoking the best interests standard, for non-beneficial pediatric research. Before turning to those arguments, let us examine other non-consequentialist analyses of this research, not already discussed above, and see why they are unpersuasive.

A. Ramsey's Objection to Non-Beneficial Pediatric Research

Let us begin with Paul Ramsey's well-known, passionate objection to enrolling children in non-beneficial research.[215] Ramsey writes unequivocally that neither children nor incompetents should ever be exposed to research risks for the good of others.[216] Non-beneficial pediatric research, in Ramsey's words, is a form of "barbarism."[217]

Ramsey's argument rests on the claim that ethically permissible research

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212. IMMANUEL KANT, GROUNDING FOR THE METAPHYSICS OF MORALS 35-37 (James W. Ellington trans., Hackett Pub'g Co. 1993) (1785).

213. RAHUL KUMAR, CONSENSUALISM IN PRINCIPLE: ON THE FOUNDATIONS OF NON-CONSEQUENTIALIST MORAL REASONING 14 (2001) [hereinafter KUMAR, CONSENSUALISM].

214. *Id.*

215. PAUL RAMSEY, THE PATIENT AS PERSON: EXPLORATIONS IN MEDICAL ETHICS (1970) [hereinafter RAMSEY, PATIENT AS PERSON]; Paul Ramsey, *Children as Research Subjects: A Reply*, HASTINGS CENTER REP., Apr. 1977, at 40; Paul Ramsey, *The Enforcement of Morals: Non-therapeutic Research on Children*, HASTINGS CENTER REP., Aug. 1976, at 21 [hereinafter Ramsey, *Enforcement*].

216. RAMSEY, PATIENT AS PERSON, *supra* note 215, at 11.

217. *Id.* at 12.

requires the "reasonably free and adequately informed consent" of the human subject.[218] Ethical research has other requirements (e.g., protocols must be of "good experimental design"), but such requirements, according to Ramsey, also apply to research on animals. Humans are distinct in having the capacity to be "joint venturers" in the quest to better their own individual and collective health, and respecting each potential subject entails asking for her consent to join in that quest. Given that children cannot consent, it follows logically, according to Ramsey, that they must never be enrolled in non-beneficial pediatric research.[219]

However, that conclusion does not follow. That informed consent is an ethical requirement for enrolling capacitated adults does not imply that it is a pre-requisite for enrolling children in research. Duties to rational adults differ from duties owed to children because, in part, the former have the capacity to make decisions for themselves. Researchers must respect rational adults' capacity to be or not to be "joint venturers." Whether it is ethical to perform research on those who cannot be joint venturers is a separate question.

We need look no further than Ramsey's own text for an obvious illustration. After stating that informed consent is a requirement for enrolling an adult in research, he states: "This holds without exception for ordinary medical practice."[220] Doctors commit a battery where they provide therapy to a capacitated adult without consent. That fact does not imply that doctors may not treat a young child. Indeed, hedging his absolute pronouncement, Ramsey acknowledges at least one exception to the rule that medical therapy requires informed consent: the case in which "consent may properly be assumed or implied when [someone is] in extreme danger and cannot [herself] consent explicitly,"[221] such as an unconscious accident victim in an emergency room. In stating that we may assume an unconscious victim's consent, Ramsey is basically stating that the victim has very good reason to authorize the doctor's treatment though the victim cannot actually consent. Those reasons are the basis for concluding that the victim *would* consent.

Furthermore, despite explicitly recognizing only one instance in which consent may be inferred, Ramsey implicitly acknowledges others. First, he rightly notes that informed consent cannot require that a prospective patient or subject be told of *every* possible consequence or risk associated with a proposed procedure. The consent process would be overwhelming in numerous ways.[222]

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218. *Id.* at 2, 3.

219. *Id.* at 11.

220. *Id.* at 7.

221. *Id.* at 7.

222. *Id.* at 3. As the Court of Appeals for the District of Columbia stated in the leading case on informed consent, to require *full*, as opposed to reasonable, disclosure of every risk, "no matter how small or remote" is "obviously prohibitive and unrealistic to expect." Canterbury v. Spence, 464

Many jurisdictions take a patient to have provided informed consent, despite not knowing the remote unknown risks, if the physician disclosed what a *reasonable* person in the patient's situation would consider relevant.[223] A physician must consider what information a patient or subject has good reason to know and not to know. Adequate informed consent is consent to the entire procedure or intervention: The consent is *explicit* with regard to what the patient knows and it is *implicit* with regard to what the patient has good reason *not* to know.[224]

Second, Ramsey highlights that "consent is a continuing and repeatable requirement."[225] But that fact, of course, does not imply that a physician must constantly ask a research subject for consent to continued participation. Some events do require a researcher to present newly learned information to a subject where that information would be material to a decision whether to continue. But generally, the researcher does not have a duty to ask constantly for the ongoing consent. Consent is implied: that is, there are good reasons from the perspective of each research subject not to require such a rule. It would provide no extra protection for research subjects and it would be ridiculously burdensome, not to mention annoying.

Thus, we can ask whether children have good reason to authorize a policy permitting non-beneficial pediatric research and/or being enrolled in a minimal risk protocol. Like unconscious patients, young children cannot give actual consent, but, as with unconscious patients, we can ask whether they have good reason to endorse the practice of non-beneficial research and their participation in it. Answering the fundamental ethical question may involve an inquiry into the reasons that have importance from the perspective of each child that speak in favor of non-beneficial pediatric research.

B. Brock's Rawlsian Argument

Dan Brock takes this promising approach to defending non-beneficial pediatric research, asking whether young children would, hypothetically, consent to participate in research.[226] The ethical justification I offer is indebted and similar to Brock's, but differs in detail because Brock's argument, as formulated,

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F.2d 772, 786 (D.C. Cir. 1972).

223. *Canterbury*, 464 F.2d at 787. Most states do not follow *Canterbury*, instead requiring physicians to provide the information that a reasonable *physician* would provide under the circumstances. However, a "majority of the population and doctors now reside in jurisdictions that have rejected [the physician-centered] standard of disclosure." PATRICIA A. KING ET AL., LAW, MEDICINE, AND ETHICS 149 (2006).

224. As Ramsey states, the informed consent document contains both explicit and "implied" permissions. RAMSEY, PATIENT AS PERSON, *supra* note 215, at 6.

225. *Id.*

226. Brock, *supra* note 18.

is problematic.

Brock aims to establish that it is morally permissible to enroll children in non-beneficial research because children have a moral obligation to participate in research.[227] The basis of the alleged obligation is the benefit conferred upon children by medical progress due to *past* human subjects research. The underlying moral principle is one of fairness:

> If one has freely participated in and accepted the benefits of a practice in which others have freely assumed burdens required by the practice for the benefit of others besides themselves, then one has a duty of fairness to do one's part by assuming similar burdens when one's turn comes in the practice to do so.[228]

As children do not "freely participate[] in and accept[] the benefits" of medical care and research,[229] it does not follow from this principle that children have a duty of fairness to assume some burdens of medical research. To accommodate that fact, Brock suggests that it is reasonable to assume each child *would* consent to participate in and accept the benefits of research, given that it would be in each child's rational self-interest to do so.[230] Thus, on Brock's reformulation, each child has a duty of fairness to children of different generations to contribute to research given that each hypothetically consents to the benefits of the practice.

But Brock first recognizes another obstacle to the argument: if one knows when in time that she exists—i.e., she knows that she already benefits from past research on children and will continue to do so—then she has no self-interested reason to agree to take on any burdens of research.[231] To address this problem, Brock suggests that we think of each child as giving hypothetical consent to the practice of non-beneficial pediatric research behind a Rawlsian veil of ignorance that blinds each party to knowledge of the generation to which she belongs.[232] If one does not know whether one belongs to a past, present, of future generation, but does assume that "the expected benefits of such research over time exceed[] its burdens," each party behind the veil would agree to accept the benefits and burdens of the practice.[233]

Before assessing whether Brock's argument represents a promising strategy,

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227. *Id.* at 91-92.

228. *Id.* at 92.

229. As Brock mentions, adults, like children, have never had the choice to live in social conditions which include the benefits of past medical research. We cannot ask our physicians to treat us without appeal to any knowledge that is based on past human subjects research. *Id.*

230. *Id.*

231. *Id.*

232. *Id.*

233. *Id.*

note that it would have to be supplemented if it is to be distinguished from a consequentialist view. Brock states that parties behind the veil would consent to a research policy if, over time, the benefits of the practice outweigh the burdens, presumably in relation to other alternative policies. But that is, in essence, how policies would be evaluated from a consequentialist perspective. As it stands, then, the argument does not offer an alternative to a consequentialist justification. What the argument needs is a non-consequentialist explanation as to why the parties would not consent to a policy that would allow some small set of children—say, wards of the state—to be exposed to serious risk when that exposure would bring about great overall benefit in comparison to the burdens placed on those few.

Instead of attempting to differentiate Brock's approach from a consequentialist analysis, I suggest rejecting the appeal to an underlying moral principle based on fair reciprocity *applied across generations*. As Brock recognizes, a principle of fair reciprocity is inapposite to the relations between generations, and the inappropriateness of applying it in this context cannot be solved by blinding parties to knowledge of their generation. The fair reciprocity principle is relevant to determining a morally acceptable division of advantages and burdens of a practice. In Brock's view, a present-day prohibition on non-beneficial pediatric research would not simply fail in furthering the interests of children in the future, but also would *wrong* past subjects by violating a duty of fairness owed to them. But research subjects of past generations cannot reap any of the advantages produced after their time; they could never have expected to reap benefits from the continuation of medical research into the future. I do not deny that we have good reason to honor and be grateful to past research subjects for their sacrifices; I deny that we must expose children to research risks now in order to be *fair* to past research subjects.

Similarly, Brock's argument implies that a prohibition on non-beneficial pediatric research would be unfair to future children. Let's put aside concerns related to Parfit's non-identity problem[234] and stipulate that it is possible to wrong future persons by choosing one policy rather than another, including by failing to enhance medical knowledge for their benefit. It still seems implausible

234. DEREK PARFIT, REASONS AND PERSONS 351-79 (1984). The non-identity problem poses a challenge for thinking about duties to future persons. If a person can be harmed only by an action or policy that makes that person's life worse off than it otherwise would have been, then it follows that a person is not harmed by an act or policy that was a but-for cause of that particular person's coming into existence. If we adopt policy *A* now (say, with regard to conserving resources or conducting medical research) instead of policy *B*, even if policy *A* were disastrous and policy *B* would produce far better outcomes, future persons would not be harmed by our adoption of policy *A* if they, themselves, would not have existed had we adopted policy *B*. For an argument that we can *wrong* future persons even where we have not harmed them (based on the "non-identity" consideration), see Rahul Kumar, *Who Can Be Wronged?*, 31 PHIL. & PUB. AFF. 99 (2003).

that we would wrong future children *by acting unfairly* toward them because future children do not bestow a benefit on today's children. An explanation for any wronging would have to be different.

The problem with the view, so far, is that it takes fairness to be connected to the idea of reciprocity across generations. However, to defend the appeal to Rawls, one might argue for *different kinds* of fairness. One kind of fairness is based on an idea of reciprocal relations among participants in a practice; but, perhaps, there is a different sense of fairness that is applicable across generations. Indeed, Rawls himself seems to endorse this possibility in his discussion of duties to future generations in *A Theory of Justice*. He begins by stipulating that the parties in the original position do not know the generation to which they belong: they do not know their "stage of civilization."[235] But because they are contemporaries (a fact that they do know), they lack reason to endorse any policy of saving capital for future generations. As Rawls states, "[e]arlier generations will have either saved or not; there is nothing the parties can do to affect that."[236] Thus, "to achieve a reasonable result," Rawls states that we should understand the parties in the original position to care about their immediate descendants and that they would wish their predecessors to have followed any principle they adopt.[237] The parties proceed to ask how much wealth they are willing to save at each stage of civilization, presuming that each prior generation saved according to the same standard and keeping in mind the objective to maintain a material base adequate to realize just institutions in which basic liberties are protected.[238]

Rawls argues that the just savings principle is based on the idea of each generation doing its fair share to preserve a just society, each generation saves for the next in return for what it received from the past.[239] Brock's argument might be construed as analogous. No reciprocal relationship exists among the generations, but nevertheless each generation has a duty of fairness to maintain some good—like a just society or the health of its citizens—through time.

The argument is flawed, though. As Rawls states, because the parties in the original position know they are contemporaries, "unless we modify our initial assumptions, there is no reason for them to agree to any saving whatever."[240] Thus, Rawls modifies the assumptions built into the original position "to achieve a reasonable result": The parties now are to choose a principle of just savings based on what they wish past generations had saved despite the possibility that past generations might have saved nothing or insufficiently. But assumptions

235. JOHN RAWLS, A THEORY OF JUSTICE 254 (rev. ed. 1999).

236. *Id.* at 255.

237. *Id.*

238. *Id.* at 255-56.

239. *Id.* at 256-57.

240. *Id.* at 254-55.

cannot be built into the original position for the sake of achieving a result deemed reasonable before determining the outcome of the procedure. The original position is supposed to define a decision procedure that yields an outcome we have good reason to believe reflects moral principles because the assumptions that shape the original position reflect our firm moral commitments. The assumptions that shape the original position cannot be totally unmotivated (or motivated only to reach a result predetermined to be the reasonable one), or else we should not see any outcome as a moral requirement.

To clarify, recall that for the purpose of discerning the principles of justice for the basic structure of society, Rawls argues that the parties in the original position should be blinded to facts about themselves—such as their race, social class, or natural assets—that "seem arbitrary from the moral point of view."[241] These moral constraints on the parties reflect our firm moral conviction that some "information is not morally relevant in arguments for principles of justice"[242] precisely because it is morally arbitrary. Because the conditions under which principles of justice are chosen reflect our commitments regarding fairness, we have good reason to conclude that the outcome of the agreement is also fair.[243] The fairness of the bargaining position "transfers" to the principles chosen.[244]

The question, then, with regard to the argument for the just savings principle (and any analogous argument to justify non-beneficial pediatric research) is this: In applying the original position decision procedure at the legislative stage, what independent moral basis supports stipulating that the parties should decide on a just savings principle (or policy on pediatric research) in light of their wishes about their predecessors' policies, regardless of the actual policies adopted by their predecessors? For any agreement to reflect a moral requirement of fairness, the constraints on the parties must reflect widely-shared and non-controversial convictions about what information is morally irrelevant to the decision procedure. The built-in assumption that the parties should consider the principle they wish their predecessors followed does not reflect widely shared, firm moral convictions. Without anchoring that built-in assumption in our shared moral convictions, we might nevertheless conclude that the parties in the original position would agree to a just savings principle or a policy authorizing non-beneficial pediatric research, but we would have no reason to view that outcome as morally binding, conveying a requirement of intergenerational fairness.[245]

241. *Id.* at 14.

242. SAMUEL FREEMAN, RAWLS 143 (2007).

243. FREEMAN, *supra* note 242, at 142; RAWLS, *supra* note 235, at 11.

244. FREEMAN, *supra* note 242, at 142.

245. I owe this point to very helpful discussions with Rahul Kumar.

C. A Non-Consequentialist Proposal

We begin by asking whether each child has reason to endorse a *policy* permitting non-beneficial pediatric research. We must assess and compare the benefits and burdens to individual children of living under the alternative policies we might adopt. Let's consider three options: a complete prohibition on non-beneficial research; a policy permitting non-beneficial pediatric research but with an extremely low ceiling on acceptable risk; and a policy allowing non-beneficial pediatric research with a higher risk ceiling. In this general discussion, I leave open whether the extremely low risk ceiling for the second option equates with minimal risk or allows a "minor increase over minimal" risk, as the federal regulations permit.[246]

The second option appears preferable to the first. This claim rests on the empirical assumption that the practice of non-beneficial pediatric research does, in fact, provide more net benefit to each child than that child would receive in a regime that bans non-beneficial pediatric research. This assumption is supportable.

First, most obviously, medical knowledge leads to new, safer, more effective treatments. Each child benefits from medical advancement by either receiving a treatment that otherwise would not have been available, or "from the availability of the treatment and the assurance that should the child need it, it would be available."[247] If "newer[,] more effective[] medication . . . has not been subjected to rigorous study in pediatric populations," pediatricians "sometimes prescribe . . . less effective, but well-tested medication."[248] The need to withhold possibly superior treatments due to a lack of research "keeps children from benefiting from state-of-the-art medication."[249]

Second, a prohibition on a child facing non-beneficial yet minimal (or minor increase over minimal) risk will only increase the risks the child will face in the medical care setting. Experimentation on children would not decrease; it would be transferred to the clinical setting where effects may not be as closely

246. Furthermore, how the appropriately low ceiling on acceptable risk should be precisely defined is a complicated topic unto itself. I am not defending or criticizing the definition of "minimal risk" in the federal regulations, and I do realize that I am not offering any alternative definition for the acceptably low ceiling on risk. One hope of this article is that a persuasive justification for non-beneficial pediatric research can help shed light on how we should define that level of risk, although I am unsure that it will.

247. Brock, *supra* note 18, at 91.

248. Ass'n of Am., Physicians & Surgeons, Inc. v. FDA, 226 F. Supp. 2d 204, 207 (D.D.C. 2002) (discussing Regulations Requiring Manufactures To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998) (codified as amended in scattered sections of 21 C.F.R.)).

249. *Id.*

monitored and where medical knowledge gained will not be generalizable. According to the American Academy of Pediatrics, "the shortage of pediatric research creates an ethical dilemma for physicians, who 'must frequently either not treat children with potentially beneficial medications or treat them with medications based on adult studies or anecdotal empirical experience in children.'"[250] Inadequate pediatric labeling not only deprives children of optimal treatment, but also "exposes [them] to the risk of unexpected adverse reactions" in the clinical setting.[251]

Third, the extremely low ceiling on risk to which we may permissibly expose children in research also contributes to the empirical assumption that permitting non-beneficial pediatric research is in the best interests of each child. The slight risks appear outweighed by the risks that would be transferred to medical care if non-beneficial pediatric research were prohibited altogether.

Inevitably, some children will be severely harmed in minimal risk research. But even these children could not reasonably object to a policy permitting non-beneficial pediatric research in favor of the *Grimes* prohibition. Were non-beneficial pediatric research prohibited, the risks they would have faced in the medical care setting would have been even worse than the risks they faced under a policy permitting minimal risk research.

Next, the third option, which would allow a high ceiling on risk, is unacceptable. Any policy that every child has good reason to endorse must place a very low ceiling on permissible risk exposure. First, we generally do not impose the moral duty on adults to help strangers when helping will come at a significant cost or risk. There is reason to be even more cautious with the risks we impose on children, and the risks that we allow their parents to impose, given their vulnerability and their inability to consent. Second, it is impossible to quantify the benefits that each child actually accrues from the practice of medical research. Given that impossibility, extreme caution warrants setting a very low limit on risk to ensure that the benefits of the practice do outweigh the risks for each child. Third, given that most children will not participate in the system and not take on any burdens, it is unfair if a few children take on very serious risks, bearing a very heavy burden for the practice. Fourth, allowing more risk will make it practically impossible to enroll any child in research whose parent comprehends that her child may be exposed to more than minimal (or more than a minor increase over minimal) risk, such that the system will not benefit each child. More importantly, we would have to suspect that children placed in such risky research were enrolled only because their parents did not comprehend the

250. INST. OF MED., *supra* note 31, at 60.

251. Regulations Requiring Manufacturers To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 62 Fed. Reg. 43,899, 43,900-01 (Aug. 15, 1997) (codified in scattered section of 21 C.F.R.).

risks involved.[252]

One might suppose that a system that allows at least *some* trials that are more risky—or even very risky—could produce even more benefits for children generally. Let's return to Wendler's example of testing an HIV vaccine by giving it to a small number of children and then deliberately exposing those children to the virus.[253] Perhaps, from the perspective of each child the risk of contracting HIV would be higher during his life than the risk of being one of the few randomly chosen subjects, and therefore there would be reason to endorse a policy allowing such a study.

That conclusion is false, though. Any child potentially chosen to be a guinea pig for the vaccine has very good reason to reject such a policy, which would obviously treat any such child arbitrarily. Reasons exist to reject a proposed policy besides those related to the policy's prospects for improving one's well-being.[254] The fact that a policy will intentionally inflict harm on some people on an arbitrary basis provides reason to reject such a policy.[255] We would condemn on similar grounds any secret government policy of holding public executions of persons who are, unbeknownst to the public, actually innocent, even if those executions reduced each individual's risk of being a crime victim by deterring potential criminals.

Two interrelated questions remain: 1) Even if each child has reason to endorse a policy permitting non-beneficial pediatric research, do we nonetheless treat any child as merely a means by placing the child at (low) risk in a specific protocol? 2) Does a government policy permitting such research invite parents to violate their parental duties by asking them to treat their children contrary to their best interests?

Whether parents have a general duty to advance their child's best interests is irrelevant. Even if they do, that duty does not entail the obligation to advance their children's interests by making sure their children are free riders on a practice from which they benefit. A parent may have good reason to decline enrolling her child in a minimal risk, non-beneficial study; perhaps her child is particularly vulnerable physically or especially anxious or fearful (these are some of the reasons why we require parental consent for research).[256] But to accept the

252. I am obviously assuming that any acceptable policy allowing pediatric research would require, as the federal regulations do, the consent of a child's guardian prior to research participation. 45 C.F.R. § 46.408 (2007).

253. Wendler, Significance, *supra* note 11, at 97.

254. SCANLON, *supra* note 208, at 206-13.

255. *Id.*

256. If minimal risk research does benefit all children, one might argue that a policy requiring parents to enroll their children at least once in research could be justified, at least under certain circumstances. However, if researchers generally are able to recruit a sufficient number of pediatric

benefits of a practice for one's child while taking the child to have no reason to participate in research expresses a disrespectful attitude toward other children who sustain the research. It is to say that one's child is special in a way that others are not, that it is acceptable to view others as merely a means to one's own ends.

One might object that accepting the benefits of the practice does not imply that one necessarily expresses a disrespectful attitude toward participants. A parent may think it is wrong for *any* child to be enrolled in research, but may nevertheless let her child accept the benefits of the practice reluctantly. After all, what is a parent to do when her child is ill? Refuse medical attention? But this response is not compelling. Once we understand that pediatric research, including non-beneficial pediatric research, benefits each child, including each pediatric subject, on what basis could a parent maintain her condemnation of the practice? As we have seen, the problem with *Grimes* is that the court failed to consider how its prohibition, if strictly obeyed, would make each child worse off. Upon acknowledgement that the *policy* is justifiable to each child, it becomes disrespectful to refuse to allow one's child to participate in the practice without any overriding considerations (e.g., one's child is particularly vulnerable). The fundamental ethical question raises concern that enrolling a child in non-beneficial pediatric research treats her solely as a means; but as it turns out, it is a principled refusal to let one's child participate in the practice that treats *other* children as merely a means to one's ends.

We now see that the *Grimes* court correctly appealed to the best interests standard to determine whether parents should have legal authority to enroll their children in research, but it misapplied the standard to the facts. What is needed is a lens to view the facts more broadly than that usually employed in a best interests analysis. *Grimes* narrowly looked to the risks and potential benefits presented to each subject by a non-beneficial protocol and, given that there is risk but no benefit, found that research participation could never be in a child's best interests. But though the court acknowledged the potential detrimental effect of its holding on the interests of children generally—aggregated across all children—it failed to consider that its rule could make *each* child worse off, *including any child who is or might be enrolled in research.* The underlying idea of this argument is that a *policy* allowing at least some non-beneficial pediatric research *is* in the best interests of each and every child, even though the policy itself puts some children at risk of being enrolled, at some point, in non-beneficial research.[257]

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subjects to conduct important research, then it seems best to allow parents to decide whether or not to enroll their children, knowing whether their children are, for example, particularly anxious or fearful in medical settings.

257. The legal argument in this Section and the related ethical argument presented in Section

D. Implications

One practical implication of the preceding argument is that the informed consent process, involving children's guardians, should be amended. Because informed consent requires researchers to inform potential subjects of all information material to the guardian's decision, parents should be informed of the basic justification for exposing their child to research risk. For any non-beneficial protocol or one involving non-beneficial interventions, parents should be informed that the research interventions are not, themselves, in the best interests of the child. But it is also appropriate to inform parents that all children who have access to medical care do benefit from research and the contributions made by research subjects.[258]

One might object that it would unduly induce parents to consent if we tell them that their child benefits from other research and that they should consider that fact: it might make them feel guilty if they do not consent. But why would this be *undue* inducement? If it is *true* that parents should be willing to enroll their children in minimal risk research, it is not unduly coercive to tell parents that their child benefits from the research participation of others.

Indeed, a strength of the view is that it suggests a plausible amendment to current informed consent practices. Consider the other proposed justifications for non-beneficial pediatric research. Should parents be informed that a non-beneficial protocol is actually justified by the best interest of their three-year-old child because the parents could use research participation to teach altruism to the child? Or might we suggest to parents that enrolling their children is a good idea because their children would otherwise be doing something else carrying at least minimal risk? Or that the parent's child owes a duty to children long gone who contributed to research? None of these suggestions is plausible. But it seems appropriate to inform parents of the importance of medical research to each child.

My account also makes good sense of our significant moral concern over whether underprivileged children—particularly children underserved by the healthcare system—are overrepresented in research.[259] The data is equivocal regarding whether the medically underserved are overrepresented in research,[260] but the matter morally requires attention. If the justification for enrolling a child in a non-beneficial protocol is tied to the benefits the child accrues from the practice, then we ought to ensure that pediatric subjects do benefit from the

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V.B, are in accordance with the approach to risk assessment that Carl H. Coleman has recently advocated with regard to incapacitated adults. Coleman, *Decisionally Incapacitated*, *supra* note 73.

258. *See id.* at 53 (making a similar suggestion with regard to decisions made for incapacitated adults).

259. *Cf. id.* at 48 (arguing that the justification for a policy permitting research enrollment of incapacitated adults requires that such adults have access to state-of-the-art health care).

260. ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 80.

healthcare system.[261] One might observe that even the underserved benefit from the advancement of medical knowledge, but even so, it would be unfair if those who derive the least benefit from the practice are those most burdened by it.[262]

Another strength of the view is that it explains why the ceiling on acceptable research risk can vary depending on the state of medicine at a specific time or during an exceptionally dangerous epidemic. As I argued, the fact that children would face increased risks in the clinical setting without non-beneficial pediatric research plays a role in justifying non-beneficial pediatric research. Therefore, the degree of risk in the medical care setting carries implications for the amount of acceptable research risk. The National Commission offered similar reasoning:

> In exceptional situations, dangers to children or the community resulting from a failure to involve children in research might exceed whatever risk is presented by that research. For instance, the threat of an epidemic that could be offset by developing a safe and effective vaccine might justify research involving greater than otherwise acceptable to establish safety, efficacy, and dosage levels for children of different ages.[263]

If children generally face very severe risks in the medical care setting, this circumstance speaks in favor of allowing somewhat more risk in the research setting if exposing children to somewhat increased research risks will help significantly reduce the risks they face from medical care.

This implication of the view represents an advantage over other proposed justifications. For example, if non-beneficial pediatric research is justified because of its alleged *non-medical* benefits for enrolled children (such as benefits associated with moral education), then an increase in allowable research risk is justifiable only to the extent that those non-medical benefits would increase under the circumstances. Thus, in Ross's view, an increase in research risk would be permissible only if the circumstances permit more effective training in altruism. Though I am skeptical, perhaps the moral educative benefit from research participation will increase in very dangerous times. Nonetheless,

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261. The right solution is not to limit the research participation of the underserved, but to ensure universal access to good medical care—but that is a separate topic, of course.

262. One might also suggest, perhaps, that it is the lack of informed consent that explains our moral concern for any overrepresentation of the underserved on the grounds that the underserved's parents are less educated and more prone to misunderstanding the purpose of research. *See* ROSS, CHILDREN IN MEDICAL RESEARCH, *supra* note 3, at 80 (suggesting that the process of informed consent serves as a "social filter" because research, at the time, concluded that "[b]etter educated and wealthier individuals are more likely to refuse to participate and are underrepresented in most research"). But while that is a concern, an overrepresentation of the underserved in research would be morally problematic even if informed consent were perfect because they would be bearing more of the burden of a practice from which they benefit least.

263. NAT'L COMM'N, *supra* note 18, at 127.

undoubtedly any increased in permissible research risk would be justified publicly by appeal to the increased health risks children would face outside the research context during such times, rather than to any increase in moral educative benefit children might receive by research participation.

Despite these strengths, the view has at least one possible drawback: it rests on an empirical assumption that may turn out to be false for some children who are or may be enrolled in research, or, even if true now, may one day cease being true. That empirical assumption is, of course, that each child is better off under a policy permitting non-beneficial pediatric research than under the *Grimes* prohibition. If the empirical assumption is or turns out to be false, does that imply that it is unethical to do non-beneficial research on a child who is not made better off by a policy permitting non-beneficial research? Perhaps. But in the next section I present a second possible justification for non-beneficial pediatric research, one that does not rest on the empirical assumption.

VI. REASON TO HELP OTHERS

A. Reviving McCormick

My argument thus far has appealed to the benefits to each child of a policy that permits non-beneficial research, with a low ceiling on risk, over a policy in line with the *Grimes* prohibition. I now present an additional reason associated with any person's point of view, including each child's, to reconcile non-beneficial pediatric research and the respect due each child. This argument focuses on the duty each person has to help others when one has the opportunity to do so at little to no cost to herself. I am not presenting an entirely novel argument. Rather, it coincides with my interpretation of Richard McCormick's work. The literature reveals that McCormick's arguments have not won the day among commentators.[264] The additional justification for non-beneficial pediatric research I offer builds on the best, most charitable interpretation of McCormick's work, and on the non-consequentialist framework presented above.

As mentioned, Paul Ramsey argues against non-beneficial pediatric research because of children's inability to consent. McCormick counters that enrolling a child in non-beneficial pediatric research can be respectful of her status as a person because each child *would* consent based on the fact that she *ought* to consent.[265] Describing what he means by "ought," McCormick states that it is

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264. *See, e.g.*, ROSS, CHILDREN, FAMILIES, *supra* note 18, at 77-79 (rejecting McCormick's view); Wendler, Significance, *supra* note 11, at 66-70; Brock, *supra* note 18, at 81-101 (presenting justifications for pediatric research but not discussing McCormick's or any similar view).

265. Richard A. McCormick, *Experimental Subjects: Who Should They Be?*, 235 JAMA 2197 (1976) [hereinafter McCormick, *Experimental Subjects*]; *see also* McCormick, *Experimentation*,

"not based on the fact we [or the child] will derive any benefit from such experiments . . . , but because others will derive benefit at no cost or minimal cost . . . ."[266] As McCormick argues, "[t]here are things we *ought* to do for others simply because we are members of the human community," which are "not works of charity or supererogation . . . but our personal bearing of our share that all may prosper."[267]

One might interpret as *empirical* McCormick's claim that a child *would* consent because she ought to.[268] That is, on one reading of McCormick, he argues that most competent adults actually do help others when they can at little to no cost to themselves (or that most do, in fact, consent to minimal risk research when invited to) because they ought to. Thus, on this reading, McCormick is merely predicting what each child will do in the future based on what most adults do. If this interpretation reflects McCormick's argument, then one might question whether any empirical data support the claim; McCormick would have to concede if the data are unsupportive.

However, this interpretation does not capture the essence of McCormick's view and is in tension with his text. He articulates how we should decide what a child *would* choose, but nowhere does he discuss what most adults actually do choose, and he explicitly recognizes the possibility that not enough people actually do volunteer.[269] Rather, in claiming that a child *would* consent because she *ought* to consent, McCormick is making a normative, not empirical, claim about what each person has *good reason* to do. He states that the criterion for a parent's proxy consent is not any predictive factor, but "its reasonableness,"[270] regarding the "goods definitive of [the child's] well-being" that he has reason to choose or "at least . . . could not reasonably object to."[271] Being a member of the human community and helping others are "goods definitive" of a person's well-being, on McCormick's account, and thus each person has good reason to help others when one can do so "at no cost or minimal cost to [oneself]."[272]

There is no need to address the controversial question of whether one's own well-being is advanced by helping others. It is sufficient to recognize that each person does have reason to help others when one can do so at little or no cost to oneself. Furthermore, the fact that it is legitimate to associate this reason with the perspective of children, as well as adults, is reflected by how we live, implicit in

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supra note 18.

266. McCormick, *Experimental Subjects*, *supra* note 265, at 2197.

267. *Id.*

268. *See, e.g.*, Wendler, Significance, *supra* note 11, at 66-67.

269. *See* McCormick, *Experimental Subjects*, *supra* note 265, at 2197.

270. *Id.* at 2197.

271. *Id.*

272. *Id.*

our firm moral commitments. Just imagine that your neighbor has suffered a bad injury and needs emergency medical attention. You can drive your neighbor to the hospital, but you would have to take your child with you. For the good of another person you would be putting the child at some risk. (This assumes the child is safer and better off playing at home, under your care and supervision, than riding in a car. Let's even stipulate that it is raining, so driving conditions are less safe than usual.) I submit that it is morally permissible to put the child in the car and go—and even morally problematic not to. In fact, it seems morally problematic even to consider *not* putting the child in the car on ground that it is not in your child's best interests. Yet imagine someone challenging your decision because it was not in your child's best interests to face the risks of car-riding. The objection seems out of place. You and your child drove your neighbor because you both had good reason to—it was the beneficent thing to do. One might be able to offer a story explaining how it is in the child's best interests that we do these things for one another. But that story does not seem necessary to justify putting the child at minimal risk for the good of another.

Without empirical data, I suspect that this argument resonates with many parents who do consent to enroll their children in non-beneficial, minimal risk research after fully comprehending that the research is solely for the good of others. I doubt parents consider that they are morally educating a young child through research participation, or that they are trying to be fair to past and future generations, or that their children would otherwise be facing the risks of daily life, etc. If we do not think that a parent wrongs a child by putting her in a car to drive an injured neighbor to the hospital, we should not think a parent wrongs a child by enrolling her in minimal risk research for the reason that it is good for others.

B. Objections and Replies

Ramsey and Ross have criticized McCormick on the ground that his argument would "justify compulsory altruism[,] . . . requir[ing] the participation of adults in research projects to which they do not give their consent."[273] This criticism, though, is misguided. That each person has good reason to help others when one is especially situated to do so at very little to no cost to oneself does not imply that the state may compel research participation or enforce that duty in any other way. Other reasons and values matter, such as those related to the importance of obtaining informed consent from persons capable of making decisions for themselves.[274] Indeed, neither McCormick's position nor the

273. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 78-79; *see also* Ramsey, *Enforcement*, *supra* note 215, at 22.

274. *See supra* notes 234-237 and accompanying text.

arguments I have presented justify the state forcing children into research without parental consent.[275]

Ramsey raises a second objection. He agrees with McCormick that a parent asked to provide proxy consent for her child should consider what the child *would* choose, but Ramsey argues that it is a "violent and false presumption" to assume a child *ought* to consent.[276] He argues that McCormick asks what a child would choose in light of what would be good for an adult to choose. In contrast, Ramsey argues that the question should be answered in light of what would be good for a child to choose. For adults and children, both Ramsey and McCormick think we need to look to the "natural tendencies" of persons to discern their good, on the assumption that they are naturally inclined toward their good. They depart in that Ramsey argues that we should determine the good of children by looking to *their* natural tendencies, not to those of adults. Because a young child is naturally inclined only toward preserving his own life, health, and growth,[277] according to Ramsey, a parent may weigh only considerations related to those self-interested goods in exercising proxy consent; moral considerations are off limits.

But, of course, we do not actually make decisions for children that are consistent with their natural inclinations—thankfully for them and us. Children naturally may be inclined to preserve themselves, but they are also naturally inclined to act irrationally. Should we then treat them in ways that promote their irrationality? Of course not. This observation illustrates the ultimate problem with Ramsey's (and McCormick's) reliance on a natural law conception of the good: the conception is guilty of what G.E. Moore termed the "naturalistic fallacy."[278] Ramsey does not recognize that deeming something "natural" leaves open the question of whether that thing is good. We make decisions for children in light of what we think they have reason to do and care about. Most of those decisions focus on their best self-interest. But their "best self-interest" does not require us to promote their *actual* wants and inclinations as children. We try to

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275. Ross argues that McCormick "realized" that his argument justified compulsory altruism. ROSS, CHILDREN, FAMILIES, *supra* note 18, at 78-79 (citing McCormick, *Experimentation*, *supra* note 18, at 42-43). But McCormick did no such thing. He explicitly stated, "Even though it can be argued that we all have duties in this area [related to research participation], duties of readiness and willingness, it is understandable, even desirable, that informed consent accompany the fulfillment of these duties. For consensual community is something to be promoted whenever possible." McCormick, *Experimentation*, *supra* note 18, at 43 (quoting McCormick, *Experimental Subjects*, *supra* note 265, at 2197). He argues that it might not be unjust for the government to recruit subjects by lottery *if* "not enough volunteers are available for minimal risk experimentation and the research seems of overriding importance to the public health." *Id.*

276. Ramsey, *Enforcement*, *supra* note 215, at 22.

277. *Id.*

278. G.E. MOORE, PRINCIPIA ETHICA 58-69 (Thomas Baldwin ed., 1993).

shape their desires, thinking about their long-term interests. If we make decisions for them in light of good reasons, it is not a mistake to consider reasons that are other-regarding. As I noted, we put the child in the car in order to aid our injured neighbor because we all have reason to help others.

A final objection is directed toward both justifications I have offered. One might argue that the non-consequentialist moral framework employed in both justifications—based on the idea of justifying an action or policy *to* an individual *as* an individual by giving reasons that have importance from that person's point of view—is inappropriate for thinking about children's issues. The purported problem is that the motivating idea behind the framework is that the property in virtue of which persons morally matter is our capacity for rational self-governance.[279] That is, on this view of moral reasoning, what matters most morally about persons is that we have the capacity to direct our own lives in light of the reasons we take ourselves to have. Justification to an individual (as opposed to the world at large) is related in that a person has reason to view the way that others treat her as respectful of her capacity for rational self-governance if their actions are justified in light of reasons that have importance from her own perspective. She can, in a sense, view their actions and their consequences "as *not* just things that *happen* to her, but as a result of what she herself has authorized."[280] But this framework, then, seems inapposite to young children, who are not capable of rational self-governance. If they are not capable of rational self-governance, why should we ask whether each child has reason to endorse a policy permitting some non-beneficial pediatric research? The final point of the objection would be that we must take a child's welfare—and not reasons—as fundamental in thinking how we may treat her, given that young children do not respond to reasons.

The moral status of children within Kantian, non-consequentialist moral theory is a difficult topic. Possible lines of response would need development to be persuasive: Perhaps the potential of young children to become rational self-governors grounds a general duty to treat each one as an end and not merely a means, requiring us to justify ourselves to each on grounds that she could not reasonably reject. Alternatively, perhaps we have good reason to endorse that general duty to young children because we cannot make fine distinctions regarding the point at which children become sufficiently rational.[281]

Regardless, scholars, policy makers, and courts have sought a justification for this research based on Kantian or non-consequentialist moral reasoning. I have not attempted to provide a full account of why we must treat each child as an end-in-herself. I begin with that assumption. If we reject the Kantian

279. *See* KUMAR, CONSENSUALISM, *supra* note 213, at 13-14; SCANLON, *supra* note 208, at 268.

280. KUMAR, CONSENSUALISM, *supra* note 213, at 14.

281. *See id.* at 22 (discussing reason to treat the sub-rational as being owed duties).

framework as inapplicable to children, on what basis are we under a duty to resist appealing to the aggregated benefits to all persons (or all sentient creatures) when justifying our decision to expose children to uncompensated research risks? A consequentialist, of course, would respond by saying that there *is no* basis. However, scholars and government agents have searched for a non-consequentialist justification, dissatisfied with defending the research on consequentialist grounds.

CONCLUSION

This Article has addressed three related questions regarding non-beneficial pediatric research: 1) Should the best interests standard determine whether non-beneficial pediatric research is ethically and legally permissible? 2) If it should, did the *Grimes* court correctly conclude that the standard precludes exposing a child to "any articulable risk beyond the minimal kind of risk that is inherent in any endeavor"?[282] In essence, was *Grimes* correct in essentially prohibiting non-beneficial pediatric research? 3) Finally, can non-beneficial pediatric research be justified only by appeal to utilitarian or otherwise consequentialist considerations? Does enrolling a child in a non-beneficial protocol necessarily treat the child merely as a means to our end of improving children's health, or is there a non-consequentialist justification for the research?

A court, invoking the state's *parens patriae* authority, should appeal to the "best interests" standard in assessing the permissibility of non-beneficial pediatric research. Though the *Grimes* court properly relied on that standard, it wrongly concluded that the standard precludes all non-beneficial research on children. Courts and other state decision-makers must consider that a policy permitting some non-beneficial pediatric research is in the best interests of *each* child, including children enrolled or potentially enrolled in research. Non-beneficial research and interventions help lead to newer, safer pediatric therapies, thereby lowering the risks children face in the medical care setting, while exposing pediatric subjects to extremely low risk.

Thus, a child's participation in a non-beneficial pediatric protocol can be respectful of that child. Each child has reason to endorse both a policy permitting non-beneficial pediatric research and to participate in a practice from which she benefits. This proposed justification offers a plausible amendment to informed consent practices and helps explain shared intuitions regarding the conditions under which it is appropriate to conduct pediatric research.

282. Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 862 (Md. 2001).

NOTE

Caring for the Uninsured: Are Not-for-Profit Hospitals Doing Their Share?

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INTRODUCTION

In 2004, the Robert Wood Johnson Foundation reported that 44 million individuals in the United States lacked health insurance, and the annual cost of uncompensated care for those individuals was $40.7 billion.[1] When individuals lacking coverage for only part of the year were also included, total medical expenditures among all uninsured patients approached $125 billion.[2] In August 2007, the Census Bureau reported even more alarming figures: The number of U.S. residents without health insurance rose by 2.2 million, to a total of 47 million, for 2006.[3] According to the report, uninsured Americans represented 15.8% of the population.[4]

Given the growth in the number of uninsured Americans, it is unsurprising that health care providers across the country have noted a significant increase in demand for medical services from individuals lacking coverage.[5] Many health care providers are struggling to keep up with this growing demand, particularly as state and federal funding has not kept pace with the increase in the number of uninsured patients seeking care.[6] As a result of this lack of funding, hospitals nationwide shoulder an enormous burden in caring for the nation's uninsured; in fact, hospitals in 2001 covered over 60% of the costs for uncompensated care

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1. JACK HADLEY & JOHN HOLAHAN, KAISER COMM'N ON MEDICAID & THE UNINSURED, THE COST OF CARE FOR THE UNINSURED: WHAT DO WE SPEND, WHO PAYS, AND WHAT WOULD FULL COVERAGE ADD TO MEDICAL SPENDING? 2 (2004), *available at* http://covertheuninsured.org/media/research/KaiserReport.pdf (calculating figures based on data from the U.S. Census Bureau).

2. *Id.*

3. CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2006, at 18 (2007), *available at* http://www.census.gov/prod/2007pubs/p60-233.pdf.

4. *Id.*

5. One report observes that "safety net providers across local communities are seeing increased demand for services" from individuals who are ineligible for public programs, a group that includes undocumented immigrants, legal immigrants who have not been U.S. residents long enough qualify for public programs, and members of the "underinsured" middle class. DEBRA A. DRAPER & PAUL B. GINSBURG, CTR. FOR STUDYING HEALTH SYS. CHANGE, HEALTH CARE COST AND ACCESS CHALLENGES PERSIST: INITIAL FINDINGS FROM HSC'S 2007 SITE VISITS 5-6 (2007), *available at* http://www.hschange.org/CONTENT/947/947.pdf; *see also* CARA S. LESSER ET AL., CTR. FOR STUDYING HEALTH SYS. CHANGE, INITIAL FINDINGS FROM HSC'S 2005 SITE VISITS: STAGE SET FOR GROWING HEALTH CARE COST AND ACCESS PROBLEMS 3 (2005), *available at* http://www.hschange.org/CONTENT/776/776.pdf (finding that providers are "struggling to keep up with growing demand" for safety net primary care services accessed by uninsured patients).

6. Erin Fries Taylor et al., *Community Approaches To Providing Care for the Uninsured*, HEALTH AFF., Apr. 11, 2006, at W173, W181-82, http://content.healthaffairs.org/cgi/reprint/25/3/w173 (describing the lack of response to the rising uninsurance rates at the state and federal levels).

incurred annually in the United States.[7]

This burden borne by health care providers carries with it serious consequences for the uninsured. Private and public insurance payors are able to negotiate large volume discounts with hospitals and set payment rates. However, hospitals have historically billed uninsured ("self-pay") patients full, undiscounted rates for medical care.[8] Following health care reforms in the mid-1980s that dramatically reduced reimbursement rates from both private and government payors—and thus significantly increased pressure on hospital margins—hospitals began to aggressively seek payment from these patients for services rendered.[9] A series of articles in the *Wall Street Journal* in the early 2000s, and industry studies commissioned shortly thereafter, described hospitals' "relentless pursuit" of payment from self-pay patients.[10] The reports depicted the

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7. HADLEY & HOLAHAN, *supra* note 1, at 3.

8. A study of Chicago-area hospitals, for example, found that each hospital charged its uninsured patients up to twice the rates the hospitals accepted from insurance plans. Beverly Cohen, *The Controversy Over Hospital Charges to the Uninsured—No Villains, No Heroes*, 51 VILL. L. REV. 95, 104 (2006) (citing HOSP. ACCOUNTABILITY PROJECT, SERV. EMPLOYEES INT'L UNION, WHY THE WORKING POOR PAY MORE: A REPORT ON THE DISCRIMINATORY PRICING OF HEALTH CARE 1 (2003), *available at* http://www.hospitalmonitor.org/pdf/working_more.pdf). However, recent proposals from various provider associations would change this practice so that self-pay patients are charged at rates that reflect actual costs, not charges, or are billed at amounts that mirror rates the hospitals receive from private or government payors. *See infra* notes 210-217 and accompanying text.

9. *See* John D. Colombo, *Federal and State Tax Exemption Policy, Medical Debt and Healthcare for the Poor*, 51 ST. LOUIS U. L.J. 433, 440 n.52 (2007) [hereinafter Colombo, *Exemption Policy*] (describing reductions in reimbursement that occurred as the federal government shifted from cost-based reimbursement to the Prospective Payment System in the early 1980s, and as corporate transformations and competitive demands rendered hospitals less capable of subsidizing indigent care).

10. *See* Cohen, *supra* note 8, at 105; *see also* Lucette Lagnado, *Anatomy of a Hospital Bill: Uninsured Patients Often Face Big Markups on Small Items*, WALL ST. J., Sept. 21, 2004, at B1; Lucette Lagnado, *Cold-Case Files: Dunned for Old Bills, Poor Find Some Hospitals Never Forget*, WALL ST. J., June 8, 2004, at A1; Lucette Lagnado, *Full Price: A Young Woman, an Appendectomy, And a $19,000 Debt*, WALL ST. J., Mar. 17, 2003, at A1; Lucette Lagnado, *Hospitals Urged To End Harsh Tactics for Billing Uninsured*, WALL ST. J., July 7, 2003, at A9; Lucette Lagnado, *Medical Seizures: Hospitals Try Extreme Measures To Collect Their Overdue Debt—Patients Who Skip Hearings on Bills Are Arrested*, WALL ST. J., Oct. 30, 2003, at A1; Lucette Lagnado, *Medical Shift: Hospitals Will Give Price Breaks to Uninsured, If Medicare Agrees*, WALL ST. J., Dec. 17, 2003, at A1; Lucette Lagnado, *Twenty Years and Still Paying*, WALL ST. J., Mar. 13, 2003, at B1. One report focused on Yale-New Haven Hospital's practices of suing uninsured patients, garnishing their wages, seizing their bank accounts, and foreclosing on their homes, even for relatively small medical bills. *See* Lucette Lagnado, *Call it Yale v. Yale – Law School Clinic Is Taking Affiliated Hospital to Court Over Debt-Collection Tactics*, WALL ST. J.,

dire consequences of medical debt for the uninsured, and painted an extremely negative and distasteful picture of the hospitals' actions; investigators "conclusively established" that health care providers "did not tell the uninsured about charity care, did not offer charity care, did not discount bills to the uninsured and aggressively pursued payment."[11]

In June 2004, in an effort to capitalize on the public concern generated by these reports, a consortium of plaintiffs' lawyers led by Mississippi-based Richard Scruggs filed a series of class-action lawsuits against not-for-profit hospitals and health systems in federal courts.[12] The plaintiffs' principal allegation was that the health care providers violated their charitable obligations as tax-exempt organizations by aggressively billing and collecting from uninsured patients. At one point, seventy-six cases were pending in federal courts against not-for-profit hospitals.[13] Cases were filed in more than forty states, and more than 600 hospitals were named as defendants.[14] Within just a few months, however, over half of the lawsuits were either dismissed by the courts or withdrawn by the plaintiffs' lawyers themselves in response to initial adverse rulings. Ultimately, nearly every case was dismissed on the pleadings.[15]

Nov. 14, 2003, at B1.

11. Cohen, *supra* note 8, at 103; *see also* Melissa B. Jacoby & Elizabeth Warren, *Beyond Hospital Misbehavior: An Alternative Account of Medical-Related Financial Distress*, 100 NW. U. L. REV. 535, 539 (2006) (describing the *Wall Street Journal* articles and serious financial distress incurred by uninsured patients). The Commonwealth Fund issued a comprehensive report in 2003 describing some of the effects of medical debt on consumers. CAROL PRYOR ET AL., COMMONWEALTH FUND, UNINTENDED CONSEQUENCES: HOW FEDERAL REGULATIONS AND HOSPITAL POLICIES CAN LEAVE PATIENTS IN DEBT (2003), *available at* http://www.accessproject.org/downloads/unintended.pdf. The report noted, for example, that in a survey of clients at a Florida consumer credit counseling agency, 40% of those seeking help restructuring debt did so due to medical bills. *Id.* at 2. The report also cited another study finding that "nearly half of personal bankruptcies result from health problems or large medical bills." *Id.* at 3 (citing Melissa B. Jacoby et al., *Rethinking the Debates Over Health Care Financing: Evidence from the Bankruptcy Courts*, 76 N.Y.U. L. REV. 375 (2001)). Low-income and uninsured consumers with medical debts reported that their debt posed "a substantial obstacle to achieving self-sufficiency because of a reduced ability to access credit, save money, or pay for the daily necessities of life." *Id.*

12. Richard Scruggs earned a national reputation as a plaintiffs' attorney for the role he played in litigation efforts against the tobacco industry. More recently, he pleaded guilty to a charge of conspiracy to bribe a Mississippi state judge to gain a favorable ruling in a lawsuit concerning the allocation of legal fees from Hurricane Katrina-related litigation. *See* Jonathan D. Glater, *Guilty Plea by Lawyer to Bribery*, N.Y. TIMES, Mar. 15, 2008, at C1.

13. Mitchell Zamoff & Christopher Zaetta, *Plaintiff's Lawyers Launch "Second Offensive"*, AHA NEWS, Mar. 7, 2005, at 4.

14. Cohen, *supra* note 8, at 111-12.

15. Susan Beck, *Mississippi Blues*, AM. LAW., Mar. 8, 2008, at 6, *available at* http://www.law.com/jsp/tal/PubArticleTAL.jsp?hubtype=Inside&id=1204212420558.

Although the widespread rejection of the plaintiffs' theories made it evident that the federal judiciary cannot supply the relief sought by uninsured patients, the cases generated important questions regarding how uninsured patients can obtain—and hold hospitals accountable for providing—necessary and affordable medical care. The litigation also raised larger questions about whether not-for-profit hospitals provide sufficient amounts of charity care to warrant continued tax exemptions, or whether they should be held to a higher standard.[16]

This recent and intense focus on hospital tax exemption may seem sudden and unexpected.[17] But, though it is an issue that has only recently grabbed national attention, it is one that has plagued the not-for-profit sector for more than two decades. States, in particular, have struggled with how to determine whether hospitals are providing a sufficient amount of free and discounted care to adequately serve their communities and warrant continued local tax exemptions.[18] Now, given the recent attention to the issue, state lawmakers are

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16. *See, e.g.*, M. Gregg Bloche, *Tax Preferences for Nonprofits: From Per Se Exemption to Pay-for-Performance*, HEALTH AFF., June 20, 2006, at W304, http://content.healthaffairs.org/cgi/reprint/25/4/W304; Jill Horwitz, *Nonprofit Ownership: Private Property, and Public Accountability*, HEALTH AFF., June 20, 2006, at W308, http://content.healthaffairs.org/cgi/reprint/25/4/W308; David A. Hyman & William M. Sage, *Subsidizing Health Care Providers Through the Tax Code: Status or Conduct?*, HEALTH AFF., June 20, 2006, at W312, http://content.healthaffairs.org/cgi/reprint/25/4/W312; Mark Schlesinger & Bradford H. Gray, *How Nonprofits Matter in American Medicine, And What To Do About It*, HEALTH AFF., June 20, 2006, at W287, http://content.healthaffairs.org/cgi/reprint/25/4/W287.

17. Many industry experts attribute the most recent surge in interest to the 2003 *Wall Street Journal* articles criticizing hospital practices, as well as the industry studies and headline-grabbing lawsuits that followed. *See, e.g.*, Cohen, *supra* note 8, at 105.

18. States paid little attention to hospital exemption standards until the 1980s, when federal reimbursement rates were cut dramatically, driving hospitals to make significant cuts to the amounts of free and discounted care they provided. Colombo, *Exemption Policy*, *supra* note 9, at 440. When this occurred in Utah, for example, the state revoked tax exempt status for a number of hospitals on the ground that they provided too little charitable care, a determination the state supreme court ultimately upheld. Utah County v. Intermountain Health Care, Inc., 709 P.2d 265 (Utah 1985); *see also* Colombo, *Exemption Policy*, *supra* note 9, at 441. Similar events occurred in Pennsylvania when the state supreme court denied a health care facility a sales tax exemption because it failed to provide sufficient charitable care. Utilization Project v. Commonwealth, 487 A.2d 1306, 1310 (Pa. 1985); *see also* Colombo, *Exemption Policy*, *supra* note 9, at 442. This trend continued through the early 1990s, with a number of states passing mandatory community benefit standards or voluntary disclosure requirements. *See* Colombo, *Exemption Policy*, *supra* note 9, at 442-43; Alice A. Noble et al., *Charitable Hospital Accountability: A Review and Analysis of Legal and Policy Initiatives*, 26 J.L. MED. & ETHICS 116, 123-28 (1998); *see also infra* notes 145-146 and accompanying text. Following these efforts, states appeared to shift focus and paid relatively little attention to the issue of community benefit until the highly publicized cases of aggressive hospital billing and collections resumed center stage in the early 2000s. *See supra* notes 10-11 and

not alone. Federal officials, too, have taken up the fight and begun to push for more rigorous federal tax exemption standards. Members of both the House and Senate have discussed the need to provide some mechanism for holding not-for-profit hospitals accountable. Lawmakers want to ensure that hospitals are offering community benefits that are commensurate with their federal tax exemptions. As a result, legislators from both houses have initiated research efforts to help inform proposals for legislative reforms.[19]

This Note will argue, first, that a litigation strategy alone will not drive the changes in hospital billing and collections practices that uninsured patients seek. Nor can litigation affect any large-scale reforms to hospital community benefit standards. Lawsuits may successfully draw attention to hospital billing and collections policies, and, more generally, the issue of hospital charity care. Lawsuits may also drive changes in provider practices. But judges are constrained by the policy choices embedded in existing exemption statutes and regulations. As the recent lawsuits demonstrate, § 501(c)(3) of the Internal Revenue Code simply does not supply federal courts with the tools to hold not-for-profit hospitals accountable for caring for uninsured patients when the complaining parties are third-party patients.[20]

In fact, even if the Internal Revenue Service (IRS), the federal agency responsible for monitoring hospital exemption, were to conduct more frequent audits of not-for-profit hospitals and file suit to enforce its exemption criteria, the agency itself would be bound by its existing regulations. The IRS could not hold hospitals to a standard other than the one established by current policy rulings, which provide that hospitals have no obligation to provide a minimum amount of

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accompanying text.

19. In May 2005, Representative Bill Thomas, a Republican from California and then-Chairman of the House Ways and Means Committee, convened a hearing on the tax-exempt hospital sector. *See* John M. Quirk, *Turning Back the Clock on the Health Care Organization Standard for Federal Tax Exemption*, 43 WILLAMETTE L. REV. 69, 85-88 (2007). Representative Thomas commissioned a report from the Congressional Budget Office on the community benefit provided by not-for-profit hospitals; that report was released in December 2006. CONG. BUDGET OFFICE, NONPROFIT HOSPITALS AND THE PROVISION OF COMMUNITY BENEFITS (2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7695/12-06-Nonprofit.pdf. In May 2005, Senate Finance Committee member and then-Chairman Charles Grassley sent letters to not-for-profit hospitals demanding that they justify their federal tax exemptions. *See* Quirk, *supra*, at 88-89. For more information on federal legislative efforts, see Cohen, *supra* note 8, at 114-16; Colombo, *Exemption Policy*, *supra* note 9, at 437 n.28, 448-49; Jacoby & Warren, *supra* note 11, at 539; and Quirk, *supra*, at 98-99.

20. *See, e.g.*, Kolari v. N.Y.-Presbyterian Hosp., 382 F. Supp. 2d 562, 565-66 (S.D.N.Y. 2005) ("Plaintiffs here have lost their way; they need to consult a map or a compass or a Constitution because plaintiffs have come to the judicial branch for relief that may only be granted by the legislative branch.").

charity care.[21] Because current IRS regulations do not permit administrative enforcement actions premised on requirements that exceed existing policy rulings, the IRS would have to either explicitly revoke or overrule those regulations before it could enforce a new regulatory standard.[22] The IRS could, for example, implement a minimum charity care requirement via formal notice-and-comment rulemaking,[23] although it could also evade the notice-and-comment process by, for example, simply changing its *reporting* requirements for not-for-profit hospitals, and thereby avoid altering the substantive standard.[24] Alternatively, Congress could pass legislation to either amend the tax exemption criteria under § 501(c)(3) or direct the IRS to change its enforcement criteria.[25]

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21. *See* Rev. Rul. 69-545, 1969-2 C.B. 117.

22. Under existing IRS regulations, exempt hospitals must provide a "community benefit," but that term has never been read to explicitly require a minimum charity care requirement. Nonetheless, the IRS has focused *primarily* on charity care as a major component of exemption determinations, and no IRS ruling or court case in the past decade-and-a-half has approved exemption for a health care provider that lacked a substantial charity care program. *See* John D. Colombo, *The Failure of Community Benefit*, 15 HEALTH MATRIX 29 (2005) [hereinafter Colombo, *Failure of Community Benefit*]. But the IRS would not be permitted to argue in an enforcement action that the text of its most recent ruling on this issue, a 1969 Revenue Ruling that explicitly abandoned a minimum charity care requirement, no longer applies. Reply Brief for the Appellant, St. David's Health Care Sys. v. United States, 349 F.3d 232 (5th Cir. 2003) (Nos. 02-50959, 02-51312), 2003 WL 23411835, at *15-19 (asserting that the lack of a charity care program was *wholly dispositive* of an organization's exemption status and that a hospital's collection efforts bore on the factual question whether the care provided was charitable); *see also St. David's Health Care Sys.*, 349 F.3d 232 (rejecting the Service's position). In short, principles of fair notice constrain the IRS's ability to enforce a definition of "community benefit" that incorporates a minimum charity care requirement as a dispositive factor.

23. The Administrative Procedure Act (APA), 5 U.S.C. § 5 *et seq.*, requires federal agencies to publish Notices of Proposed Rulemaking in the Federal Register; this process of formal "notice-and-comment" rulemaking ensures that the public and regulated parties are given an opportunity to participate, provide information and suggest alternatives to the proposed rule. *See* Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc., 435 U.S. 519, 523-25, 545-48 (1978) (describing the statutory requirements for rulemaking imposed by the APA).

24. The IRS has recently done just that. In December 2007, the IRS released a revised Form 990 and sixteen new associated schedules. All hospitals and medical providers must complete Schedule H, which, in its revised form, includes questions regarding the community benefits provided by tax-exempt hospitals. Hospitals will, however, have a year to submit the information contained in Schedule H, as they are only required to provide identifying information beginning in tax year 2008. *See* Press Release, Internal Revenue Serv., IRS Releases Final 2008 Form 990 for Tax-Exempt Organizations, Adjusts Filing Threshold To Provide Transition Relief (Dec. 20, 2007), http://www.irs.gov/newsroom/article/0,,id=176722,00.html [hereinafter IRS Releases Final 2008 Form 990]. *See generally* Internal Revenue Serv., Form 990 Redesign Discussion Draft, June 14, 2007, http://www.irs.gov/charities/article/0,,id=171216,00.html [hereinafter Form 990 Redesign].

25. Of course, one might argue that simply empowering the IRS to increase its enforcement

Even if one were to turn to a legislative approach to modify the federal tax-exemption standards for not-for-profit hospitals, the relatively limited success achieved by analogous state legislation counsels the need for a cautious approach. State efforts indicate, for example, that minimum community benefit laws may be insufficient to significantly improve access to affordable care for the uninsured, particularly if those laws lack precise definitions for how providers should measure and account for charity care.[26] If hospitals are permitted to include bad debt expenditures in their charity care reports, for example, then improper revenue collection practices or inflated charges could make a hospital appear as though it were providing high levels of charity care. Alternatively, inconsistent and poorly managed billing procedures may make it difficult for hospitals to effectively distinguish between charity care and bad debt, rendering reported figures relatively useless. Furthermore, when it comes to federal legislation, lawmakers appear unlikely to support more rigorous standards than those imposed by most states.[27] Hospital industry experts have questioned how

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activity is insufficient, as hospitals have already curbed their most objectionable practices following the flood of negative publicity about their billing and collections policies. *See* ANDREA B. STAITI ET AL., CTR. FOR STUDYING HEALTH SYS. CHANGE, BALANCING MARGIN AND MISSION: HOSPITALS ALTER BILLING AND COLLECTION PRACTICES FOR UNINSURED PATIENTS 1 (2005), *available at* http://www.hschange.org/CONTENT/788/788.pdf (describing providers' efforts nationwide to implement new charitable care policies). That is, given the extent of voluntary reforms, heightened enforcement of existing exemption criteria might have little effect on the day-to-day activities of most health care institutions or on the aggregate amount of charity care provided to local communities. That said, the notion that questionable hospital billing and collections practices can be cured, and that hospitals will continue to meet their obligations to both indigent patients and taxpayers to provide discounted or free care, is certainly a questionable one. *See infra* note 203 and accompanying text.

26. A review of various state-level approaches, for example, found that in states requiring hospitals to report annual charitable care levels, the hospital reports often are not read by state regulators due to a lack of funding for audit and enforcement activities. Noble et al., *supra* note 18, at 130-32; *see also* Kevin M. Wood, *Legislatively-Mandated Charity Care for Nonprofit Hospitals: Does Government Intervention Make Any Difference?*, 20 REV. LITIG. 709, 723-36 (2001). In fact, legislators in Texas passed a 1995 revision to the state's charity care statute, explicitly permitting hospitals to include bad debt in their charity care reports. Wood, *supra*, at 735-36; *see also* TEX. HEALTH & SAFETY CODE ANN. §§ 311.041 to .048 (Vernon 2008); TEX. TAX CODE ANN. § 11.1801 (Vernon 2008).

27. Legislators have in the past proven to be highly responsive to industry interest groups, such as the American Hospital Association (AHA), thus making it hard to imagine that they would support more drastic measures, including mandatory minimum care requirements with steep penalties for noncompliance. For example, the IRS proposed a revised version of Schedule H (an attachment to the Form 990 submitted by exempt entities) that would have required hospitals to provide detailed reports on how they comply with the community benefit standard. That proposal evoked a "strong display of congressional concern." Matthew Malamud, *Most House Members*

politically feasible some of the more drastic reforms, including a minimum charity care requirement, might be, given the difficult policy questions such reforms would generate, including which revenues will be used to cover the increased costs of indigent care, how to address geographic variations in how much care is needed and how much care is available, and how to ensure that uninsured patients receive adequate preventative health services.[28] Some academics have wondered whether Congress has the necessary incentives to pass laws that would require hospitals to provide significantly greater amounts of uncompensated care given the extent to which hospitals are dependent on federal funds to survive.[29]

Want Full-Value Reporting for Tax-Exempt Hospitals, AHA NEWS, Nov. 12, 2007, at 1; *see also* Letter from Stephanie Tubbs Jones and Jon Porter, Members of the House of Representatives, to Steven T. Miller, Comm'r, Tax Exempt & Gov't Entities Div., Internal Revenue Serv. (Nov. 7, 2007), http://www.aha.org/aha/letter/2007/071108-let-tubbsj-porter-irs.pdf [hereinafter Letter from Representatives Tubbs Jones and Porter]. Lawmakers urged the IRS to reduce hospitals' reporting obligations and delay the filing deadline under the new Schedule H to tax year 2010. That House members supported the AHA's position on this issue is unsurprising given the organization's lobbying efforts. *See* Letter from Rick Pollack, Executive Vice President, Am. Hosp. Ass'n, to Members of House of Representatives (Oct. 10, 2007), http://www.aha.org/aha/letter/2007/071010-let-rp-house.pdf [hereinafter Letter from Rick Pollack] (advocating that members of Congress sign a letter urging the IRS to modify its Form 990 and Schedule H); *see also* Matthew DoBias, *Grassley Hears, But Will He Listen? Community-Benefit Draft Needs Work, Execs Say*, MODERN HEALTHCARE, Nov. 5, 2007, at 9 (noting the AHA's lobbying efforts). The AHA is a powerful organization, and lawmakers may be particularly attuned to its advocacy efforts given the importance of health care issues to many voters and given that each member will have at least one hospital in his or her district. Moreover, the opposition to the AHA is relatively weak and poorly organized. *See Hearing on the Tax-Exempt Hospital Sector Before the H. Comm. on Ways & Means*, 109th Cong. (2005) [hereinafter *Hearing on the Tax-Exempt Hospital Sector*] (reflecting few submissions to the record in favor of imposing a more stringent charity care standard); David L. Nie, *Nonprofit Hospital Billing of Uninsured Patients: Consumer-Based Class Actions Move to State Courts*, 4 IND. HEALTH L. REV. 173, 190-92 (2007) (describing some of the advocacy groups working on behalf of uninsured patients). *But see* Serv. Employees Int'l Union, Hospital Accountability Project, http://www.hospitalmonitor.org/about.htm (last visited May 1, 2008) (a "research and advocacy initiative" intended to "hold nonprofit, charitable hospitals accountable to their mission of placing the needs of patients, communities, and workers ahead of financial objectives" and providing links to other, similar advocacy organizations).

28. *Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 91 (statement of John D. Colombo, Professor, Univ. of Ill. Coll. of Law).

29. Because the federal government funds the Medicare and Medicaid programs, legislators are arguably predisposed to favor efficient hospitals that minimize unreimbursed expenses. Accordingly, the federal government may be unlikely to require higher levels of charity care in exchange for exemptions. Such legislation would almost inevitably generate additional pressure from providers to increase Medicare reimbursement rates to help offset the costs of caring for the uninsured. Jack Burns, *Are Nonprofit Hospitals Really Charitable?: Taking the Question to the*

But even if lawmakers should exercise caution before imposing drastic reforms, that caution should not preclude progress toward implementing new community benefit *reporting* requirements. Industry associations themselves support reforms to enforce uniform accounting and reporting standards, and industry leaders and lawmakers alike have applauded these efforts.[30] The IRS, too, has recently made changes to its reporting requirements for exempt hospitals.[31] These reforms, if successful, will provide significant benefits. Most existing community benefit data currently suffer from a severe lack of uniformity both within and across institutions. Lack of consistency in intra-hospital financial reporting may mean that policymakers are unable to compare community benefit information to other hospital financial data. And because definitions for critical reporting terms have changed over time, regulators may also be unable to track hospital performance over time.[32] Moreover, ambiguity in standards can make enforcement difficult.[33] Thus, new reporting requirements that prescribe uniform community benefit standards may both enhance transparency in hospital community benefit reporting and enable more meaningful comparisons across exempt institutions. These results will enable policymakers to effectively assess whether hospitals are meeting their obligations to taxpayers to provide a measurable public good in exchange for tax exemptions and determine whether additional policy responses are necessary.[34]

Part I of this Note reviews the recent lawsuits in which plaintiffs unsuccessfully sought to use the Internal Revenue Code to hold not-for-profit hospitals accountable for providing higher levels of charity care. Part II offers an overview of federal requirements for tax exemption and describes the evolution of IRS policy under the statutory guidelines. In particular, this Part explains why current regulatory tools preclude the IRS from changing its exemption criteria without explicitly revoking or overruling prior rulings. Part III explores why a new community benefit standard—implemented either by the agency directly or via a congressional mandate—might be hampered by many of the same problems

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State and Local Level, 29 IOWA J. CORP. L. 665, 678 (2004); *see also Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 90 (statement of John D. Colombo, Professor, Univ. of Ill. Coll. of Law) (observing that hospitals will have to reallocate revenues from other sources in order to provide greater amounts of free care, which may result in a "hidden tax" on paying patients, as well as third-party and government insurers).

30. *See infra* text accompanying notes 210-220.

31. *See supra* note 22.

32. Noble et al., *supra* note 18, at 129.

33. *See Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 118 (statement of Nancy M. Kane, Professor of Mgmt., Harvard Sch. of Pub. Health).

34. *See* Darryll K. Jones, *Third-Party Profit-Taking in Tax Exemption Jurisprudence*, 2007 BYU L. REV. 977, 979-80, 982-83 (citing Bruce Chapman, *Between Markets and Politics: A Social Choice Theoretic Appreciation of the Charitable Sector*, 6 GEO. MASON L. REV. 821 (1998)).

that have plagued analogous state laws enacted in recent years. Finally, Part IV discusses voluntary reforms hospitals have undertaken to improve transparency in billing and collection practices and also addresses proposals for standardizing community benefit reporting. Ultimately, this Part concludes that lawmakers would be wise to allow recently implemented regulatory changes and industry-driven approaches to take effect before imposing any more drastic and controversial reforms.[35]

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35. A number of scholars have discussed the evolution of not-for-profit hospital exemption criteria, the success of current standards, the recent attention to the plight of uninsured patients seeking affordable medical care, and the potential efficacy of proposed legislative and regulatory changes. Much of the recent academic literature has focused on the increased attention not-for-profit providers have received in recent years, discussing the basis for recent criticism of hospital policies. *See, e.g.*, Leah Snyder Batchis, *Can Lawsuits Help the Uninsured Access Affordable Hospital Care?: Potential Theories for Uninsured Patient Plaintiffs*, 78 TEMP. L. REV. 493 (2005); Neville M. Bilimoria, *Patients Challenge Nonprofit Hospital's Charitable-Care Practices*, 93 ILL. B.J. 134 (2005); Cohen, *supra* note 8; Jack Hanson, *Are We Getting Our Money's Worth? Charity Care, Community Benefits, and Tax Exemption at Nonprofit Hospitals*, 17 LOY. CONSUMER L. REV. 395 (2005); Jacoby & Warren, *supra* note 11; Nie, *supra* note 27. Other authors have focused on historic and ongoing efforts at the state and federal levels to modify hospital exemption standards, often assessing the merits of the various legislative and regulatory approaches. *See, e.g.*, Gabriel O. Aitsebaomo, *The Nonprofit Hospital: A Call for New National Guidance Requiring Minimum Annual Charity Care To Qualify for Federal Tax Exemption*, 26 CAMPBELL L. REV. 75 (2004); Burns, *supra* note 29; Nancy M. Kane, *Tax-Exempt Hospitals: What Is Their Charitable Responsibility and How Should It Be Defined and Reported?*, 51 ST. LOUIS U. L.J. 459 (2007); Douglas M. Mancino, *The Impact of Federal Tax Exemption Standards on Health Care Policy and Delivery*, 15 HEALTH MATRIX 5 (2005); Noble et al., *supra* note 18; Quirk, *supra* note 19; Helena G. Rubinstein, *Nonprofit Hospitals and the Federal Tax Exemption: A Fresh Prescription*, 7 HEALTH MATRIX 381 (1997); Wood, *supra* note 26. Professor John D. Colombo has provided particular insightful commentary on the issue, having written extensively about hospital tax exemption, focusing largely on the history and success of the community benefit standard and whether alternative standards could provide more straightforward and coherent exemption criteria for not-for-profit hospitals. *See, e.g.*, Colombo, *Exemption Policy*, *supra* note 9; Colombo, *Failure of Community Benefit*, *supra* note 22; John D. Colombo, *The Role of Access in Charitable Tax Exemption*, 82 WASH. U. L.Q. 343 (2004) [hereinafter Colombo, *Role of Access*]; John D. Colombo, *The Role of Tax Exemption in a Competitive Health Care Market*, 31 J. HEALTH POL. POL'Y & L. 623 (2006) [hereinafter Colombo, *Competitive Health Care Market*]. Thus, in reviewing the media attention to not-for-profit providers and the lawsuits alleging uncharitable billing and collections policies, and in discussing the evolution of the federal exemption criteria, this Note covers ground that has been covered before. Those parts of the story are necessary, however, for understanding the arguments put forth in Parts III and IV. Part III likewise treads on some familiar ground when discussing the success of state-based initiatives, but draws independent conclusions about the potential success of federal reforms based on analysis of the state-level efforts. Finally, Part IV also charts new territory when discussing very recent industry reforms and revisions to regulatory requirements.

I. LAWSUITS AGAINST NOT-FOR-PROFIT HOSPITALS

This Part addresses how uninsured patients, spurred on by aggressive plaintiffs' attorneys, sought to use the federal tax code to challenge providers' billing and collection practices. Despite plaintiffs' best efforts, however, federal district court judges have uniformly rejected the attempt to use § 501(c)(3) of the Internal Revenue Code to hold hospitals accountable for providing minimum amounts of free or discounted care.

Plaintiffs' lawyers initially moved to consolidate all of the federal cases into a single proceeding, contending that centralization was warranted because the lawsuits all sought to challenge similar billing and collections strategies by not-for-profit hospitals and health systems.[36] The plaintiffs were dealt an early setback in October 2004, however, when the Judicial Panel on Multidistrict Litigation denied their motion.[37] The Panel held that centralization would neither serve the convenience of the parties and witnesses nor further the fair and efficacious conduct of the litigation.[38]

The denial of consolidation was followed by virtually unanimous dismissal of the federal claims by district courts nationwide.[39] The courts that so ruled

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36. The plaintiffs' attorneys may have sought to consolidate out of a desire to increase their bargaining leverage in prospective settlement negotiations; litigation in a class-action context is more likely to attract additional plaintiffs to the suit and, because of the consolidated damages amounts, more amenable to settlement than individual suits might be. *See* Victor E. Schwartz et al., *Addressing the "Elephantine Mass" of Asbestos Cases: Consolidation Versus Inactive Dockets (Pleural Registries) and Case Management Plans that Defer Claims Filed by the Non-Sick*, 31 PEPP. L. REV. 271, 298 (2003) (noting that consolidation can invite new case filings); Peyton Sturges, *Multidistrict Judicial Panel Rejects Motion To Consolidate, Transfer Charity Care Cases*, 13 BNA HEALTH L. REP. 1533 (2004), *available at* http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-667KU7?OpenDocument. Viewing their motivations in a more generous light, it is also possible that the plaintiffs' attorneys merely sought to obtain the benefits of scale that consolidation can provide.

37. *In re* Not-For-Profit Hosps./Uninsured Patients Litig., 341 F. Supp. 2d 1354, 1356 (J.P.M.L. 2004) (denying centralization of actions, which may be permitted at the district court's discretion pursuant to 28 U.S.C. § 1407(a) (2000)).

38. *Id.*; *see also* Cohen, *supra* note 8, at 128. The Panel held that, "notwithstanding the numerosity of actions, movants have failed to persuade us that these actions share sufficient common questions of fact to warrant 1407 transfer." *In re Not-For-Profit Hosps.*, 341 F. Supp. 2d at 1356.

39. The one exception to this pattern is a lawsuit that Scruggs settled. The lawsuit was one of the earliest cases he filed. Press Release, Richard Scruggs, Largest Rural Nonprofit Hospital in America Becomes First To Reach Settlement With Uninsureds (Aug. 5, 2004), http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/08-05-

dismissed with prejudice the claims under § 501(c)(3), as well as any allegations under the Fair Debt Collection Practices Act, the Emergency Medical Treatment and Active Labor Act, and 28 U.S.C. § 1983.[40] The courts also typically declined jurisdiction over the various state law claims raised, dismissing them without prejudice so that the plaintiffs would be able to re-plead the claims in state forums if they so chose.

At the core of the plaintiffs' claims were charges alleging that the defendant

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2004/0002226562&EDATE=. Dismissal of the claims by the remaining federal courts likely discouraged other defendants from prematurely settling, however.

40. *See* Amato v. UPMC, 371 F. Supp. 2d 752, 758-59 (W.D. Pa. 2005); Grant v. Trinity Health-Mich., 390 F. Supp. 2d 643, 658 (E.D. Mich. 2005); Lorens v. Catholic Health Care Partners, 356 F. Supp. 2d 827, 835 (N.D. Ohio 2005); McCoy v. E. Tex. Med. Ctr. Reg'l Healthcare Sys., 388 F. Supp. 2d 760, 770-71 (E.D. Tex. 2005); Quinn v. BJC Health Sys., 364 F. Supp. 2d 1046 (E.D. Mo. 2005); Valencia v. Miss. Baptist Med. Ctr., Inc., 363 F. Supp. 2d 867, 873-76 (S.D. Miss. 2005); Hudson v. Cent. Ga. Health Servs., No. 5:04CV301 (DF), 2005 U.S. Dist. LEXIS 2613, at *28 (M.D. Ga. Jan. 13, 2005); Shriner v. ProMedica Health Sys., Inc., No. 3:04CV7435, 2005 U.S. Dist. LEXIS 894, at *2 (N.D. Ohio Jan. 21, 2005); Washington v. Med. Ctr. of Cent. Ga., Inc., No. 5:04-cv-185 (CAR), 2005 U.S. Dist. LEXIS 2614, at *26 (M.D. Ga. Jan. 21, 2005); Daly v. Baptist Health, No. 4:04CV789GH, 2005 U.S. Dist. LEXIS 6270, at *14 (E.D. Ark. Jan. 31, 2005); Peterson v. Allina Health Sys., Nos. 04-2973 ADM/AJB, 04-2974 ADM/AJB, 2005 U.S. Dist. LEXIS 1962, at *8 (D. Minn. Feb. 1, 2005); Hagedorn v. St. Thomas Hosp., Inc., No. 3:04-0526, 2005 U.S. Dist. LEXIS 7259 (M.D. Tenn. Feb. 7, 2005); Schmitt v. Protestant Mem'l Med. Ctr., Inc., No. 04-CV-00577-DRH, 2005 U.S. Dist. LEXIS 7449, at *28 (S.D. Ill. Feb. 23, 2005); Wright v. St. Dominic Health Servs., Inc., No. 3:04CV521LN, 2005 U.S. Dist. LEXIS 8086, at *7 (S.D. Miss. Mar. 1, 2005); Fields v. Banner Health, No. CIV-04-1297-PHX-SRB, 2005 U.S. Dist. LEXIS 13481, at *5 (D. Ariz. Mar. 23, 2005); Watts v. Advocate Health Care Network, No. 04 C 4062, 2005 U.S. Dist. LEXIS 7418, at *6 (N.D. Ill. Mar. 30, 2005); Corley v. John D. Archibald Mem'l Hosp., Inc., No. 1:04-CV-110 (WLS), 2005 U.S. Dist. LEXIS 8057, at *7 (M.D. Ga. Mar. 31, 2005); Ellis v. Phoebe Putney Health Sys., No. 1:04-CV-80 (WLS), 2005 U.S. Dist. LEXIS 19935, at *3-4 (M.D. Ga. Apr. 8, 2005); Gardner v. N. Miss. Health Servs., No. 1:04cv235, 2005 WL 1312753, at *3 (N.D. Miss. May 31, 2005); Cygan v. Resurrection Med. Ctr., No. 04 C 4168, 2005 U.S. Dist. LEXIS 19867, at *1-2 (N.D. Ill. July 27, 2005); Kabeller v. Orlando Reg'l Healthcare Sys., No. 6:04-cv-1106-Orl-19DAB, 2005 U.S. Dist. LEXIS 20219, at *5 (M.D. Fla. Aug. 11, 2005); Feliciano v. Thomas Jefferson Univ. Hosp., No. 04-CV-04177, 2005 U.S. Dist. LEXIS 21565, at *21 (E.D. Pa. Sept. 28, 2005); Hutt v. Albert Einstein Med. Ctr., No. 04-03440, 2005 U.S. Dist. LEXIS 21548, at *6 (E.D. Pa. Sept. 28, 2005); Ferguson v. Centura Health Corp., 358 F. Supp. 2d 1014, 1021 (D. Colo. 2004); Kizzire v. Baptist Health Sys., Inc., 343 F. Supp. 2d 1074, 1085 (N.D. Ala. 2004); Darr v. Sutter Health, No. C 04-02624 WHA, 2004 WL 2873068, at *6 (N.D. Cal. Nov. 30, 2004); *see also* Burton v. William Beaumont Hosp., 373 F. Supp. 2d 707, 713-24 (E.D. Mich. 2005) (dismissing federal claims under Emergency Medical Treatment and Active Labor Act and state law claims); Burton v. William Beaumont Hosp., 347 F. Supp. 2d 486, 501 (E.D. Mich. 2004) (dismissing all federal claims except for Emergency Medical Treatment and Active Labor Act). For further discussion of the outcomes of these cases, see Cohen, *supra* note 8, at 113-14, 127-29.

hospitals' billing and collection practices were inconsistent with their obligations as not-for-profit, tax-exempt organizations. Both the legal and equitable claims reflected a theory that the grant of tax exemption under § 501(c)(3) created a contractual relationship between the health care provider and the federal government. The complaints typically alleged: 1) third-party breach of contract between hospitals and the federal government; 2) third-party beneficiary claims for breach of the same alleged contract; 3) breach of duty of good faith and fair dealing, based on the alleged contract; 4) breach of charitable trust for failure to provide affordable medical care to the uninsured in exchange for federal, state, and local tax exemption; and 5) unjust enrichment and constructive trust, also based on the theory that the hospitals owed a duty to provide affordable medical care to the uninsured in exchange for federal, state, and local tax exemptions.[41] In short, through these claims, addressed in turn below, the plaintiffs sought to hold not-for-profit health care providers liable for delivering insufficient levels of charity care and failing to adequately accommodate uninsured patients.

First, regardless of whether there was a contractual relationship under § 501(c)(3)—and a corresponding cause of action to sue to enforce the contract—the courts uniformly held that the plaintiffs lacked standing to sue to enforce the federal tax code. As one court explained, "§ 501(c)(3) does not create a direct right of compensation for indigent or uninsured hospital patients" but "only creates a tax exemption for qualifying entities."[42] Because plaintiffs were unable to demonstrate a direct right to compensation, they were held to be merely "incidental beneficiaries of the tax exempt status conferred by § 501(c)(3)."[43] Yet, "[i]ncidental beneficiaries of a government contract generally have no standing to enforce the contract."[44] Therefore, even had the courts recognized *both* a contractual obligation on not-for-profit providers *and* an implied cause of action under § 501(c)(3), uninsured patients would not have been granted standing to sue to enforce that obligation.[45]

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41. *See* cases cited *supra* note 40.

42. Grant v. Trinity Health-Mich., 390 F. Supp. 2d 643, 651 (E.D. Mich. 2005); *see also* Jellison v. Fla. Hospital Healthcare Sys., Inc., No. 6:04-cv-1021-Orl-28KRS, 2005 U.S. Dist. LEXIS 8036, at *10-11 (M.D. Fla.) (ruling that there is no language in § 501(c)(3) demonstrating that plaintiffs were the intended beneficiaries of the hospital's tax-exempt status).

43. *Grant*, 390 F. Supp. at 651.

44. *Id.*

45. For claims that hospitals have violated their obligations under § 501(c)(3), only the IRS would have standing to enforce a claim that the hospital has violated its statutory obligation. *See* Allen v. Wright, 468 U.S. 737 (1984) (finding, outside the hospital setting, that only the IRS has standing to enforce the charitable purpose requirements of § 501(c)(3)). The IRS has, at times, invoked this authority. *See, e.g.*, IHC Health Plans, Inc. v. Comm'r, 82 T.C.M. (CCH) 593, 605 (2001) (challenging the tax-exempt status of a corporate subsidiary of Intermountain Health Care in Utah); IHC Group, Inc. v. Comm'r, 82 T.C.M. (CCH) 606, 615 (2001) (same); IHC Care, Inc. v.

Next, the courts typically considered the merits of the plaintiffs' claims. First, in response to plaintiffs' contention that § 501(c)(3) creates a binding contract between the federal government and the recipient, the courts generally held that, absent statutory language indicating congressional intent to create a contract, the presumption is that statutes do not create contracts.[46] In some cases, the plaintiffs unsuccessfully attempted to rebut this presumption by analogizing to the federal Hill-Burton Act,[47] 1940s legislation intended to "promote the construction and modernization of hospitals" that has been held to create contracts between the federal government and participating institutions.[48] As one court explained, however, the Hill-Burton Act is "fundamentally different from § 501(c)(3)"; unlike § 501(c)(3), the Hill-Burton Act explicitly required hospitals seeking construction grants to agree to provide medical services to persons unable to pay and expressly conditioned the grant of federal funds on that promise.[49] Moreover, also unlike § 501(c)(3), "the Hill-Burton Act expressly provides for a private right of action to enforce the Act."[50] Thus, the courts, in no uncertain terms, rejected plaintiffs' assertion that § 501(c)(3) should *also* be read to impose a contractual obligation on hospitals.[51] Still not deterred, plaintiffs alleged that even in the absence of an express cause of action, § 501(c)(3) should be read to contain an *implied* cause of action. The courts also uniformly rejected this claim, however, on the ground that there was no evidence of congressional intent to create an implied cause of action.[52]

Comm'r, 82 T.C.M. (CCH) 617, 625 (2001) (same); Geisinger Health Plan v. Comm'r, 62 T.C.M. (CCH) 1656 (1991), *rev'd*, 985 F.2d 1210 (3d Cir. 1993) (denying exemption to a health maintenance organization). For claims that hospitals have violated *state* exemption requirements, the state attorney general is the proper party to sue. *See* Alice M. Maples, *State Attorney General Oversight of Nonprofit Healthcare Corporations: Have We Reached an Ideological Impasse?*, 37 CUMB. L. REV. 235, 237 (2007) (explaining state attorney generals' obligation to provide oversight of charitable organizations).

46. *See supra* note 40.

47. *See* Hospital and Medical Facilities Amendments of 1964, Pub. L. No. 88-443, § 3(a), 78 Stat. 447 (1964) (codified at 42 U.S.C. § 291 *et seq.*); Survey and Construction Act, Pub. L. No. 88-443, § 3(a), 78 Stat. 447 (codified as amended at 42 U.S.C. § 291).

48. *See* Baptist Hosp. E. v. Sec'y of Health & Human Servs., 802 F.2d 860, 869 (6th Cir. 1986) (citing St. Mary of Nazareth Hosp. Ctr. v. Dep't of Health & Human Servs., 698 F.2d 1337, 1343 (7th Cir. 1983)).

49. *See* Grant v. Trinity Health-Mich., 390 F. Supp. 2d 643, 650 (E.D. Mich. 2005).

50. *See id.*

51. *See, e.g., id.*

52. The District Court for the Northern District of Ohio, for example, explained that:

> [T]here is no evidence that Congress intended to create a private cause of action. The statute does not describe who may receive the benefits of a 501(c)(3) organization's activities; rather, it describes the types of organizations that may seek tax exemption. Where the statute focuses "on the person regulated rather than

In many cases, plaintiffs also alleged that hospitals' billing and collections practices toward uninsured patients breached a duty of good faith and fair dealing. A duty of good faith and fair dealing, however, exists only where the parties are bound by a contractual relationship.[53] And, because "a contractual relationship between the federal government and a non-profit entity is not created by § 501(c)(3)," the courts that were called upon to make this determination dismissed these claims as well.[54]

In many cases, the courts next had to assess whether the hospitals were liable for breach of charitable trust for their failure to offer discounted rates to the uninsured.[55] The plaintiffs claimed that by accepting federal, state, and local tax exemptions, the hospitals entered into a public charitable trust to provide affordable medical care to uninsured patients; according to this theory, the hospitals breached that trust by overcharging those patients, the intended beneficiaries of the trust.[56] Not surprisingly, the courts that were called upon to evaluate these claims rejected them, holding that charitable trusts are only enforced where there is clear language in a statute or implementing regulation demonstrating a specific intent to create a trust,[57] and plaintiffs' complaints failed to even allege that such language existed.[58] Furthermore, as with the contract-based claims, even had a charitable trust existed, the plaintiffs would have lacked standing to bring an enforcement action; "the Attorney General of the [state in which the hospital is located] is the only proper party" to enforce such a trust.[59]

> the individuals protected . . . [there is] 'no implication of an intent to confer rights on a particular class of person.'" Accordingly, there can be no implication of an intent to confer a private right of action on Plaintiff in this case. If Congress had wanted to create a private cause of action for the uninsured or for indigent patients, it knew how to do so.

Lorens v. Catholic Health Care Partners, 356 F. Supp. 2d 827, 833 (N.D. Ohio 2005) (citations omitted) (quoting Alexander v. Sandoval, 532 U.S. 275, 289 (2001) (quoting California v. Sierra Club, 451 U.S. 287, 294 (1981))).

53. McCoy v. E. Tex. Med. Ctr. Reg'l Healthcare Sys., 388 F. Supp. 2d 760, 768 (E.D. Tex. 2005); Peterson v. Allina Health Sys., Nos. 04-2973 ADM/AJB, 04-2974 ADM/AJB, 2005 U.S. Dist. LEXIS 1962, at *20 (D. Minn. Feb. 1, 2005).

54. *See, e.g.*, *Grant*, 390 F. Supp. 2d at 652.

55. *See, e.g.*, Amato v. UPMC, 371 F. Supp. 2d 752, 758-59 (W.D. Pa. 2005); Grant v. Trinity Health-Mich., 390 F. Supp. 2d 643, 658 (E.D. Mich. 2005).

56. *See, e.g.*, *Grant*, 390 F. Supp. 2d at 652.

57. *See, e.g.*, Amato v. UPMC, 371 F. Supp. 2d 752, 757 (W.D. Pa. 2005) (finding IRS revenue rulings did not indicate the creation of charitable trust under §501(c)(3)); *Lorens*, 356 F. Supp. 2d at 834; Quinn v. BJC Health Sys., 364 F. Supp. 2d 1046, 1052 (E.D. Mo. 2005).

58. *Grant*, 390 F. Supp. 2d at 652.

59. *Id.* (citing Burton v. William Beaumont Hosp., 347 F. Supp. 2d 486, 494 (E.D. Mich. 2004)).

Often, the courts were quite dismissive of plaintiffs' equitable claims for unjust enrichment and constructive trust. Those claims were also based on the theory that the hospitals owed a duty to provide affordable medical care to the uninsured in exchange for tax exemption.[60] The plaintiffs complained that their tax-exempt status unjustly enriched the hospitals, which failed to utilize their substantial net assets and revenues to provide discounted care.[61] Accordingly, plaintiffs argued entitlement to constructive trust on all profits obtained by the hospitals as a result of "charging [the plaintiffs] the highest and full undiscounted cost of medical care."[62] Specifically, they sought "the difference between the amount. . .charged Plaintiffs and the Class and the amount charged insured patients," as well as "an amount sufficient to provide Plaintiffs and the Class mutually affordable medical care."[63]

The courts disagreed, however, holding that federal law imposes no obligation on hospitals to provide affordable medical care, and even if § 501(c)(3) *did* impose such a duty, the claim for unjust enrichment was merely "a collateral attack on the IRS's decision to grant . . .tax exempt status" and therefore should fail.[64] Plaintiffs presented insufficient evidence of the necessary scienter; a constructive trust may not be imposed without a showing that the defendants obtained the property at issue by fraud, bad faith, duress, undue influence, or other improper means.[65] As the plaintiffs acknowledged that they received appropriate medical treatment and failed to proffer any evidence of bad faith by the defendant hospitals in requesting payment, the courts dismissed the equitable claims.[66] Moreover, many courts noted that even *had* the hospitals been unjustly enriched by failing to meet their obligations under § 501(c)(3), the plaintiffs once again lacked standing to assert unjust enrichment claims, as only the IRS may challenge the tax status of a qualified tax-exempt entity.[67]

In sum, the plaintiffs' federal court cases were doomed when the district courts all held that § 501(c)(3) creates neither an express nor an implied contract between the recipient of the tax exemption and the federal government[68] and that legal authority did not "support the notion that a theory of liability exists based

60. *See id.* As equitable claims, the allegations regarding unjust enrichment and imposition of constructive trust are valid claims to recovery in the absence of a legal contract.

61. *See id.*

62. *See, e.g., id.*

63. *See, e.g., id.*

64. *See, e.g., id.*

65. *See, e.g.*, Peterson v. Allina Health Sys., Nos. 04-2973 ADM/AJB, 04-2974 ADM/AJB, 2005 U.S. Dist. LEXIS 1962, at *23-24 (D. Minn. Feb. 1, 2005).

66. *See, e.g., id.*

67. *See, e.g., id.* at *24.

68. *See* Cohen, *supra* note 8, at 129 & n.211 (citing relevant cases).

on [a hospital's] status as a [tax-exempt] organization."[69] The decisions in the cases were remarkable both for the uniformity in their outcomes and for the strong reactions evoked among the presiding judges. One district court judge admonished the plaintiffs, stating that the legal premise underlying claims was "patently untenable" and that "formulating federal health care policy is not a proper function of a [federal] court."[70] Another chastised, "[p]laintiffs have lost their way; they need to consult a map or a compass or a Constitution because plaintiffs have come to the judicial branch for relief that may only be granted by the legislative branch."[71] At least one judge indicated significant frustration with the plaintiffs, observing that despite the rash of dismissals that had occurred prior to his judgment, the plaintiffs "persisted in presenting the very same claims and arguments with this court."[72]

Responding to the initial dismissals of their claims, the plaintiffs' attorneys voluntarily withdrew from those federal courts in which cases were still pending in order to re-file in state courts under state law.[73] Perhaps fearing adverse judgments in state venues,[74] or perhaps simply weary of litigation, many, if not

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69. *Grant*, 390 F. Supp. 2d at 651.

70. Ferguson v. Centura Health Corp., 358 F. Supp. 2d 1014, 1016 (D. Colo. 2004).

71. Kolari v. N.Y.-Presbyterian Hosp., 382 F. Supp. 2d 562, 565-66 (S.D.N.Y. 2005).

72. Collins v. Baptist Hosp, Inc., No. 3:04CV00276, 2005 U.S. Dist. LEXIS 12144 (N.D. Fla. Dec. 10, 2004) (noting that some of the plaintiffs' claims "were so untenable from the outset as to be frivolous").

73. Cohen, *supra* note 8, at 129; Zamoff & Zaetta, *supra* note 13.

74. Like the federal claims, the state claims alleged unlawful billing practices for medical services rendered to uninsured patients. *See generally* Press Release, Richard Scruggs, Statement from Dick Scruggs Nonprofit Hospital Litigation Status (Oct. 11, 2005), http://www.cliffordlaw.com/not-for-profit-hospital-class-action-litigation/press-releases/statement-from-dick-scruggs-nonprofit-hospital-litigation-status. Unlike the federal claims, however, the state claims alleged failure to comply with *state* common law or statutory schemes. A suit in Illinois, for example, asserted that the Carle Foundation Hospital violated the Illinois Consumer Fraud and Deceptive Business Practices Act and breached the hospital's state law duty "to only charge people the fair and reasonable value of the services provided to them." *See* Press Release, Richard Scruggs, Class Action Lawsuit Filed by Uninsured Patients Against Carle Foundation Hospital in Illinois State Court (Jan. 24, 2005), http://www.cliffordlaw.com/not-for-profit-hospital-class-action-litigation/press-releases/class-action-lawsuit-filed-by-uninsured-patients-against-carle-foundation-hospital-in-illinois-state-court. In California, the plaintiffs alleged five state law causes of action: "violation of unfair competition law, violation of the consumers legal remedies act, unjust enrichment, breach of contract and breach of the covenant of good faith and fair dealing." *In re* Sutter Health Uninsured Pricing Cases, No. JC4388, 2005 WL 1842582, at *1 (Cal. Sup. Ct., July 16, 2005). Because these complaints were based on state law theories, the federal results were not necessarily indicative of favorable outcomes for the defendant hospitals in the state fora. For more on some of these various state-level regulatory schemes, see Part III, *infra*.

all, of these hospital systems chose to settle the plaintiffs' claims.[75] Although it is impossible to determine what the success of these state law-based actions would have been had they proceeded, the federal cases made it clear that any claims under the *federal* tax code will fail, and § 501(c)(3) may not be used to hold hospitals accountable for providing minimum amounts of free or discounted care.

II. STATUTORY AND REGULATORY REQUIREMENTS FOR FEDERAL TAX EXEMPTION UNDER § 501(C)(3) AND SUBSEQUENT IRS REVENUE RULINGS

This Part provides an overview of the statutory and regulatory framework governing federal tax exemption for not-for-profit hospitals. This Part also explains why any new criteria for hospital tax exemption may only be implemented via legislative reform or through a new IRS policy.

A. Statutory Obligations and Regulatory Interpretations of the "Charitable Purpose" Requirement

Under § 501(c)(3), not-for-profit entities are exempt from federal taxation requirements provided that they are "organized and operated exclusively for . . . charitable . . . purposes."[76] The provision further specifies various qualifying "exempt" purposes, including those that are "charitable." It is this "charitable" purpose criterion that governs exemption for not-for-profit hospitals. In recognition of the lack of statutory guidance regarding the meaning of this term, the IRS has issued a series of regulatory rulings clarifying what activities qualify as "charitable" for purposes of federal tax exemption. The regulatory requirements have changed dramatically over time. In 1956, in its first revenue ruling governing hospital qualification for tax exemption, the IRS required hospitals to provide health care services either free or at discounted prices.[77] Since then, however, policy statements have dramatically scaled back the requirements hospitals must meet in order to qualify as exempt organizations.[78]

In Revenue Ruling 56-185, issued in 1956, the IRS set forth four "general

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75. *See, e.g.*, Nie, *supra* note 27, at 193-94, 202-03; Cinda Becker, Patients Push for Price Data, MODERN HEALTHCARE, Nov. 20, 2006, at 6-7, 16; Mark Taylor, Legal Harbinger? Consumer Fraud Settlement May Lead to More, MODERN HEALTHCARE, June 20, 2005, at 8, 8; Press Release, Sarah Patterson, Executive Vice President, Va. Mason Med. Ctr., Statement on Settlement of Class Action Lawsuit (Nov. 2, 2006), https://www.virginiamason.org/home/body.cfm?xyzpdqabc=0&id=158&action=detail&ref=96.

76. 26 U.S.C. § 501(c)(3) (2000).

77. Rev. Rul. 56-185, 1956-1 C.B. 202 (establishing the "financial ability" standard).

78. *See, e.g.*, Rev. Rul. 69-545, 1969-2 C.B. 117 (articulating a less rigorous "promotion of health" standard); *see also* Colombo, *Exemption Policy*, *supra* note 9, at 437-38; Hanson, *supra* note 35, at 409-10; Mancino, *supra* note 35, at 9-11; Quirk, *supra* note 19, at 73-74.

requirements" that a health care organization was obligated to meet in order to be deemed "charitable" for federal tax exemption purposes.[79] For exempt health care providers, perhaps the most notable of these requirements was that a hospital must serve those who are unable to pay for health services, and not exclusively care for patients who can afford the costs.[80] Thus, the ruling effectively obligated hospitals to provide care either free or at below-cost rates; the extent of this obligation turned on the "financial ability" of the hospital to provide discounted services to those who could not pay. In what became known as the "relief of the poor" standard, the ruling also required that the organization "not . . . refuse to accept patients in need of hospital care who cannot pay for such services."[81]

The IRS qualified these seemingly stringent charity care obligations, however, cautioning that "[t]he fact that its charity record is relatively low is not conclusive that a hospital is not operated for charitable purposes to the full extent of its financial ability."[82] It seemed that even a relatively modest amount of charity care therefore might still be deemed to satisfy the "financial ability" standard such that a hospital would qualify for federal tax exemption. Such a provision may have seemed necessary in order to ensure that facilities would receive tax-exempt status even if they faced low market demand for discounted services in their particular community.[83]

In 1969, the IRS changed course, largely in response to demands from the hospital community that it accommodate the new federal Medicare and Medicaid programs.[84] The agency articulated a new standard that measured the

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79. Rev. Rul. 56-185, 1956-1 C.B. 202. Specifically, the ruling required that the institution be organized as a charitable organization that, to the extent of its financial ability, provides care for those unable to pay for services, and not only serve patients who are able to pay. The ruling also required that the hospital "have an open staff policy in that its facilities are not restricted to use or access by a particular group of physicians or surgeons" and that net earnings not "inure directly or indirectly to the benefit of any private shareholder or individual." *Id.*; *see also* Jack E. Karns, *Justifying the Nonprofit Hospital Tax Exemption in a Competitive Market Environment*, 13 WIDENER L.J. 383, 401 (2004).

80. Karns, *supra* note 79, at 401.

81. Bilimoria, *supra* note 35, at 135.

82. Rev. Rul. 56-185, 1956-1 C.B. 202.

83. *See* Karns, *supra* note 79, at 417-18. Presumably, this qualification was intended to accommodate hospitals located in relatively affluent areas that might not see as much community demand for free or discounted services.

84. When Congress began considering the Medicare and Medicaid legislation in the mid-1960s, exempt hospitals began to advocate for reconsideration of exemption standards, largely driven by fears that between private medical insurance and the new federal programs there would be insufficient demand for charity care to satisfy existing IRS standards. *See* Colombo, *Competitive Health Care Market*, *supra* note 35, at 625, 628 (explaining that the community benefit standard in Revenue Ruling 69-545 "emerged from the IRS largely as the response by a staff attorney at the

"community benefit" provided by the organization rather than simply the amount of discounted care provided. In Revenue Ruling 69-545, the IRS concluded that a hypothetical institution that did *not* provide free or discounted services to indigent patients nevertheless qualified for a tax exemption.[85] The agency grounded this conclusion in "the general law of charity," and the notion that the "promotion of health, like the relief of poverty and the advancement of education and religion, is one of the purposes in the general law of charity that is deemed beneficial to the community as a whole."[86] The hypothetical institution's mere "promotion of health" was therefore held to be a charitable purpose sufficient to qualify the provider for tax-exempt status.[87]

This landmark ruling moved away from a rigorous charity care requirement, offering a far more flexible standard than the one previously imposed by Ruling 56-185.[88] Hospitals were no longer obligated to provide charity care to non-emergent, indigent patients in order to qualify for federal tax exemption; in fact, an institution could admit only those who could pay for care and still retain its tax-exempt status. Also, a hospital could qualify for federal tax-exemption even when its annual revenues exceeded expenses and when its annual surplus was used for purposes other than to provide indigent patients with free care.[89]

The validity of Revenue Ruling 69-545's new, relatively lenient "community benefit" standard was quickly challenged in federal court by a class of indigent patients who had been refused medical treatment at tax-exempt hospitals due to their inability to pay. In *Eastern Kentucky Welfare Rights Organization v. Shultz*, the district court granted summary judgment to the plaintiffs, holding that the ruling was invalid and that exempt organizations remained obligated to admit and provide free services to indigent patients.[90] On appeal, the D.C. Circuit held that

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agency to complaints by nonprofit hospitals" that the new federal laws "would make charity care an anachronism").

85. Rev. Rul. 69-545, 1969-2 C.B. 117.

86. *Id.*

87. *Id.*; Karns, *supra* note 79, at 419; *see also* Aitsebaomo, *supra* note 35, at 82-83; Batchis, *supra* note 35, at 515-16; Bilimoria, *supra* note 35, at 135; William P. Gunnar, *The Fundamental Law that Shapes the United States Health Care System: Is Universal Health Care Realistic Within the Established Paradigm?*, 15 ANNALS HEALTH L. 151, 175 (2006).

88. Revenue Ruling 69-545 provided hospitals with the same favorable tax treatment they had received under the 1956 standard, without requiring them to engage in any charity care, as the old standard did. *See* Colombo, *Failure of Community Benefit*, *supra* note 22, at 30-31; Noble et al., *supra* note 18, at 118; Quirk, *supra* note 19, at 73-74; Rubinstein, *supra* note 35, at 396; Wood, *supra* note 26, at 715.

89. Karns, *supra* note 79, at 404.

90. E. Ky. Welfare Rights Org. v. Shultz (*Shultz*), 370 F. Supp. 325 (D.D.C. 1973), *rev'd sub nom.*, E. Ky. Welfare Rights Org. v. Simon (*Simon I*), 506 F.2d 1278 (D.C. Cir. 1974), *rev'd on other grounds*, Simon v. E. Ky. Welfare Rights Org. (*Simon II*), 426 U.S. 26 (1976).

the earlier, more stringent definition of "charitable" had to give way to the "changing economic, social and technological" realities of contemporary society.[91] Accordingly, the court upheld the 1969 ruling and confirmed that it superseded the more strict "relief of the poor" standard imposed by the 1956 policy.[92] Eventually, the case reached the U.S. Supreme Court, which reversed the judgment of the D.C. Circuit on unrelated grounds,[93] and directed the district court to dismiss the complaint.[94] As a result, both the 1956 and 1969 revenue rulings remained in place as originally issued by the IRS.

In 1983, the IRS modified the community benefit standard to clarify that the operation of an emergency room was only *one* of a number of factors that might demonstrate the hospital's benefit to the community and that having an operational emergency department was not a necessary criterion for tax exemption under § 501(c)(3).[95] The other requirements established by the 1969 ruling were unchanged, however; thus, the extent to which a hospital "promoted health" for the benefit of the community remained the governing standard for hospital tax exemption. Yet, the 1983 policy statement seemed to confirm the agency's continued move away from the focus on charity and indigent care initially imposed in the 1956 ruling.[96]

B. Evolution of the "Promotion of Health" Standard Through Regulatory Adjudications and Internal Enforcement Directives

From the late 1980s through the mid-1990s, the IRS retreated from the generous "promotion of health" standard established by the 1969 revenue ruling, primarily through a series of regulatory challenges to providers' tax-exempt status. Although the agency did not issue a new revenue ruling or otherwise revoke the 1969 policy, its enforcement actions against providers that offered little or no discounted care allowed the IRS to establish that, for all practical purposes, charity care is a determinative factor in consideration for tax

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91. *Simon I*, 506 F.2d at 1288.

92. *Id.*

93. *Simon II*, 426 U.S. at 37. The Supreme Court held that the federal courts should not have exercised jurisdiction because the plaintiffs lacked standing to sue, as they failed to establish that their alleged injuries were the consequence of the health care providers' actions.

94. *Id.* at 46.

95. Rev. Rul. 83-157, 1983-2 C.B. 94. Other "significant factors" included "a board of directors drawn from the community, an open medical staff policy, treatment of persons paying their bills with the aid of public programs like Medicare and Medicaid, and the application of any surplus to improving facilities, equipment, patient care, and medical training, education, and research." *Id.*; *see also* Karns, *supra* note 79, at 404, 421-23.

96. *See generally* Colombo, *Exemption Policy*, *supra* note 9, at 437-49; Mancino, *supra* note 35, at 12; Quirk, *supra* note 19, at 74-75.

exemption.[97] Thus, while the community benefit (or "promotion of health") test is still the official standard by which not-for-profit hospitals are evaluated for tax-exempt status, a series of administrative and judicial decisions has suggested that the most important factor in exemption decisions is the operation of a charity care program.[98]

The agency's own informal position statements, including internal memoranda and audit guidelines issued throughout the 1990s and early 2000s, reinforce the notion that charity care has become a major part of exemption analysis for health care providers.[99] A 2001 Field Service Advice (FSA) memorandum,[100] for example, stated that a provider's mere adoption of a charity care policy is insufficient; instead, hospitals must show that they provide a "reasonable amount" of charity care, that their charity care policy has been communicated to the public, and that charity care patients do not suffer routine discrimination.[101] Perhaps not surprisingly, the FSA cites no legal authority for its suggestion that § 501(c)(3) establishes a minimum charity care requirement but apparently relies only on the recent trend toward such a standard. In its 2002 *Healthcare Update*, a yearly tax policy review that serves as a guide to field agents, the IRS reaffirmed its position that enforcement agents should hold charity care to be central to exemption determinations.[102] Thus, by 2002, internal agency policy guidance confirmed that charity care remained a critical threshold

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97. In an article reviewing the history of the community benefit test, Professor Colombo explains the agency's effort to shift away from the text of the 1969 ruling toward a more aggressive standard, explaining that "the community benefit test as articulated in [the 1969] ruling has proven to be a complete failure" and has "failed as a legal test for tax exemption, having been virtually abandoned in practice by the courts and the IRS, who have pretty much morphed it back into a charity-care standard for exemption." Colombo, *Failure of Community Benefit*, *supra* note 22, at 29; *see also* Colombo, *Role of Access*, *supra* note 35, at 349-54 (reviewing IRS rulings and court decisions that suggest that ensuring equal access to care has been a central criterion for tax exemption).

98. *See, e.g.*, IHC Care, Inc. v. Comm'r, 82 T.C.M. (CCH) 617, 625 (2001) (enforcement action challenging the tax-exempt status of a corporate subsidiary of Intermountain Health Care in Utah); IHC Group, Inc. v. Comm'r, 82 T.C.M. (CCH) 606, 615 (2001) (same); IHC Health Plans v. Comm'r, 82 T.C.M. (CCH) 593, 594, 606 (2001) (same); Geisinger Health Plan v. Comm'r, 62 T.C.M. (CCH) 1656 (1991), *rev'd*, 985 F.2d 1210 (3d Cir. 1993) (enforcement decision denying exemption to a health maintenance organization). *But see supra* note 22.

99. *See* Colombo, *Failure of Community Benefit*, *supra* note 22, at 35.

100. Field Service Advice is an internal procedure by which the IRS Chief Counsel's office provides case-specific advice to field personnel. Daniel J. Wiles, *Taxpayer FSA Use*, TAX ADVISER, July 1, 2002, at 448.

101. I.R.S. Field Serv. Adv. 2001-10030, 2001 FSA LEXIS 1, at *2-3, *8-10 (Feb. 5, 2001).

102. Batchis, *supra* note 35, at 511. The update did, however, leave room for providers to argue that even though charity care was a "highly significant" factor in exemption decisions, it was not necessarily dispositive of tax-exempt status. *Id.*

inquiry for organizations seeking tax-exempt status, and without a demonstrated commitment to serving the indigent, a provider would face significant difficulty in obtaining exemption.

But the agency's ability to intensify its enforcement efforts and unilaterally hold providers to a higher standard (a minimum charity care requirement, for example) is limited. In 2002, a federal district court rejected the IRS's attempt to adopt a "financial ability to pay" standard, noting that "the government relies on this requirement as stated in Revenue Ruling 56-185," but Revenue Ruling 69-545 unambiguously "remov[ed] that requirement."[103] The Fifth Circuit's rebuke related to the IRS's decision in 2000 to revoke St. David's Health Care System's tax exemption after it forged a partnership with HCA, Inc., a for-profit health care company.[104] The IRS claimed that the partnership, combined with the fact that the hospital formally ceded control to the for-profit corporation, meant that the health care system could no longer qualify as a charitable entity under § 501(c)(3).[105] St. David's formally protested the IRS action and filed suit against the IRS to recover the money. During the course of litigation, the IRS asserted—consistent with the position it had held for over a decade—that a health care organization must maintain a charity care program in order to qualify for tax exemption.[106] This stance presented a nuanced but important change from the agency's earlier arguments in enforcement proceedings, however. The IRS also argued that charity care alone is not enough. The existence of a charity care program is irrelevant for determining tax-exemption, the government argued, if the hospital is controlled by a for-profit entity.[107] The government also asserted that the hospital's collection efforts bore on the factual question of whether the care provided was charitable, stating that "aggressive collection efforts can have a chilling effect on indigent patients, preventing them from seeking care even though a hospital has an 'open admissions' policy."[108] As collections are typically sought for bad debt, but not charity care, the government also contended that an exempt provider may not treat bad debt write-offs as charity care.[109] The

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103. *See* St. David's Health Care Sys. v. United States, No. Civ-A-01-CA-046-N, 2002 WL 1335230, at *4 (W.D. Tex. June 7, 2002), *vacated*, 349 F.3d 232 (5th Cir. 2003). On appeal, the Fifth Circuit also declined to adopt the position advocated by the IRS, largely ignoring the government's arguments about the issue of charity care. *St. David's Health Care Sys.*, 349 F.3d at 235-36; *see also* Quirk, *supra* note 19, at 81-83.

104. *St. David's Health Care Sys.*, 2002 WL 1335230, at *1.

105. *Id.*

106. Reply Brief for the Appellant, St. David's Health Care Sys. v. United States, 349 F.3d 232 (5th Cir. 2003) (Nos. 02-50959, 02-51312), 2003 WL 23411835, at *20 (contending that the "taxpayer should have a charity care plan and may not treat bad debt write-offs as charity care").

107. *Id.* at *10.

108. *Id.* at *21 n.8.

109. *Id.* at *21 ("For almost fifty years, the IRS has taken the position that bad debts are not

unstated implication of these arguments was that health care organizations would receive tax exemption only in exchange for care delivered for free or at a discounted rate and, critically, for which the hospital never made any attempt to seek full reimbursement.

The IRS cited *Eastern Kentucky Welfare Rights Organization* for the proposition that Revenue Ruling 69-545 did not overrule Revenue Ruling 56-185, but simply provided an "alternative" test for charitable status.[110] Through this claim, the agency effectively sought to hold health care providers to the "relief of the poor" standard first established in the 1956 ruling. But the district court, in no uncertain terms, rejected the IRS's argument, stating that the 1969 ruling was "far more relevant" than the 1956 test, because it was "undisputed" that the institution satisfied the criteria set forth in the 1969 ruling, which had eliminated "[t]he requirement of providing free or below-cost care."[111] The court further explained that "it is difficult to view 69-545 as anything but an overruling of 56-185 when the later ruling says that '56-185 is hereby modified.'"[112] Accordingly, the district court granted summary judgment in favor of the health system.[113]

On appeal to the Fifth Circuit, the government specifically disavowed any argument that hospitals were still obligated to meet the indigent care standard established by the 1956 policy and that health care institutions had to account in "any particular way" for uncompensated care.[114] These statements were undoubtedly responsive to the lower court's rebuke of the government's effort to distinguish the 1969 ruling and thereby establish an exemption standard that combined the indigent care requirement of Ruling 56-185 with the community benefit standard of Ruling 69-545. In dicta, the Fifth Circuit appeared to side with the lower court, specifically rejecting the notion that the institution's collections efforts "create[d] a genuine issue of fact as to whether the partnership facilities dispense charity care."[115]

C. Regulatory and Congressional Efforts To Establish a New Statutory Standard

In recent years, the IRS has focused primarily on charity care as a major

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charity care. Therefore, 'monthly' reports regarding 'uncompensated care' (which could be either bad debt or charity) are no substitute for the annual report regarding 'charity care' . . . .") (citations omitted).

110. *St. David's Health Care Sys.*, 2002 WL 1335230, at *3-4. See *supra* notes 90-94 and accompanying text for a discussion of *Eastern Kentucky Welfare Rights Organization*.

111. *St. David's Health Care Sys.*, 2002 WL 1335230, at *4.

112. *Id.*

113. *Id.* at *8.

114. Reply Brief for the Appellant, *supra* note 106, at *20-21.

115. St. David's Health Care Sys. v. United States, 349 F.3d 232, 236 n.3 (5th Cir. 2003).

component of exemption determinations, and no IRS ruling or court case in the past fifteen years has approved exemption for a health care provider that lacked a substantial charity care program.[116] Nevertheless, for the IRS, the 1969 Revenue Ruling establishes a clear rule on which third-party health care providers have relied.[117] For the IRS to enforce a definition of "charitable" that includes a new, minimum indigent care requirement, it would need to first expressly revoke or overrule Ruling 69-545's "promotion of health" (or "community benefit") test.[118]

Nevertheless, the IRS has begun to gather information from exempt hospitals to inform future decision-making. In April 2006, the agency announced that it would send questionnaires to approximately 600 hospitals "asking them to provide information on . . . how they meet the community benefit standards for purposes of § 501(c)(3)."[119] In February 2007, the agency released a set of nine voluntary governance guidelines addressing tax-exempt organizations, including hospitals (though the guidelines did not discuss factors that may be of particular relevance to health care providers, such as the role of a charity care policy in the exemption decision or the institution's billing and collections practices).[120] The guidelines encourage such organizations to adopt policies and procedures to ensure that their financial statements are "complete" and "accurate" and available to the public on request.[121]

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116. Colombo, *Failure of Community Benefit*, *supra* note 22.

117. *See supra* notes 22-23 and accompanying text.

118. The furthest courts appear comfortable deviating from the text of Revenue Ruling 69-545 is reflected in the Tenth Circuit's 2003 decision in IHC Health Plans, Inc. v. Comm'r, 325 F.3d 1188 (10th Cir. 2003), in which it adopted the IRS's "health care plus" formula. The court held that merely providing health services to all paying patients is insufficient to justify exemption; rather, not-for-profit institutions had to provide an additional "plus," such as charity care, health education, or health research programs. *Id.* at 1197; *see also* Colombo, *Competitive Health Care Market*, *supra* note 35, at 626; Quirk, *supra* note 19, at 79-80. Thus, the court denied exemption to an HMO whose membership was open to everyone in the community because the organization did not have any of those "pluses." *IHC Health Plans*, 325 F.3d 1188; *see also* Colombo, *Competitive Health Care Market*, *supra* note 35, at 626.

Notably, the IRS's revised Form 990 and its associated schedules do *not* alter the definition of "charitable." The new Schedule H only gathers information from tax-exempt hospitals about charity care, benefits to the community, calculation of bad debt expense, and emergency department policies and procedures. *See* IRS Releases Final 2008 Form 990, *supra* note 24; *see also Final Form 990, Schedule H Reflects Many Changes Favored by Hospitals*, AHA NEWS, Jan. 7, 2008, at 1, 1 [hereinafter *Final Form 990*].

119. Gerald M. Griffith et al., *IRS To Send Community Benefit Questionnaires to 600 Hospitals Nationwide,* MONDAQ, Apr. 26, 2006, *available at* http://www.mondaq.com/article.asp?articleid=39354.

120. Internal Revenue Serv., Good Governance Practices for 501(c)(3) Organizations, Feb. 7, 2007, http://www.aha.org/aha/content/2007/pdf/501c3org-goodgovpract.pdf.

121. *Id.*

Several months later, in June 2007, the IRS released draft revisions to Form 990 and its accompanying Schedules, the forms that tax-exempt hospitals must file annually with the IRS.[122] After receiving numerous comments from the hospital community and Congress on its draft proposal, the IRS issued the revised Form 990 in December 2007.[123] The new Schedule H applies solely to tax-exempt hospitals and establishes a uniform framework for how hospitals nationwide must report aggregate community benefit and related information on billings and collections, including data on charity care, benefits to the community, "community building" activities, Medicare underpayments, bad debt expenses, and emergency department policies and procedures.[124] The new form was supported by Senator Grassley, one of the most vocal critics of the non-profit hospital industry and the ranking member of the Senate Finance Committee, which oversees tax-exempt policy. Senator Grassley said the new form will promote transparency and enable comparisons of community benefit provision across not-for-profit hospitals.[125]

Even absent more drastic action by the IRS—issuance of a new revenue ruling, for example, or revocation of the 1969 standard—a possibility exists that Congress may nevertheless impose a minimum charity care obligation on hospitals. Both the House and Senate have launched investigations into hospital tax exemption, with the stated long-term goal of clarifying standards for hospital exemption under § 501(c)(3).[126] The congressional attention to hospital charity care standards began in the summer of 2003, when the House Energy and Commerce Committee commenced an investigation of hospital billing and collections practices, sending letters to hospitals and health systems containing detailed questions about their charity care policies.[127] In June 2004, a subcommittee of the Energy and Commerce Committee held a hearing on the same issue.[128] Nearly a year later, the committee sent additional requests for information to ten leading hospitals, seeking to understand how hospital charges are presented to, explained to, and understood by medical consumers, and also requesting explanations of how patients are affected by hospital charges.[129]

The House Ways and Means Committee has also been active in investigating

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122. Form 990 Redesign, *supra* note 24.

123. IRS Releases Final 2008 Form 990, *supra* note 24. *See generally supra* note 24 and accompanying text.

124. *See* Internal Revenue Serv., Form 990 Redesign for Tax Year 2008: Schedule H, Hospitals – Highlights, Dec. 20, 2007, http://www.irs.gov/pub/irs-tege/highlights_schedule_h.pdf.

125. *Final Form 990*, *supra* note 118, at 3.

126. *See supra* note 19.

127. Cohen, *supra* note 8, at 114.

128. *A Review of Hospital Billing and Collections Practices: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 108th Cong. 1 (2004).

129. Cohen, *supra* note 8, at 117-18.

hospital exemption; in December 2006, the Congressional Budget Office released a report requested by the committee's then-Chairman Bill Thomas regarding the community benefit provided by not-for-profit hospitals.[130] The House Ways and Means Subcommittee on Oversight also held a hearing on tax-exempt organizations in July 2007, with the stated intent of reviewing "charities' efforts to assist diverse communities" including "activities and measures" taken by not-for-profit organizations "for ensuring public accountability and good governance."[131]

The Senate has also initiated investigations of its own. In May 2005, then-Chairman of the Senate Finance Committee Charles Grassley sent letters to not-for-profits demanding that they justify their federal tax exemptions.[132] Senator Grassley sought information on the IRS's review and enforcement activities regarding tax-exempt hospitals in the spring of 2006.[133] At the behest of the Finance Committee, the Treasury Inspector General for Tax Administration began to review the IRS's planned actions regarding the community benefit standard and, in March 2007, recommended that the IRS present its plans to address the community benefit standard in its July 2007 interim report.[134]

Members of both the House and the Senate have sent strong signals that new legislation may be forthcoming. Representative Thomas proposed the Tax Exempt Hospitals Responsibility Act of 2006 in December 2006; the bill would impose penalties on not-for-profit hospitals that fail to deliver a minimum level

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130. CONG. BUDGET OFFICE, *supra* note 19.

131. Press Release, H. Comm. on Ways & Means Subcomm. on Oversight, Lewis Announces Overview Hearings on Tax-Exempt Charitable Organizations (July 9, 2007), http://waysandmeans.house.gov/hearings.asp?formmode=view&id=6224.

132. Quirk, *supra* note 19, at 88-89.

133. *IRS Tax-Exempt Info Sought by Grassley*, AHA NEWS, June 12, 2006, at 6.

134. TREASURY INSPECTOR GEN. FOR TAX ADMIN., TAX-EXEMPT HOSPITAL INDUSTRY COMPLIANCE WITH COMMUNITY BENEFIT AND COMPENSATION PRACTICES IS BEING STUDIED, BUT FURTHER ANALYSES ARE NEEDED TO ADDRESS ANY NONCOMPLIANCE (2007), *available at* http://www.treas.gov/tigta/auditreports/2007reports/200710061fr.pdf. The IRS responded and, in its July 2007 report, the agency summarized hospital responses to its May 2006 questionnaire. INTERNAL REVENUE SERV., EXECUTIVE SUMMARY: HOSPITAL COMPLIANCE PROJECT INTERIM REPORT (2007), *available at* http://www.aha.org/aha/content/2007/pdf/070719-IRSReport.pdf. The agency determined that 97% of respondents provided uncompensated care to the community. *Id.* at 3. It also determined that those institutions reported providing $9.3 billion in community benefit expenditures. *Id.* at 48. The study reported that the mean percentage of total revenues spent by the 487 hospital respondents on potential community benefit expenditures was 8.8%, and the median percentage of total revenues spent on all community benefit expenditures by those institutions was 5.4%. *Id.* at 50. Over 20% reported spending less than 2% of total revenue on community benefit, however, and a little more than half of the institutions spent more than 5% on community benefit. *Id.* at 50.

of charity care.[135] In July 2007, the Republican minority staff on the Senate Finance Committee issued a "discussion draft" on potential reforms for not-for-profit hospitals.[136] The draft recommended that hospitals seeking exemption under § 501(c)(3) be required to conform to new standards regarding, in part, 1) the creation and publication of charity care policies, 2) "quantitative" (i.e., percentage-based) standards for charity care, 3) "limiting charges billed to the uninsured," 4) "curtailing unfair billing and collection practices," 5) "transparency and accountability requirements," and 6) "sanctions for failure to comply."[137] Significantly, the minority staff draft suggested abolishing the community benefit standard for tax exemption[138] and replacing it with a percentage-based test for charity care—the very kind of test that was rejected by the courts and Congress in the 1960s.[139]

All of these efforts—both congressional and administrative—indicate that a new tax exemption standard for not-for-profit health care providers may be forthcoming.[140] Providers are bracing for this event, though many are hoping to forestall the congressional reform proposals through enhanced lobbying efforts. Hospitals have lodged strenuous objections to the minority staff discussion draft through the American Hospital Association (AHA). In October 2007, an AHA board member spoke at the Senate Finance Committee roundtable meeting and warned that the discussion draft presented "problematic" proposals.[141] He was particularly critical of a recommendation that would require hospitals to dedicate a minimum of 5% of their operating expenses to charity care in order to maintain tax-exempt status; he warned that such a requirement "will not capture the many contributions that hospitals make to those they serve."[142]

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135. H.R. 6420, 109th Cong. (2006); Kane, *supra* note 35, at 461.

136. SENATE COMM. ON FINANCE—MINORITY, TAX-EXEMPT HOSPITALS: DISCUSSION DRAFT (2007), *available at* http://finance.senate.gov/press/Gpress/2007/prg071907a.pdf. This draft was apparently the product of a Finance Committee hearing held in September 2006 when Senator Grassley, the ranking member of the Republican minority in July 2007, was still the chairman of the Committee. Cinda Becker, *Community Center of Attention; IRS, Finance Poised To Pounce on Tax-Exempt Status*, MODERN HEALTHCARE, July 23, 2007, at 8.

137. SENATE COMM. ON FINANCE—MINORITY, *supra* note 136, at 3, 7.

138. *Id.* at 3 (stating that the proposal would replace Rev. Rule 69-545, which articulates the community benefit test).

139. *Id.* at 7 (proposing a percentage-based standard).

140. Kane, *supra* note 35, at 461 (stating that "the federal government is likely to pass a bill in the near future").

141. Nicholas Wolter, AHA Statement for the Roundtable on the Senate Finance's Minority Staff Discussion Draft (Oct. 30, 2007), *available at* http://www.aha.org/aha/testimony/2007/071030-tes-senate-finance.pdf.

142. *Id.* The statement likely references services such as health education, screening programs, support groups, health promotion events, and clinic services for indigent populations. *See, e.g.*, Sister Carol Keehan, Commentary, *Charitable Formula: Catholic Hospitals More Clearly Define*

The evidence to date indicates that the hospital lobbying efforts have been effective. Notably, more than five years after the *Wall Street Journal* placed the spotlight on non-profit hospitals, Congress has not passed any major reforms. In addition, more than 300 members of the House called for improvements to the IRS's proposed new Schedule H because of the "unnecessary reporting burdens" it imposed on hospitals. In response, the IRS did in fact remove the most objectionable portions of the Schedule in its final draft, including a section on hospital billing information. The IRS also agreed to give hospitals a year before they will be required to submit the information contained in Schedule H.[143] Despite this initial success, however, the investment that both houses of Congress have made to investigate hospital tax exemption suggests that legislators will not abandon the issue easily. Thus, even if the IRS's revised forms prove helpful in ameliorating legislators' concerns about the tax-exempt hospital industry, hospitals may still face an uphill battle in their efforts to convince federal lawmakers that new exemption criteria are unnecessary.[144]

III. IMPOSING A HEIGHTENED CHARITY CARE REQUIREMENT: LESSONS FROM THE STATES

Although it is clear that federal lawmakers are contemplating new exemption criteria, it is far less clear how effective a new standard would be. In fact, it is entirely possible that even a minimum charity care requirement might do little to enhance the amount of free care and other health-related services not-for-profit hospitals provide their communities. To understand this claim, it is instructive to first assess state legislative reforms regarding the tax-exempt hospital sector.[145]

How They Measure Community Benefit, MODERN HEALTHCARE, June 26, 2006, at 18 [hereinafter *Charitable Formula*]. It may also encompass the common view among hospital executives that bad debt and Medicare shortfalls should be included within community benefit calculations. *See* Kane, *supra* note 35, at 465-66.

143. *Final Form 990*, *supra* note 118; Letter from Rick Pollack, *supra* note 27.

144. It is far too early to determine if the revised Form 990 and Schedule H will delay or even ward off additional, congressionally-imposed changes to existing requirements for not-for-profit hospitals.

145. Most of these efforts occurred in the late 1980s and early 1990s. *See* Colombo, *Competitive Health Care Market*, *supra* note 35, at 627; Colombo, *Exemption Policy*, *supra* note 9, at 443. I do not address very recent state legislative efforts to ensure that all citizens receive minimum amounts of health care through state-run universal insurance coverage. Massachusetts launched a landmark reform effort in 2007 that requires most uninsured adults in the state to have insurance coverage and provides free or subsidized insurance for the lowest income population. Other states are contemplating similar reforms. DRAPER & GINSBURG, *supra* note 5, at 5-6.

A. State-Level Reforms

In 1993, Texas became the first state to pass legislation requiring hospitals to allocate a specific percentage of hospital revenues for charity care and community benefit.[146] Under the Texas statute, to qualify for tax-exempt status, a hospital must provide community benefits. The exact amount of the benefits must reflect: 1) a level reflective of a community needs assessment; 2) an amount equal to or at least 100% of the hospital's or system's tax-exempt benefits; or 3) an amount equal to at least 5% of the institution's net patient revenue.[147]

Only a few other states, such as Pennsylvania, Utah, and West Virginia, have passed similarly prescriptive statutes requiring hospitals to provide a minimum amount of community benefit (and threshold amount of charity care) in exchange for state and local tax exemptions.[148] In Illinois, legislators passed a law requiring community benefit reporting in 2003.[149] Several years later, during the 2006 legislative session, the state Attorney General proposed a far more rigorous standard, one that would mandate that hospitals commit 8% of their annual operating costs to charity care. But the Attorney General later withdrew the proposal in order to allow her to discuss the merits of the proposal with representatives from the state hospital association.[150] Lawmakers also proposed regulations in Rhode Island that would require that 1% of net patient revenue should be used for charity care purposes, though the final rules did not reflect this proposal.[151]

Although many of the proposals that would require a minimum level of

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146. TEX. TAX CODE ANN. § 11.1801 (Vernon 2008). The Texas law applies to those hospitals that wish to qualify as charitable organizations and thus receive exemptions from state property taxes. *See* Bilimoria, *supra* note 35, at 137; Burns, *supra* note 29, at 680; Hanson, *supra* note 35, at 399; Wood, *supra* note 26, at 725.

147. TEX. TAX CODE ANN. § 11.1801 (Vernon 2008).

148. Batchis, *supra* note 35, at 511; Cinda Becker, *Charitable Intentions: CHA, VHA Unveil Community-Benefit Guidelines Developed To Help Not-for-Profit Hospitals Justify Tax Exemptions*, MODERN HEALTHCARE, June 5, 2006, at 6.

149. Kane, *supra* note 35, at 460.

150. SENATE COMM. ON FINANCE—MINORITY, *supra* note 136, at 9 n.22; Colombo, *Exemption Policy*, *supra* note 9, at 444 (citing Shruti D. Singh, *Madigan To Negotiate Terms of Charity Care Bill—To a Point*, CHICAGO BUS., Apr. 26, 2006, http://www.chicagobusiness.com/cgi-bin/news.pl?post_date=2006-04-26&id=20365).

151. DEPARTMENT OF HEALTH, STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS, RULES AND REGULATIONS FOR LICENSING OF HOSPITALS, R23-17-HOSP, §§ 1.6, 8.7, 8.8 (2007), *available at* http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/4895.pdf; SENATE COMM. ON FINANCE—MINORITY, *supra* note 136, at 10; DEP'T OF HEALTH, STATE OF R.I. & PROVIDENCE PLANTATIONS, RULES AND REGULATIONS FOR LICENSING OF HOSPITALS, R23-17-HOSP, §§ 1.6, 8.7, 8.8 (2007), *available at* http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/4895.pdf.

community benefit have not passed into law,[152] legislators in numerous other states have taken a more process-oriented approach to enhancing charity care.[153] While the laws do not impose minimum charity care obligations, they do require not-for-profit health care institutions to conduct community health needs assessments and to develop community health benefit plans in return for state and local tax exemptions.[154] In addition, these laws often require that hospitals report the amount of charity care they provide to the state agency responsible for regulating the health care sector.[155]

Using yet another strategy, other state legislatures have proposed various measures to restrict hospitals' current financial billing and collection practices.[156] Rather than regulating hospital charity care at an organizational level, these states directly regulate hospital interactions with individual uninsured patients. In Connecticut, for example, recently passed laws prevent hospitals from collecting more than the cost of care from patients that meet a statutory definition of "uninsured." The law also imposes collection restrictions, limiting the extent to which hospitals may levy on or execute against a patient's property.[157]

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152. Kane, *supra* note 35, at 461.

153. Colombo, *Competitive Health Care Market*, *supra* note 35, at 627; Hanson, *supra* note 35, at 399.

154. *Hanson*, *supra* note 35, at 399. A community benefit plan (CBP) sets forth how an institution will "serve the community's health care needs," as determined by community-wide needs assessments. *See, e.g.*, TEX. HEALTH & SAFETY CODE ANN. §§ 311.041 to .048 (Vernon 2008); TEX. TAX CODE ANN. § 11.1801 (Vernon 2008). Indiana, for example, passed legislation requiring "enhanced financial reporting" and the development of CBPs. Noble et al., *supra* note 18, at 123-28; Wood, *supra* note 26, at 723-24. The state's reporting requirements are intended to capture and make available to the public specific information about levels of charity and government-sponsored indigent care provided by local hospitals. Noble et al., *supra* note 18, at 123-28; Wood, *supra* note 26, at 723-24. The New York legislature began to require submission of an annual Community Service Plan (CSP) in 1991 and, since 1996, has required that hospitals file CSPs every three years. Noble et al., *supra* note 18, at 123-28; Wood, *supra* note 26, at 723-24. Since 1994, the California legislature has also required not-for-profit hospitals to develop annual CBPs and to conduct community needs assessments, which are reported annually to the state. Noble et al., *supra* note 18, at 123-28; Wood, *supra* note 26, at 723-24. Massachusetts and Missouri have created reporting systems that "encourage" hospitals to voluntarily report the community benefits they provide in order to promote uniform standards for the hospital industry. Noble et al., *supra* note 18, at 123-28; Wood, *supra* note 26, at 723-24. Finally, states such as Virginia, Montana, North Carolina, and South Carolina have taken a different approach, and often condition approval of certain transactions or certificate-of-need applications on whether hospitals provide a "reasonable amount" of care to the poor. Noble et al., *supra* note 18, at 123.

155. Colombo, *Competitive Health Care Market*, *supra* note 35, at 627; Wood, *supra* note 26, at 723.

156. Jacoby & Warren, *supra* note 11, at 541 & nn.42-47.

157. *Id.* at 540-41.

B. State Efforts Achieve Limited Success

Academics and industry experts have criticized most of the state-level approaches as ineffective in actually enhancing levels of discounted or free care.[158] The relatively lax reporting requirements often add little transparency to the process of indigent care delivery, and, due to a lack of resources devoted to oversight, many statutes have effectively become self-reporting mechanisms, rather than true regulatory enforcement tools.[159]

Under the most prevalent strategy, in which state laws mandate that hospitals conduct community health assessments and draft community benefit plans,[160] the reports generated often receive little attention from state officials, likely due to a lack of sufficient funding for officials to properly evaluate and audit the data that is submitted.[161] When reports *are* read by state officials, they may be of little value, as they may lack depth, or the attached financial statements may have inconsistencies in data reporting.[162] Making matters worse—and severely undermining regulators' ability to monitor hospital performance—the states that

158. *See* Hanson, *supra* note 35, at 406; Noble et al., *supra* note 18, at 131-32; Wood, *supra* note 26, at 733-34. The research to which much of the commentary cited in this section is directed was performed by health care finance experts Alice Noble, Andrew Hyams, and Nancy Kane. *See* Noble et al., *supra* note 18. Those researchers continue to cite their 1998 study findings as valid and maintain that states have had limited success in strengthening standards for state and local tax exemptions. Thus, although their research may be somewhat dated, it remains one of the most comprehensive efforts to assess state-level reform efforts related to not-for-profit hospitals, and academics continue to rely on it. *See, e.g.*, Aitsebaomo, *supra* note 35; Bilimoria, *supra* note 35; Burns, *supra* note 29; Wood, *supra* note 26. That said, more recent research also supports the early findings that state laws have not achieved great success. A 2006 empirical study of state community benefit laws concluded that community benefit laws were *not* effective in compelling or inducing hospitals to offer significantly more health promotion services, though the laws were effective in compelling a subset of not-for-profit hospitals to report increased community orientation (the use of community intelligent to address present and future community health needs), and the laws also resulted in a net decrease in differences between not-for-profit and investor-owned facilities. Gregory O. Ginn & Charles B. Moseley, *The Impact of State Community Benefit Laws on the Community Health Orientation and Health Promotion Services of Hospitals*, 31 J. HEALTH POL. POL'Y & L. 321 (2006).

159. *See, e.g.*, Ginn & Moseley, *supra* note 158, at 341 ("Whatever penalties may be associated with noncompliance, there is not much evidence that any of these laws are strongly enforced. Indeed, some states do not have laws but only voluntary guidelines.").

160. Noble et al., *supra* note 18, at 123-28; Wood, *supra* note 26, at 723-24; *see also*, CAL. HEALTH & SAFETY CODE §§ 127340-127365 (West 2008); IND. CODE ANN. § 16-21-6-6 *et seq.* (West 2007); N.Y. PUB. HEALTH LAW § 2803-*l* (McKinney 2008).

161. Hanson, *supra* note 35, at 406-07; Noble et al., *supra* note 18, at 123-28; Wood, *supra* note 26, at 733-36.

162. Wood, *supra* note 26, at 735.

have adopted these reforms may lack uniform quantitative and qualitative standards for determining what constitutes a community benefit across different hospitals.[163] In Texas, for example, which requires hospitals to file an Annual Statement of Community Benefits Standard documenting compliance with the state's statutory charity care requirement, not only is the state agency responsible for monitoring compliance unable to compare community benefit information to other hospital financial data due to definitional differences and varying timing for reports, but because the definitions for critical reporting terms have changed over time, regulators are unable to effectively track hospital performance over time.[164] This lack of uniform, consistent, and easy to scrutinize data may allow hospitals with poor revenue collection processes or inflated charges to appear to provide higher levels of charity care than their peers.[165] Thus, as Professor Nancy Kane summarized in her testimony before the House Ways and Means Committee: "[A]mbiguous state standards of community benefit, coupled with limited resources for monitoring and enforcement, have hampered state efforts to increase the provision of charity care by exempt hospitals."[166]

Even Texas-style requirements that all hospitals commit to delivering a set amount of charity care are subject to criticism and may be fraught with pitfalls. Indeed, the many secondary questions such approaches generate reveal that they do not present the panacea that many legislators might initially hope. Although fixed standards may provide an "objective tool for determining whether nonprofit hospitals are satisfying their respective obligation to the communities they serve,"[167] they also may impose a disproportionate burden on smaller hospitals or single-facility institutions located in rural areas or lower socio-economic neighborhoods.[168] By contrast, the ability of some systems to report community benefits at aggregate levels (accounting for multi-hospital systems in one report) may mask lower amounts of care provided by hospitals located in more affluent settings.[169] Furthermore, the implementation of strict charity care standards requires that legislators confront significant practical hurdles and make difficult policy decisions. John D. Colombo, an expert in hospital tax exemption, highlighted some of these difficult policy choices:

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163. Noble et al., *supra* note 18, at 128-29.

164. *Id.* at 129.

165. Wood, *supra* note 26, at 735-36. In fact, Texas legislators explicitly created such a loophole in the state's charity care statute by amending the law in 1995 to allow the inclusion of bad debt in annual charity care reports. Noble et al., *supra* note 18, at 129.

166. *Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 118 (statement of Nancy M. Kane, Professor of Mgmt., Harvard Sch. of Pub. Health).

167. *Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 99 (statement of John T. Thomas, Senior Vice President, Baylor Health Care Sys.).

168. Noble et al., *supra* note 18, at 130; Wood, *supra* note 26, at 736.

169. Wood, *supra* note 26, at 736-37.

> whether to measure charity care on the basis of costs or charges, and if on costs, whether to use marginal or average costs; what the minimum level of charity care would be to justify exemption; whether that minimum level would have to be in excess of what for-profits write off each year in bad debt (since presumably this is the baseline of "free care" that is being provided by the for-profit providers without tax exemption); and whether nonprofits should have to separate "true" charity care from bad debt in making a charity care measurement (e.g., whether the measurement should be total uncompensated care or a more narrow subset of uncompensated care involving up-front decisions that a patient is a "charity" patient and will not be charged for service).[170]

An effort to impose a federal minimum charity care requirement—whether initiated by Congress or by the IRS—would face similar obstacles and therefore might encounter a significant uphill battle to passage.[171] As Professor Colombo notes, the policy issues he identifies "certainly can be resolved." But doing so will not be easy, and would likely generate lengthy, and perhaps intractable, debate.[172] Moreover, enforcement costs would also undoubtedly be high, perhaps prohibitively so, particularly given that the IRS already receives inadequate funding to review hospital finance data..[173] Professor Nancy Kane reported, for example, that "[f]rom 1996 through 2001, staffing for the tax-exempt division of the I.R.S. fell by 15%, while the number of Form 900s filed by charities increased by 25%. The Form 990 examination rate for all charities was less than

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170. *Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 90 (statement of John D. Colombo, Professor, Univ. of Ill. Coll. of Law) (internal citations omitted). As noted above, *see supra* note 165, Texas legislators chose to include bad debt within the state's charity care requirement.

171. For a discussion of the hospital industry's political influence, see *supra* note 27.

172. *Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 90 (statement of John D. Colombo, Professor, Univ. of Ill. Coll. of Law).

173. *See* Kane, *supra* note 35, at 470 ("The I.R.S. receives Form 990 filings from hospitals every year, but it lacks the resources to even review the forms, much less determine whether or not the content is valid or the reported activities appropriate."); *see also* James J. Fishman, *Wrong Way Corrigan and Recent Developments in the Nonprofit Landscape: A Need for New Legal Approaches*, 76 FORDHAM L. REV. 567, 588 (2007) (commenting that "[i]t is doubtful that the IRS will be given sufficient resources to substantially improve its oversight capacity" of exempt institutions); Marion Fremont-Smith, *The Search for Greater Accountability of Nonprofit Organizations: Recent Legal Developments and Proposals for Change*, 76 FORDHAM L. REV. 609, 641 (2007) (noting consensus among scholars that funding for IRS administration of the tax-exemption provisions is already inadequate); Quirk, *supra* note 19, at 101 (lauding the Texas charity care law but acknowledging that "instituting a federal standard similar to the Texas statute may necessitate additional oversight and record keeping by the IRS").

1% over that period."[174] In short, even if a uniform, federal charity care mandate did provide an "administrable standard of accountability"[175] that invited straightforward comparisons across institutions, it is possible that a poorly enforced regulation seeking to standardize complex not-for-profit finance metrics would do little to drive change in the day-to-day operations of not-for-profit health care organizations.[176]

IV. VOLUNTARY CHANGES AND PROPOSALS FOR LEGISLATIVE REFORM

A. Voluntary Reforms to Charity Care Policies and Billing Practices

Providers acknowledge the need for reforms to hold hospitals more accountable for delivering community benefit services, but they are nevertheless quick to note that they have already made a number of voluntary reforms to their charity care policies and have substantially curbed overly aggressive billing and collections practices.[177] A 2005 study by PriceWaterhouseCoopers supports this claim; the firm found "that nearly 70 percent of hospitals had voluntarily revised their charity care policy within the last year."[178] It reported that "[i]n almost every case, the change was to expand eligibility" for charity care, and that "[m]any hospitals also instituted sliding scale discounts or made existing sliding scale discounts more liberal."[179] The study also found that many hospitals had moved toward flat-fee discounts for uninsured patients who did not qualify for free care, charging uninsured patients at rates equivalent to those applied to bills for Medicare or managed care patients.[180] By expanding eligibility for charity care programs and changing their billing policies to offer greater discounts to uninsured patients, hospitals both expanded access to care for uninsured patients and ensured more consistent delivery of community benefit to this population.

Many institutions made these changes in response to intense public criticism

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174. *See* Kane, *supra* note 35, at 470.

175. *Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 90 (statement of John D. Colombo, Professor, Univ. of Ill. Coll. of Law).

176. *See* Kane, *supra* note 35, at 470. Of course, as noted previously, a strict charity care standard might ensure that hospitals satisfy their obligations to taxpayers to provide a sufficient amount of community benefit in exchange for tax exemption. *See supra* notes 31-34 and accompanying text.

177. *See Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27, at 103 (statement of Sister Carol Keehan, Chair, Bd. of Trs., Catholic Health Ass'n).

178. HEALTH RESEARCH INST., PRICEWATERHOUSECOOPERS, ACTS OF CHARITY: CHARITY CARE STRATEGIES FOR HOSPITALS IN A CHANGING LANDSCAPE 15 (2005).

179. *Id.*

180. *Id.* at 15-17.

of their own practices. They found themselves as defendants—or potential defendants—in the recent wave of federal litigation.[181] Others simply felt the aftermath of the lawsuits, as their communities began to also question whether local hospitals made adequate efforts to ensure access to care for the uninsured—and whether, therefore, those institutions remained deserving of local and state tax exemptions.[182] Thus, such hospitals may have developed more clear charity care policies in order to preempt state legislation.[183]

Examples abound nationwide. The Center for Studying Health System Change reported that, in each of the twelve nationally-representative communities it studies, most hospitals have "many hospitals have modified billing and collection practices, for low income, uninsured patients."[184] Most hospitals interviewed through the Center's research also increased the income threshold at which the organization provides full charity care or discounted services. North Shore-Long Island Jewish Health System provides reduced fees to patients earning up to 300% of the federal poverty level.[185] Baptist Health System of South Florida increased its charity care income threshold from 200-300% of the national poverty level and reports that it is considering increasing charity care eligibility to 500% of the poverty level.[186] Other providers have developed prompt-pay discounts for self-pay patients; these discounts may bring prices down to the level of rates negotiated with major private insurers or government reimbursement programs.[187]

National and state-level provider associations have strongly encouraged these reform efforts by issuing recommendations and guidelines regarding provider billing and collection polices.[188] The AHA suggested that its members

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181. *Id.* at 1, 15-17; STAITI ET AL., *supra* note 25. While plaintiffs suing not-for-profit hospitals have so far fared poorly in federal courts, providers may have continued to reform their billing and collections procedures—and publicize their new practices—in part to avoid litigation in state forums. *See supra* note 74 and accompanying text.

182. *See infra* notes 233-238 and accompanying text.

183. See STAITI ET AL., *supra* note 25, at 3, for descriptions of some of the varying approaches taken by health care providers. Some received publicity on the changes they have made. *Id.* at 4.

184. STAITI ET AL., *supra* note 25, at 1; *see also* Press Release, Ctr. for Studying Health Sys. Change, Hospitals Alter Billing and Collection Practices for Uninsured Patients (Oct. 12, 2005), http://www.hschange.org/CONTENT/789/.

185. North Shore-Long Island Jewish Health Sys., Financial Assistance Program, http://www.northshorelij.com/body.cfm?id=1361 (last visited Mar. 23, 2008).

186. STAITI ET AL., *supra* note 25, at 2.

187. *Id.*

188. Of course, the fact that hospital associations have adopted guidelines or recommendations does not ensure that the member hospitals in fact follow the recommended practices. It is in the associations' interests to adopt such policies and advertise that fact when lobbying members of Congress or defending their member institutions to the public. The associations may be particularly

clearly state their charges to patients before treatment, work to identify patients that might qualify for free or discounted care, and cease harsh collection tactics.[189] It also encouraged hospitals to communicate clearly with patients about charges, counsel low-income and uninsured patients about payment options, assist such patients in applying for free or discounted care, double-check bills as a way to make sure they are fair, and pursue patient accounts in a fair manner.[190] The AHA also strongly urged hospitals to report the full value of the community benefit they provided—including "bad debt and the unpaid costs of government-sponsored health care—in part so "that the information could be shared with elected officials and government agencies."[191] Initial results indicate that AHA's guidelines have been adopted by 3000 of its member hospitals.[192]

State hospital associations, too, have published billing and collections guidelines for not-for-profit hospitals and urged more generous financial aid policies for uninsured patients.[193] The Healthcare Association of New York State, for example, recommended that not-for-profit hospitals establish policies to financially assist all patients below 200% of the federal poverty level, as well as offer sliding-scale discounts to indigent patients who earn more than the federal poverty level.[194] The Association also suggested that hospitals charge uninsured patients the same rates provided to Medicaid or private insurers and then offer to educate patients about their billing policies.[195] Finally, it advocated against foreclosure on patients' primary residences and requested that hospitals not garnish patients' wages unless the hospitals had evidence that patients are able to pay the bills.[196] State hospital associations in California, Oregon, Illinois, and Tennessee have urged their members to adopt similar billing and collection guidelines.[197]

Although providers have not made the argument explicitly, one might read the reported adoption of these voluntary guidelines to indicate that additional regulatory or statutory reforms are unnecessary to improve the actual amount of

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attuned to the impact a public relations strategy may have given that many attribute the recent attention to hospital billing and pricing practices to the 2003 *Wall Street Journal* articles. *See, e.g.*, Cohen, *supra* note 8, at 105; Colombo, *Exemption Policy*, *supra* note 9, at 442-43; Kane, *supra* note 35, at 459.

189. Batchis, *supra* note 35, at 538-39; Cohen *supra* note 8, at 139.

190. Cohen, *supra* note 8, at 139.

191. *Hospitals Urged To Report Dollar Value of Their Community Benefit*, AHA NEWS, Nov. 13, 2006, at 1, 3.

192. Cohen, *supra* note 8, at 139.

193. *Id.* at 139-40 nn.271-76; Jacoby & Warren, *supra* note 11, at 541 & n.49.

194. Cohen, *supra* note 8, at 139-40 (citation omitted).

195. *Id.*

196. *Id.*

197. *Id.* at 140.

community benefit delivered by not-for-profit hospitals.[198] As this argument would go, providers have already made sufficient improvements, and further regulatory or legislative efforts would merely duplicate voluntary reforms. Moreover, one might argue that hospital associations have become more attuned to the attention their member institutions have received from trial attorneys, government officials, and the media, and that they will ensure that their member institutions follow the recommended guidelines. But those arguments hinge on the theory that the current public attention to hospitals will last indefinitely, or, if it does not, then providers will have other incentives to sustain recently implemented reforms. But however powerful they may be for public relations purposes, the "recommended guidelines" that associations have promulgated are non-binding and cannot, themselves, drive actual operational changes in hospitals. One must also be skeptical of what it means when hospitals announce that they have rededicated themselves to serving the indigent in their communities. Surely, such actions are motivated by a true desire to ensure that uninsured patients receive necessary care. But the timing of these recent reforms indicates that they may be, in equal part, calculated public relations efforts to both mitigate and ward off criticism regarding charity care policies. For these reasons, more lasting reforms can only be achieved through either regulatory or statutory measures that, themselves, obligate hospitals to modify their current practices.

B. Improving Transparency in Hospital Billing and Collections Policies and Standardizing Community Benefit Reporting

Many federal, state, and local lawmakers have endorsed reforms that would impose voluntary disclosure and reporting requirements upon not-for-profit hospitals, presumably on the theory that if hospitals must disclose their charity and collections policies they will be pressured to adopt more "charitable" policies and procedures.[199] The AHA, too, has proposed that states, hospital associations, and insurance companies collaborate to make pricing schemes available to

198. *See, e.g.*, *Hearing on the Tax-Exempt Hospital Sector*, *supra* note 27 (statement of Sister Carol Keehan, Chair, Bd. of Trs., Catholic Health Ass'n).

199. Cohen, *supra* note 8, at 141-43. Congress has, for example, considered a statute that would require not-for-profit providers to disclose their charges. *Id.* at 143 (citing Hospital Price Disclosure Act of 2005, H.R. Res. 1362, 109th Cong. (2005) (requiring hospitals and ambulatory surgery centers to disclose charges for their twenty-five most frequently performed inpatient and outpatient procedures, and their fifty most frequently administered drugs dispensed to inpatients)); *see also* HEALTH RESEARCH INST., PRICEWATERHOUSECOOPERS, MY BROTHER'S KEEPER: GROWING EXPECTATIONS CONFRONT HOSPITALS ON COMMUNITY BENEFITS AND CHARITY CARE 10-11 (2006) [hereinafter MY BROTHER'S KEEPER] (describing community benefit reporting measures adopted in a number of states).

consumers so they can compare services across institutions and make an educated choice before they receive treatment.[200]

When it comes to pricing schemes and billing policies, these lawmakers and industry advocates may be correct that disclosure requirements alone will suffice to pressure providers into adopting approaches that are in line with those of their competitors.[201] As those hospitals subject to the *Wall Street Journal*'s scathing reports found, negative media attention about "uncharitable" billing and collection policies can be devastating to a hospital's reputation within the community and with local lawmakers.[202] Thus, if one's only concern is ensuring that uninsured patients receive affordable medical care, then disclosure requirements, alone—whether self-imposed, adopted pursuant to an association's "recommended guideline," or mandated by state or federal lawmakers—may be sufficient to ensure that not-for-profit hospitals reform their billing and collections procedures and provide adequate care to self-pay patients.[203]

But when it comes to the larger issue of whether not-for-profit hospitals are in fact "earning" their tax exemptions, disclosure requirements, alone, may be of little benefit to consumers and lawmakers unless those requirements also contain standardized metrics for reporting community benefit.[204] Under existing

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200. MY BROTHER'S KEEPER, *supra* note 199, at 19.

201. *Cf. id.* (observing that public access to pricing and quality information may drive improvements in quality even if prices remain consistent because consumers will be able to make direct comparisons across institutions; also noting that disclosure of pricing data "empowers" uninsured patients by allowing them to make price-conscious decisions about their care).

202. *See generally supra* note 17 and accompanying text.

203. One might nevertheless argue that legislation requiring only voluntary disclosure of billing and collection practices would be of little marginal value, as hospitals already face sufficient pressure from their communities, peer facilities, and trade associations to increase access to care for the uninsured, offer discounted prices, and engage in compassionate collection practices—or at least promote the fact that they will do so. But this claim is subject to multiple criticisms. First, as with mandatory disclosure requirements, there is little reason to believe that hospitals would change their practices any more than absolutely necessary to avoid further public scrutiny. Nor is there reason to believe that this level of change would strike the appropriate balance to warrant continued tax exemption. Second, although recent public scrutiny *has* driven many institutions to change their billing and collections practices, there is no way to "enforce" voluntary adherence to a self-imposed standard. Thus, should the public criticism fade, hospitals would be free to revert to their old ways. Finally, as discussed above, *supra* note 18, demand from community members and lawmakers that hospitals meet minimal community benefit standards shifts over time, as federal reimbursement rates change and hospitals alter their baseline levels of free and discounted care in response to changing margin pressure. These shifts in public scrutiny make it all the more likely that voluntary measures would be short-lived.

204. *See, e.g.*, Cecilia M. Jardon McGregor, *The Community Benefit Standard for Non-Profit Hospitals: Which Community, and for Whose Benefit?*, 23 J. CONTEMP. HEALTH L. & POL'Y 302, 335-39 (2007) (advocating for a minimum charity care standard, but also explaining that any

practices, differences in how hospitals chose to report this data would render it difficult to compare self-calculated community benefits across institutions. Accordingly, even if the IRS were to dramatically increase enforcement efforts based on the information hospitals currently disclose to the agency, those efforts would still be hamstrung by the fact that the agency lacks a clear standard by which to measure whether hospital exemption status is merited.[205]

The solution to lawmakers' concerns about hospital exemption, therefore, may lie instead in a requirement that *both* requires hospitals to disclose their self-calculated community benefit *and* that prescribes precise metrics for how hospitals may calculate the community benefit they are reporting.[206] This type of approach would leverage existing pressures on providers to disclose billing and charity care information. At the same time, it would ensure that the data provided could be used in a meaningful manner by local and national lawmakers and administrators. But, because such a requirement would *not* impose any of the more draconian measures that some providers fear—notably, a percentage-based minimum charity care requirement or revocation of hospital tax exemption[207]—it would be far more likely to generate support among industry interest groups. Hospitals would be happy to avoid mandatory charity care requirements, which threaten to increase the already-heavy burden not-for-profit hospitals bear in caring for the nation's underinsured and uninsured populations.[208] Industry

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reforms must include more clear guidance regarding what qualifies as a community benefit).

205. There remains significant disagreement, even among industry experts, about whether charity care should account for costs or charges and whether and how disclosure must account for bad debt, as well as inevitable "Medicare shortfalls." *Id.* at 468; *see also* Nancy M. Kane & William H. Wubbenhorst, *Alternative Funding Policies for the Uninsured: Exploring the Value of Hospital Tax Exemption*, 78 MILBANK Q. 185, 190 (2000).

206. The effect of the new disclosure requirements imposed by the revised Form 990 and Schedule H will remain unclear until hospitals actually submit that data for fiscal year 2008.

207. Although not addressed by this Note, revocation of hospital tax exemption altogether poses a number of critical flaws and would likely deny hospitals far more funds than the federal government would realize in tax revenues due to loss of grant money and donations and the elimination of eligibility for tax-exempt debt. Kane, *supra* note 35, at 471; *see also* McGregor, *supra* note 204, at 338-39; Quirk, *supra* note 19, at 102-03. *But see* Colombo, *Competitive Health Care Market*, *supra* note 35, at 629-35 (describing conflicting findings in empirical studies regarding the value of hospital tax exemption).

208. *See, e.g.*, Letter from Rick Pollack, *supra* note 27 (noting that federal programs often do not pay the full cost of care for covered patients, and hospitals must absorb the shortfalls); Am. Hosp. Ass'n, Issue Paper, Improving Accountability for Tax-Exempt Status (May 2007), http://www.aha.org/aha/content/2007/pdf/07-am-accountability-tax-exempt.pdf ("[H]ospitals shoulder the burden of bad debt, much of which comes from low-income patients, who . . . do not apply for financial assistance.").

What providers frequently fail to note in these communications is that there are significant differences between hospitals in the provision of uncompensated care (including both bad debt and

members objected strenuously to a draft proposal for revising the IRS Form 990, for example. They complained, in particular, that the proposed Schedule H, which sought information regarding hospital compliance with the community benefit standard, failed to "incorporate the full value of community benefit that hospitals provide," including Medicare underpayments and bad debt, and also imposed "burdensome and misleading questions . . . unrelated to community benefit or compliance."[209]

Perhaps in recognition of the fact that an approach based on precise disclosure standards is most likely to satisfy lawmakers and also avoid more drastic changes for the industry, the Catholic Healthcare Association (CHA), the VHA, and the AHA have all proposed new standards for reporting community benefits.[210] The VHA and the CHA released "Community Benefit Reporting: Guidelines and Standard Definitions for the Community Benefit Inventory for Social Accountability," which provides guidelines regarding how hospitals should account for and quantify community benefit.[211] The report identifies eight

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free care) among private not-for-profit hospitals and for-profit hospitals that are publicly and privately owned. A 2005 Government Accountability Office (GAO) report concluded that government-owned hospitals had significantly higher uncompensated care burdens (i.e., the ratio of uncompensated care relative to total operating expense) than privately owned institutions. DAVID M. WALKER, U.S. GOV'T ACCOUNTABILITY OFFICE, NONPROFIT, FOR-PROFIT, AND GOVERNMENT HOSPITALS: UNCOMPENSATED CARE AND OTHER COMMUNITY BENEFITS 3 (2005), *available at* http://www.gao.gov/new.items/d05743t.pdf. The report found differences in uncompensated care burden between not-for-profit private and investor-owned hospitals. *Id.* It also noted that a relatively small proportion of hospitals maintained the greatest proportion of the private, not-for-profit uncompensated care burden. *Id.*; *see also* Kane, *supra* note 35, at 465 (describing GAO findings). A new standard would likely have little impact on the amount of care provided by those hospitals that currently provide the greatest share of the uncompensated care burden.

209. Am. Hosp. Ass'n, Comments on Draft Schedule H, Aug. 21, 2007, *available at* http://www.aha.org/aha/letter/2007/070821-let-IRSSchH.pdf; *see also* Letter from Representatives Tubbs Jones and Porter, *supra* note 27 (noting concern that the proposed "new form and schedules [Form 990 and Schedule H] will place a disproportionate burden on these hospitals, which already are overburdened with the many challenges of providing care in their communities").

210. *See Hearing on the Tax-Exempt Hospital Sector*, *supra* note 279, at 103 (statement of Sister Carol Keehan, Chair, Bd. of Trs., Catholic Health Ass'n); *Id.* (statement of Edward Goodman, VHA, Inc.); Kane, *supra* note 35, at 468. The CHA is the national membership association of the Catholic health ministry; it represents more than 2000 sponsors, systems, facilities, and related organizations. *See generally* Catholic Health Ass'n, http://www.chausa.org (last visited Apr. 28, 2008). VHA, Inc. is a national cooperative of community-owned health care systems and physicians; it serves more than 1400 not-for-profit hospitals and more than 21,000 non-acute health care organizations nationwide. *See generally* VHA, Inc., https://www.vha.com (last visited Apr. 1, 2008).

211. CATHOLIC HEALTHCARE ASS'N & VHA, INC., COMMUNITY BENEFIT REPORTING: GUIDELINES AND STANDARD DEFINITIONS FOR THE COMMUNITY BENEFIT INVENTORY FOR SOCIAL

categories of community benefits, and also argues that hospitals should not count either bad debt or Medicare shortfalls in their community benefit reports, though they may include Medicaid shortfalls, given the relative consensus regarding the under-funded nature of that program.[212] Critically, the CHA/VHA report also prescribes accounting methods based on hospital costs rather than hospital charges.[213]

In May 2006, the CHA released a separate document, "A Guide for Planning and Reporting Community Benefit," which combines the standard definitions and guidelines developed by CHA and VHA with CHA consensus guidelines for accounting for charity care.[214] CHA officials encouraged providers to adopt these common reporting mechanisms for charity care not only to improve provider-specific budgeting and advocacy, but also to enable analysis of consolidated information across institutions and respond to both local and congressional concerns about whether not-for-profit providers are charitable enough to merit continued tax exemption.[215] Initial data suggest that the CHA and VHA efforts

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ACCOUNTABILITY (2005), *available at* http://www.chausa.org/NR/rdonlyres/1E9B545E-BD93-4F46-B6F2-3FE18578CB41/0/commbenguidelines.pdf. The guidelines explain that providers should include within a quantifiable inventory services that, 1) "[r]esult in a financial loss to the organization, requiring subsidization of some sort," 2) may "[b]est be quantified in terms of dollars spent or numbers of persons served," 3) are not "of a questionable nature that jeopardizes the credibility of the inventory, and 4) are accounted for within "an explicit budget." *Id.* at 8. The guidelines also suggest that other items may be accounted for within a narrative summary, such as services that 1) "Are of significant community benefit, but break even or involve minimal cost"; 2) "Are better appreciated by a reader when described in terms of benefit provided or numbers served rather than dollars spent"; 3) "Are provided entirely by volunteers or involve staff donating their own time to the program"; and 4) "Are somewhat controversial as to whether they represent a 'true' community benefit." *Id.*

212. Those eight categories include: charity care, shortfalls from Medicaid and other government-funded indigent care programs, community health improvement services, health professional education, subsidized services, research, financial contributions, and community-building activities. *See* Becker, *supra* note 148; Keehan, *supra* note 142; Professor Nancy M. Kane has endorsed the exclusion of Medicare shortfalls from the accounting formula, explaining that "Medicare payment rates are supposed to be what efficient hospitals can live with. . . . If the payment rates are below cost, the suggestion is that (the hospital) is inefficient and it's not doing the community a big favor." *Id.*; *see also* Keehan, *supra* note 142.

213. *Charitable Formula*, *supra* note 142, at 18 (stating, on behalf of CHA, that "we have worked with the VHA to identify eight categories of community benefit, including charity care (reported as cost, not charges)").

214. For information on the guide, see Quirk, *supra* note 19, at 98; *see also* Catholic Health Ass'n, Executive Summary, http://www.chausa.org/Pub/MainNav/ourcommitments/CommunityBenefits/Resources/TheGuide/.

215. Julie Trocchio & Keith Hearle, *Calculating the Cost of Charity Care*, HEALTHCARE FIN. MGMT., Feb. 1, 2007, at 115.

have been successful; in the fall of 2007, the CHA announced that its May guidelines were formally adopted by 95% of its member health systems and 90% of its member hospitals.[216]

The AHA proposal resembles the CHA guidelines and also supports improvements in pricing transparency and community benefit reporting.[217] The association encouraged hospitals to provide free care to uninsured patients with incomes below 100% of the federal poverty line, and suggested that hospitals bill those with incomes between 100-200% of the poverty level no more than 125% of the rate established by either Medicare or other public or private payors.[218] Unlike the CHA and VHA guidelines, however, the AHA would permit hospitals to also account for both bad debt and Medicare shortfalls when accounting for charity care.[219]

Perhaps not surprisingly, given that they have been proposed by industry leaders, these proposals have been well received within the industry. Some experts, however, continue to suggest that even more comprehensive reforms may be needed.[220] Professor Nancy Kane proposes a slightly more rigorous approach, one that encompasses more "meaningful behavioral expectations of tax exempt hospitals."[221] Although providers would likely resist a standard that would afford them less accounting flexibility than the CHA and AHA guidelines provide, Professor Kane's proposals arguably would provide legislators and communities with more concrete tools with which to hold hospitals accountable for maintaining adequate community benefit programs. She suggests, first, that hospitals tie eligibility for free care to the magnitude of the self-pay portion of the patient's bill relative to that individual's ability to pay; further, she proposes that hospitals post their billing policy both on their websites and on a disclosure

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216. Carol Keehan, *A Promise Kept*, HEALTH PROGRESS, May/June 2007, at 6.

217. *See* Zigmond & Evans, *supra* note 153.

218. *Id.*

219. Quirk, *supra* note 19, at 103-04. A fourth industry association, the Healthcare Financial Management Association ("HFMA"), adopted standards that incorporate elements of both the AHA proposal and the CHA/VHA standard. Melanie Evans, *Tussling Over Benefits: HFMA Accounting Rules Straddle AHA, CHA Methods*, MODERN HEALTHCARE, Dec. 4, 2006, at 12. The HFMA would exclude bad debt as a community benefit, but would permit hospitals to count Medicare losses toward community benefit expenses. *Id.* The association also endorsed the use of costs, rather than charges, to value these expenses. *Id.*

220. *See* Quirk, *supra* note 19, at 98, 103-04 (describing positive response among legislators). *But see* Kane, *supra* note 35, at 468 (criticizing the lack of a uniform and easily enforced reporting standard); Quirk, *supra* note 19, at 104 (observing that the AHA proposal, in particular, "fails to provide objective benchmarks for levels of 'charity care' and other 'community benefits,'" and concluding that therefore "it is unsuccessful in remedying the problems of uncertainty inherent in Revenue Ruling 69-545's 'Community Benefit Standard'").

221. Kane, *supra* note 35, at 471-72.

form attached to the IRS Form 990.[222] If hospital bills are tied to patient resources, she explains, patients might be more likely to actually pay for the services they receive. Second, she would require health care providers to improve communication with uninsured patients; administrators would enforce this provision by "monitoring of the level of awareness in the community of the hospital's charity care and discounted care policies."[223] Third, hospitals would have to justify their debt collection practices to the IRS in terms of the methods they employ and the rates at which they collect. The IRS, in turn, would regularly review the hospital reports to police against overly aggressive collection practices.[224] Fourth, hospitals would be required to partner with community groups to improve access to care and report on their efforts to both the IRS and the board of the provider institution.[225] Fifth, hospital boards would be required to maintain a permanent committee to review, monitor, and report on compliance with exemption requirements.[226] Finally, and perhaps more importantly, hospitals would be required to produce a community benefit report in accordance with the CHA guidelines and make that report available both as an attachment to the IRS Form 990 and on hospital websites.[227] Professor Kane explains that these goals would not be "onerous" for hospitals already providing sufficient levels of charity care and would simply "set forth more clearly than does current law what behaviors are expected of our charitable hospitals."[228]

Despite these varied proposals for enhancing and standardizing community benefit reporting, some industry analysts still maintain that reporting requirements are insufficient to ensure that hospitals deliver charity care equal to or in excess of the tax benefits they receive. These analysts argue that only a minimum charity care requirement will suffice.[229] Ultimately, these critics may prove correct; when the data from the revised Form 990 and Schedule H becomes available, it may in fact demonstrate that minimum charity care requirements are necessary. But this will not occur for at least another year. For an industry known for its slow rate of change, particularly when it comes to financial and accounting matters, prescriptive reporting and disclosure guidelines are a necessary interim step toward resolving concerns about not-for-profit hospitals' charity care practices. Therefore, federal lawmakers should reject proposals to adopt a minimum charity care standard and instead adopt a wait-and-see approach before

222. *Id.* at 471.
223. *Id.* at 471-72.
224. *Id.* at 472.
225. *Id.*
226. *Id.*
227. *Id.*
228. *Id.* at 471-72.
229. *See, e.g.*, McGregor, *supra* note 204, at 335-36.

initiating more sweeping—and controversial—reforms. This would allow the IRS to gather community benefit data from its revised Form 990 and Schedule H and use that information to help legislators determine whether, and to what extent, additional reforms are necessary. The Form 990s may reveal that many hospitals already provide sufficient community benefits, and that there is no need for specific expenditure requirements in order to justify the hospitals' tax-exempt status. Alternatively, the new forms may reveal that hospitals are not spending nearly enough on their communities. The point is that we will not know until the results come in from the new reporting requirements.

That said, the IRS *should* incorporate into its existing requirements more prescriptive guidelines such as those suggested by Professor Kane. Professor Kane's proposals would ensure that hospitals receive adequate guidance, and also guarantee that the IRS receives data that allows for meaningful aggregation and comparison across institutions. As noted above, providers may feel free to disregard or abandon purely voluntary standards, and the IRS would be unable to enforce such guidelines if that occurred. The agency must, therefore, incorporate more detailed guidance into its existing Form 990 requirements, using the industry-based proposals as a starting point. This approach would strike an appropriate balance between allowing providers to initiate improvements within their industry and assuring lawmakers and taxpayers that those changes will be lasting and that hospitals may be held accountable for any underperformance.

CONCLUSION

Although the 2004 lawsuits helped to shed light on the question of whether hospitals are providing sufficient amounts of care to uninsured populations, developments since those suits were filed have reinforced the district court decisions in favor of the defendant health care institutions. Had the courts permitted individual patients to enforce federal tax exemption standards, and had the judges, themselves, fashioned the remedy for those patients, there would have been enormous and likely ill-fated repercussions on the health care industry. Not only would such a regime be difficult to manage from a judicial standpoint, but it also could potentially expose providers to virtually unending suits from indigent patients (and the plaintiffs' bar). The critical questions underlying the present uninsurance crisis are not ones that can or should be answered in an ad hoc manner with only one provider or set of community standards in mind. Rather, these questions are ones that should be addressed in a political forum with opportunities for debate from both government and industry representatives.

Moreover, had the judiciary ceded to plaintiffs' requests to return to a standard akin to the 1956 Revenue Ruling and read into the federal tax code a minimum charity care requirement—and, further, allowed third-party patients to enforce this standard—hospitals would have faced an enormous burden to pay for indigent care. As most not-for-profit institutions already struggle to attain

financial margins sufficient to support their operations, this type of cost-shifting would have a major impact on health care providers.[230] Somewhat ironically, many would likely increase their prices—both the "list" prices that some institutions still charge to self-pay patients and the negotiated rates offered to managed care companies—in order to maintain their financial margins.[231] Of course, because uninsured patients rarely pay the full list price, these individuals would likely see little, if any, effect of across-the-board rate increases. Rather, the impact of price increases would be felt primarily by third-party payors, who would almost certainly then pass the increased costs on to employers. And, as current efforts to manage employer health care costs demonstrate,[232] this problem is too large and too pervasive for the judiciary to augment it by construing the federal tax code to include new charity care obligations on not-for-profit providers.

It is important to recognize, however, one of the major lessons of the recent lawsuits and legislative debates: increased public scrutiny has the power to drive

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230. Despite the outcry within the industry that a minimum charity care standard would spell disaster for hospitals' abilities to maintain sustainable margins, no expert to assess the issue has concluded that hospitals would become financially insolvent if Congress were to reformulate the community benefit standard or impose a strict charity care standard. *See, e.g.*, Kane, *supra* note 35, at 472 (concluding that "[t]hese guidelines would not be onerous for the many hospitals seeking to behave appropriately"). But hospitals already operate at extremely thin margins, and many operate at a loss. One author notes that although hospital financial performance has improved steadily since 2002, for not-for-profit hospitals rated by Moody's investment service, operating margins slipped in 2006 to only 2.3% and expenses exceeded revenues, suggesting future operating pressures. The author also observed that roughly one-third of hospitals currently operate at a loss. *See* Melanie Evans, *On Solid Ground: Revenue Gains Continue To Outpace Growth In Expenses, Allowing U.S. Hospitals To Enjoy Record Profit and Margins*, MODERN HEALTHCARE, Oct. 29, 2007, at 6-7. Many hospitals do not, however, have room in their margins to accommodate significantly greater amounts of charity care. *See also* DRAPER & GINSBURG, *supra* note 5, at 5-6 (observing that safety net providers have had to "pursu[e] strategies aimed at improving their financial health," including seeking higher reimbursement rates from federal payors and referring patients to outpatient clinics in order to manage costs associated with increased demand for safety net services).

231. Even if hospitals were to abandon charging uninsured patients based on charges rather than costs, as the CHA and VHA have proposed, if those institutions were to tie rates for uninsured patients to those rates paid by private payors, an increase in negotiated rates would also affect self-pay patients.

232. For discussion of the difficulty employers face in managing health care costs, see Jon Gabel et al., *Health Benefits in 2005: Premium Increases Slow Down, Coverage Continues To Erode*, 24 HEALTH AFF. 1273 (2005); *see also* Victor R. Fuchs & Ezekiel J. Emanuel, *Health Care Reform: Why? What? When?*, 24 HEALTH AFF. 1399, 1400 (2005); Robert S. Galvin & Suzanne Delbanco, *Why Employers Need To Rethink How They Buy Health Care*, 24 HEALTH AFF. 1549 (2005); James D. Reschovsky et al., *Why Employer-Sponsored Insurance Coverage Changed, 1997–2003*, 25 HEALTH AFF. 774 (2006).

enormous voluntary reforms industry-wide. The recent attention has also spurred political entities—which are far more suited to the task than the judiciary—to initiate steps toward effecting more lasting changes. Thus, the plaintiffs in the Scruggs litigation have succeeded in generating change within the health care industry, even if, as individuals, they were denied the direct relief they sought.

Notwithstanding these widespread changes within the industry, increased grassroots activity at the state level confirms that local advocacy groups still fear that voluntary hospital efforts and slow-moving federal reforms may be insufficient to ensure that hospitals are meeting their obligations to provide discounted medical services to their local communities.[233] Under pressure from local activists, state tax officials have begun to examine more closely the community benefits delivered by health care providers and, in some cases, have sought to revoke state and local property tax exemptions.[234]

Responding to—and hoping to leverage—these local concerns about whether not-for-profit hospitals continue to merit state and local tax breaks, Richard Scruggs and his colleagues re-focused their attention on state-level litigation efforts against not-for-profit providers.[235] Early results suggest that the state court venues are more receptive to the plaintiffs' claims; judges in several states certified plaintiffs' classes.[236] Hospitals appeared concerned enough about the possibility of adverse judgments—or at least protracted litigation, expensive legal fees, and negative media attention—to settle the claims.[237] Thus, even if they have yet to succeed on the legal merits, the plaintiffs in these actions have kept the spotlight on local providers' charity care policies. They have also, somewhat ironically, caused a possible negative effect. The money hospitals used to pay the legal bills could have instead been given directly to charity care.[238]

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233. *See* John D. Colombo, *Hospital Property Tax Exemption in Illinois: Exploring the Policy Gaps*, 37 LOY. U. CHI. L.J. 493 (2006) [hereinafter Colombo, *Hospital Property Tax Exemption*] (describing how, in response to community activists and upon the recommendation of the Champaign County Board of Review, the Illinois Department of Revenue revoked the property tax exemption for Provena Covenant Medical Center).

234. *See, e.g.*, Cohen, *supra* note 8, at 138 (describing efforts by Illinois tax officials to deny property tax exemptions for parcels of land owned by the Carle Foundation); Heather Knight, *Report Ranks 2 Hospitals on Charity Care*, S.F. CHRON., Jan. 29, 2008, at D1 (comparing charity care among five San Francisco-area hospitals); *see also* Colombo, *Hospital Property Tax Exemption*, *supra* note 233.

235. Cohen, *supra* note 8, at 135-38; Ceci Connolly, *Tax-Exempt Hospitals' Practices Challenged*, WASH. POST, Jan. 29, 2005, at A1.

236. *See supra* note 74.

237. *Id.* Because the state claims all depend on unique interpretations of common law or upon particular language of state statutes, however, outcomes in one set of state courts do not predict success in other states.

238. *See* Cohen, *supra* note 8, at 144.

For individual patients, litigation may appear to address the problems they face in obtaining affordable care. But even if plaintiffs achieve indirect success on that front—through favorable settlement negotiations, for example—these lawsuits cannot solve the problems identified by Senator Grassley and others who have challenged the underlying rationale for hospital tax exemption. When it comes to ensuring that not-for-profit providers are delivering adequate and consistent amounts of community benefits, only legislatures can make the systematic and lasting changes needed to hold hospitals accountable for adhering to any new charity care standards. However painful a new federal standard may be to not-for-profit hospitals, and however limited the final compromise may be, a legislative response will be far superior to a litigation strategy in providing a more equitable and sustainable long-term solution. A legislative solution is more likely to balance taxpayers' interest in obtaining a public good from tax-exempt hospitals with the concern that hospitals not bear a disproportionate burden of covering the costs of caring for the nation's uninsured.