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Recalibrating the Legal Risks of Cross-Border Health Care

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INTRODUCTION

Three patients leave the United States for surgery. The first is self-employed and has no health insurance. He needs life-prolonging heart surgery that would cost at least \$50,000 in the United States. On the Internet, he finds a cardiac surgeon at a private hospital in New Delhi, India, who can perform the surgery for no more than \$10,000.¹ Terms and conditions on the hospital's website require patients to resolve any complaints in Indian courts or in one of India's consumer dispute forums. Civil litigation in India can take fifteen to twenty years to resolve, and India's consumer forums cannot grant non-economic damages like pain and suffering.

The second patient works for a large, self-insured manufacturer. To compete with foreign manufacturers, his employer must cut jobs and benefits. After seeing a segment on medical tourism on the news, the manufacturer's benefits manager contacts a medical tourism facilitator in North Carolina.² Together, the companies craft a plan to outsource expensive surgeries by paying employees for travel expenses and offering them 25% of the cost-savings, up to \$10,000.³ The employee needs knee surgery, so the facilitator arranges for it at a famous private hospital in Bangkok, Thailand. The contract stipulates that the facilitator shall not be held responsible for any negligence committed by the Thai hospital or physicians. Moreover, the employee must sign a waiver agreeing not to hold the employer liable. The average malpractice payout in Thailand is less than \$2500.⁴

The third patient buys health insurance through her employer. The insurance company recently added to its provider network a private hospital in Monterrey, Mexico, and it now offers a plan with much lower premiums and deductibles to patients willing to visit Mexico for certain procedures. The patient visits Monterrey for cataract surgery. The insurance policy states that all network providers are independent contractors and are not agents of the insurer. Mexican law pegs tort compensation to very modest awards in its federal workers' compensation statute. Moreover, under Mexico's new medical arbitration system,

1. All amounts are in U.S. dollars, unless otherwise indicated. Though the legal details are hypothetical, I adapted this scenario from the highly publicized case of Howard Staab. See *The Globalization of Health Care: Can Medical Tourism Reduce Health Care Costs?: Hearing Before the S. Spec. Comm. on Aging*, 109th Cong. 1 (2006) [hereinafter Senate Hearing] (statement of Maggi Ann Grace).

2. Some argue that the label "medical tourism" trivializes the phenomenon. See, e.g., Michele Masucci & Scott Simpson, *Outsourcing Care: Medical Tourism Is the Globalization of the American Operating Room*, 238 N.Y. L.J. 11 (2007). Though I agree, I use "medical tourism" because it reflects the dominant nomenclature.

3. Though the legal details are hypothetical, I adapted this scenario from the highly publicized example of Blue Ridge Paper Products. See Senate Hearing, *supra* note 1 (statement of Bonnie Grissom Blackley).

4. See *infra* text accompanying notes 312-316.

the average malpractice recovery is roughly \$4800.⁵

These patients have three things in common. They are gainfully employed. They are leaving the United States to save money on medical expenses. And they have very little legal recourse should they fall victim to medical negligence.

These three scenarios reflect the essential tradeoff. The first patient, by agreeing to Indian jurisdiction, sacrifices potential legal remedies in exchange for life-prolonging medical care that he otherwise could not afford. The risks and benefits accrue directly to the patient. The second and third patients also sacrifice potential legal remedies, as jurisdiction likely resides in Thailand and Mexico. But the benefits accrue diffusely—outsourcing saves money for the patient, employer, and insurer alike.

Do these parties fully appreciate the tradeoff? Employers and insurers seem to—they use releases, waivers, disclaimers, and other contractual devices to limit their legal liabilities when sending patients abroad. And the medical tourism companies that facilitate these transactions use a similar combination of legal prophylaxes. However, it is unclear whether patients fully understand the legal risks. Patients may vaguely comprehend that they might not receive the same legal or regulatory protections overseas. But there is reason to suspect that they do not fully digest just how few legal remedies remain or what options they have if something goes awry.

More and more patients are accepting this tradeoff, wittingly or not. The patients diligent enough to investigate these legal disparities will not find much helpful information. Currently, the literature assumes that foreign jurisdictions provide lesser legal remedies, but until now, no one has tested or supported these assumptions.⁶ To date, there are no reliable, comprehensive sources for patients

5. See *infra* text accompanying note 601.

6. See, e.g., MILICA Z. BOOKMAN & KARLA R. BOOKMAN, MEDICAL TOURISM IN DEVELOPING COUNTRIES 156 (2007) (stating, without identifying jurisdictions for comparison, that other legal systems may not handle disputes as efficiently as U.S. courts); Nathan Cortez, *Patients Without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care*, 83 IND. L.J. 71, 106-07 (2008) (briefly identifying problems with malpractice suits in Malaysia, Singapore, India, and Thailand); Michael Klaus, *Outsourcing Vital Operations: What if U.S. Health Care Costs Drive Patients Overseas for Surgery?*, 9 QUINNIPIAC HEALTH L.J. 219, 235-39 (2006) (stating, without citing authority, that malpractice laws “either do not exist or are not enforced” in Asia and that patients in India and Thailand “bear the full costs of the medical errors” by physicians); Masucci & Simpson, *supra* note 2 (stating, without citing authority, that “a medical malpractice plaintiff is unlikely to be made whole by a foreign judgment”); Nicolas P. Terry, *Under-Regulated Health Care Phenomena in a Flat World: Medical Tourism and Outsourcing*, 29 W. NEW ENG. L. REV. 421, 464 (2007) (asserting that medical tourists may experience “reduced legal outcomes (compensation)” overseas, but acknowledging the lack of information on this point); Marcia S. Wagner, *Medical Tourism and Group Health Plans*, J. COMP. & BENEFITS, Sept./Oct. 2006, at 26 (stating, without citing authority, that most host countries “have weak malpractice laws”); Kristen Boyle, *A Permanent Vacation: Evaluating Medical Tourism’s Place in*

to learn about legal recourse for malpractice committed in those jurisdictions.⁷

As such, it is highly doubtful that most U.S. patients fully appreciate the legal risks of medical travel.⁸ The three scenarios above reflect increasingly common arrangements. Patients are being asked to forego potential legal claims in U.S. courts, leaving them to rely on foreign judicial systems for compensation, venues where it is unlikely they will recover adequate compensation by U.S. standards. For example, the mean and median recoveries by malpractice victims in the United States (\$311,000 and \$175,000, respectively) dwarf the average recoveries in Thailand (\$2500) and Mexico (\$4800).⁹ Perhaps for this reason, industry observers and representatives warn patients not to travel overseas if they are at all concerned with their potential legal remedies.¹⁰

If patients travel overseas for less expensive health care (particularly if they are encouraged to do so), they should understand precisely what remedies they are sacrificing.¹¹

This Article recalibrates the legal risks of medical travel by assessing whether patients injured overseas have adequate legal recourse either in the

the United States Healthcare System, HEALTH LAW., June 2008, at 42, 46 (stating, without citing authority, that patients have more difficulty suing overseas); Howard D. Bye, *Shopping Abroad for Medical Care: The Next Step in Controlling the Escalating Health Care Costs of American Group Health Plans?*, HEALTH LAW., Apr. 2007, at 30, 31 (stating that lawsuits against foreign providers “can be severely limited by local law” and citing only Klaus, *supra*).

7. R.K. Nayak, *Medical Negligence, Patients’ Safety and the Law*, REGIONAL HEALTH F., Vol. 8, No. 2, 2004, at 15, 23 (noting that except for India, there is very little information on medical malpractice law in Southeast Asia). There are impressive comparative works on medical malpractice laws. See, e.g., DIETER GIESEN, *INTERNATIONAL MEDICAL MALPRACTICE LAW: A COMPARATIVE LAW STUDY OF CIVIL LIABILITY ARISING FROM MEDICAL CARE* (1988). But these tend to focus on highly developed countries rather than on the developing countries that patients increasingly visit.

8. Of course, medical travel presents non-legal risks as well. For example, traveling for surgery may complicate a patient’s recovery. See Cortez, *supra* note 6, at 103-04. This Article focuses on the legal element to these risks, particularly the risk that patients will not have adequate legal recourse if subject to medical malpractice.

9. See *infra* text accompanying notes 99, 317-320, 611.

10. See, e.g., Julie Davidow, *Thousands of ‘Medical Tourists’ Are Traveling Abroad To Save Money – And at Their Own Risk*, SEATTLE POST-INTELLIGENCER, July 24, 2006, at A1 (quoting the author of a medical tourism guide, who says, “My sort of blunt advice is that if your primary concern in going to a doctor, surgeon, or dentist is whether or not you’re going to have legal recourse if you don’t like the work you get, you shouldn’t go overseas”); Toby Manthey, *Surgery Costs Drive Americans Abroad: Arkansans Join Tourism Trend for Cheaper Meds*, ARKANSAS DEMOCRAT-GAZETTE, May 6, 2007, at 60 (“If someone is considering suing someone, for whatever reason, don’t [seek treatment abroad.] That’s all we have to say.”).

11. In Subsection III.B.3, *infra*, I discuss whether patients should be able to waive legal remedies in exchange for less expensive health care.

United States or in one of four common destinations: India, Thailand, Singapore, and Mexico. I conclude that U.S. medical tourists will struggle to obtain adequate compensation, either here or abroad. Patients looking to sue in U.S. courts for medical malpractice abroad will face difficulties locating a proper defendant, venue, and theory of liability. Patients suing overseas will also face obstacles recovering adequate, timely compensation in legal systems that use unfamiliar procedures, communicate in foreign languages, limit the remedies available, and impose more onerous burdens of proof. Moreover, I argue that patients cannot accurately appraise the legal risks because 1) no dispositive case law exists indicating whether medical tourists can recover in U.S. courts and 2) until now, there were no reliable resources that explained the remedies patients might have in foreign jurisdictions. In this Article, I attempt to fill this void. Given this information, I also discuss how policymakers might reallocate these risks more fairly and efficiently.

Part I begins by evaluating whether medical tourists can recover in U.S. courts. I use existing scholarship to outline the legal theories patients might use against certain defendants. I emphasize the term “theories” here because courts have yet to test these claims. First, I discuss how patients will struggle to prevail on issues of jurisdiction, venue, and choice of law if they sue foreign providers in U.S. courts. I then discuss how patients will face different obstacles if they attempt to recover from U.S.-based employers, insurers, and medical tourism facilitators. I evaluate several theories of liability, including corporate negligence, informed consent, vicarious liability, and negligent credentialing. Part I concludes by discussing how the industry uses releases, waivers, disclaimers, and other contractual prophylaxes to shift the legal risks in two directions—toward patients and toward foreign jurisdictions.

Part II proceeds on the assumption that patients will have difficulty suing in U.S. courts for malpractice committed overseas. I evaluate the means of redress available in four popular destinations: India, Thailand, Singapore, and Mexico.

In India, patients can sue in civil court or in one of India’s consumer forums. India also relies on criminal prosecution, self-regulation, and hospital accreditation to impose quality standards on providers. But none of these systems enforce much accountability. Civil litigation is an extremely long process, even by U.S. standards. India’s consumer forums provide an efficient alternative, but patients must contend with procedural hurdles and overcome difficulties securing medical records and expert testimony simply to recover rather modest compensation. Criminal prosecution is rare. Government regulation is virtually non-existent, and self-regulation by the medical councils is deeply flawed. Hospital accreditation is establishing some standards, but does not pretend to address negligence. India should be credited for acknowledging these shortcomings and attempting to mitigate them through its consumer forums. But given the relatively small size of malpractice recoveries reported by the Indian

media, it is doubtful that U.S. patients will be satisfied with the remedies offered by these forums.

In Thailand, patients also struggle to hold someone accountable for medical negligence. Few patients file any sort of complaint—either in civil court or with the Thai Medical Council, the Ministry of Public Health, or the Consumer Protection Agency. Those suing in civil courts face several obstacles. Thai malpractice law is underdeveloped. Patients often cannot access their medical records. Thai courts communicate solely in Thai, do not allow pretrial discovery, and seem hostile to tort claims in general. Finally, the average Thai patient recovers less than \$2500, which most U.S. patients would find unsatisfying. But like most countries, Thailand is searching for the appropriate balance and is considering several major reforms, including no-fault liability and a patient's compensation fund. Thus, the Thai system remains in flux.

In Singapore, patients face yet other obstacles. In negligence cases, Singapore adheres to the notorious *Bolam* rule, an English trial court opinion from 1957 that strongly favors physicians by instructing courts to use a deferential interpretation of the appropriate standard of care. Patients in Singapore also remain exceedingly reluctant to sue, in part because Singaporean law imposes costs on the losing litigant and prohibits contingency fee arrangements. Finally, compensation is modest not only by U.S. standards, but by standards we might expect for a nation with Singapore's wealth. Nonetheless, Singapore comprehensively regulates its health care providers, and the government seems to be committed to understanding and reducing the frequency of medical errors.

Finally, patients in Mexico must contend with a legal system that uses neither juries nor *stare decisis* and a civil code that pegs compensation to a formula used in workers' compensation cases. Tort litigation is virtually nonexistent in Mexico, and most U.S. tort victims injured there prefer to sue in the United States if they can. Although Mexico has implemented an innovative new medical arbitration system that is viewed favorably by both patients and physicians, the average recovery is only \$4800 per patient, which, again, most U.S. patients would find inadequate.

In addition to obstacles unique to each jurisdiction, suing overseas could discourage even the most resolute plaintiffs, who must retain local counsel, navigate a foreign legal system (most likely in a foreign language), travel to hearings, prove their cases, and perhaps even enforce judgments in their favor.¹² These factors may combine to effectively preclude legal recourse.

Part III concludes by exploring how the public and private sectors might

12. See Thomas R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities*, 14 ANNALS HEALTH L. 205, 247-55 (2005); Terry, *supra* note 6, at 465; Jorge A. Vargas, *Mexican Law and Personal Injury Cases: An Increasingly Prominent Area for U.S. Legal Practitioners and Judges*, 8 SAN DIEGO INT'L L.J. 475, 505 (2007).

reallocate—and perhaps mitigate—the legal risks of medical travel. In the private sector, an industry association recently began certifying medical tourism facilitators, and this process seems to encourage companies to disclose the legal remedies their customers might have, including remedies in foreign jurisdictions. Also, at least one insurance company now offers medical tourism insurance, and the American Medical Association has published industry guidelines. Part III examines the strengths and weaknesses of these approaches, and concludes by proposing ways the public sector could intervene. Legislatures could impose statutory strict liability on employers, insurers, and intermediaries that send patients overseas. Lawmakers could require these companies to insure against medical errors or pay for any pre-screening or post-operative care that may be necessary. They could invalidate any releases or waivers of liability. Or, policymakers might simply try to correct the information asymmetries that contribute to the current misallocation of legal risks. I propose a combination of these methods that would ease legal impediments to suing in the United States and inform patients of the risks of agreeing to assert claims in foreign courts. Even if these efforts do not generate precisely the same remedies as those available to patients treated in the United States, they should better spread the risks among the parties that benefit from these transactions.

This Article has two major goals, one descriptive and one prescriptive. First, the descriptive goal is to provide much-needed basic information about the legal systems in four countries that foreign patients increasingly visit. As I describe the medical malpractice compensation systems in India, Thailand, Singapore, and Mexico, I try to outline the basic mechanics of each system and the obstacles that might preclude foreign patients from receiving meaningful compensation.¹³ Hopefully, this information will be useful to patients, the industry, and policymakers alike.

The second, prescriptive goal of this Article is to suggest how both the public and private sectors might reallocate the legal risks more fairly and efficiently, so they do not fall solely, or even squarely, on patients. I scrutinize private-sector responses to the legal imbalance and recommend specific public sector options that would both eliminate impediments to hashing out these legal claims in the United States and better inform patients who agree to foreign jurisdiction just what they are sacrificing. Again, the goal is to guide this market toward a more optimal allocation of risks and responsibility.

13. I should note that this Article is not a traditional comparative work. I do not attempt to compare the malpractice systems of these countries to the American system, nor do I try to extract any policy lessons or identify the most fair and efficient method of compensating aggrieved patients. Rather, my goal is to fill a void in the literature by examining how patients might fare in select jurisdictions and whether U.S. patients will be satisfied with these remedies. Each jurisdiction deserves much closer scrutiny than anyone can provide in one article, and a pure comparative analysis would require better empirical data than is currently available.

I. SEEKING REDRESS IN THE UNITED STATES

Many believe cross-border medical treatment could be the next big trend in global health care. The phenomenon has triggered a torrent of media coverage and academic articles trying to predict what will come of it.¹⁴ Health economist Uwe Reinhardt says it “has the potential of doing to the U.S. health care system what the Japanese auto industry did to American carmakers.”¹⁵

Estimates vary widely on the precise number of U.S. patients that travel overseas for treatment each year. A 2008 report estimates that only 5000 to 10,000 Americans travel each year specifically for inpatient procedures.¹⁶ But a separate report estimated that 750,000 U.S. patients traveled overseas for medical care in 2007, and some predict that five or six million will do so in 2010.¹⁷ In either case, a mounting number of employers and insurers is garnering national media attention for adding foreign hospitals to their provider networks.¹⁸ Moreover, foreign hospitals and governments are intensifying their efforts to attract American patients.¹⁹ Because the industry remains embryonic, now may be the perfect time to influence how it allocates legal risks.

Before evaluating how aggrieved patients might fare abroad, I describe how they might fare in the United States. In this Part, I draw on existing scholarship to summarize whether U.S. patients who obtain treatment overseas might be able to recover from specific defendants in U.S. courts, including the legal theories they might use. I emphasize the word “theories” because these suits have not been tested. A major caveat in any legal analysis of medical tourism is the pervasive uncertainty over who might be liable for malpractice overseas. It remains entirely unclear whether medical tourists can recover in U.S. courts. My research found no reported opinions or test cases, and I suspect that providers and facilitators have strong incentives to settle complaints outside the public eye. Moreover, the

14. See, e.g., Cortez, *supra* note 6, at 72 n.5 (noting that the World Trade Organization, World Health Organization, World Bank, and U.S. Senate have all studied medical tourism).

15. Unmesh Kher, *Outsourcing Your Heart*, TIME, May 21, 2006, at 44 (quoting Reinhardt).

16. Tilman Ehrbeck, Ceani Guevara & Paul D. Mango, *Mapping the Market for Medical Travel*, MCKINSEY Q., May 2008, at 2-3, 6 (acknowledging that a substantial number of patients may travel for outpatient rather than inpatient procedures and distinguishing treatments given to medical tourists from those given to visitors and expatriates).

17. DELOITTE CTR. FOR HEALTH SOLUTIONS, MEDICAL TOURISM: CONSUMERS IN SEARCH OF VALUE 4 (2008), available at [http://www.deloitte.com/dtt/cda/doc/content/us_chs_MedicalTourismStudy\(3\).pdf](http://www.deloitte.com/dtt/cda/doc/content/us_chs_MedicalTourismStudy(3).pdf); Ann Tatko-Peterson, *Going Abroad for Health Care*, SAN JOSE MERCURY NEWS, Oct. 16, 2006, at A3.

18. See, e.g., Janet Fullwood, *Medical Tourism: Booming Trend is Standard Operating Procedure*, MIAMI HERALD, Nov. 2, 2008, at J4 (citing BlueCross BlueShield of South Carolina); Roni Caryn Rabin, *Insurer Offers Options for Surgery in India*, N.Y. TIMES, Nov. 21, 2008, <http://www.nytimes.com/2008/11/21/health/21abroad.html> (citing Wellpoint).

19. See Cortez, *supra* note 6, at 89-95.

industry is quickly formulating ways to avoid liability, and patients may not appreciate just how few legal remedies remain.²⁰

A. Suing Foreign Providers in the United States

Victims of medical malpractice overseas might logically seek recourse directly from the foreign hospital or medical professional that caused the injury. However, the most obvious defendants may also be the most difficult to haul into U.S. courts.

1. Personal Jurisdiction

The first obstacle to suing a foreign provider in the United States is establishing that a U.S. court has personal jurisdiction over the defendant.²¹ The law of personal jurisdiction generally requires that a defendant has “minimum contacts” with the forum state through some purposeful contacts or through substantial and continuous connection with the forum.²² Finding minimum contacts is never straightforward, but medical tourist arrangements complicate the analysis by involving foreign health care providers who communicate with patients to varying degrees over the Internet.²³

First, in the medical context, courts traditionally have been reluctant to assert jurisdiction over physicians who reside and practice even in another state, particularly if the physician does not make any “systematic or continuing effort” for his or her services “to be felt in the forum state.”²⁴ Although this analysis should differ if foreign providers systematically target U.S. residents through websites or other avenues, my research uncovered few cases on point.²⁵

20. See, e.g., Wagner, *supra* note 6, at 4 (recommending that health plans have patients release the plan from liability, noting that such a release “may or may not be valid in a court of law . . . but could have a chilling effect on potential plaintiff litigation”); Scott A. Edelstein, Partner, Squire, Sanders, & Dempsey, Addressing Liability Issues in Structuring Medical Tourism Programs: Address at the 2008 World Medical Tourism & Global Health Congress (Sept. 9, 2008) (slides on file with author).

21. Philip Mirrer-Singer, *Medical Malpractice Overseas: The Legal Uncertainty Surrounding Medical Tourism*, 70 LAW & CONTEMP. PROBS. 211, 212-15 (2007).

22. See *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 nn.8-9 (1984) (distinguishing “specific” and “general” jurisdiction); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 291-92, 297-98 (1980).

23. I use the term “Internet” here to denote contacts through cyberspace and other computer networks. See A. Benjamin Spencer, *Jurisdiction and the Internet: Returning to Traditional Principles To Analyze Network-Mediated Contacts*, 2006 U. ILL. L. REV. 71.

24. Mirrer-Singer, *supra* note 21, at 213 n.9 (quoting *Wright v. Yackley*, 459 F.2d 287, 290 (9th Cir. 1972)).

25. For example, a U.S. court has extended jurisdiction over a foreign website operator that targeted U.S. students as customers. *Graduate Management Admission Council v. Raju*, 241 F.

An aggrieved patient might also argue for jurisdiction based on a state's long-arm statute if the foreign provider transacts or solicits business in the state.²⁶ But courts have been reluctant to exert jurisdiction on this basis alone.²⁷ Even a steady stream of referrals from the United States may not establish personal jurisdiction.²⁸ However, courts have exercised personal jurisdiction over out-of-state health care providers that have ongoing relationships with referral sources in the forum.²⁹ Thus, a signed contract between a foreign provider and a U.S. referral source may establish jurisdiction,³⁰ even though, again, some courts have refused to find jurisdiction based solely on a contract—particularly if the contract does not pertain to conduct being challenged in the litigation.³¹ For example, in *Romah v. Scully*, a federal district court recently held that a Toronto hospital being sued for malpractice by a U.S. patient was not subject to the court's jurisdiction.³² Although the hospital had signed contracts with entities in the forum state, the contracts were executed in Canada, and the hospital performed the required work in Canada.³³

Pervasive contact via the Internet, however, could establish jurisdiction over a foreign provider that specifically targets U.S. patients.³⁴ At least one court has exercised jurisdiction over an Indian defendant based on a website that specifically targeted U.S. customers.³⁵ Moreover, in *Romah v. Scully*, part of the reason the court did not accept jurisdiction over the Toronto hospital was that the patient offered weak evidence that the hospital had targeted patients in the forum state.³⁶ Although many medical tourists may be able to muster more concrete evidence that the foreign entity solicited U.S. patients, these analyses are so fact-specific that it is difficult to predict whether any given U.S. court would assert

Supp. 2d 589, 599 (E.D. Va. 2003). See Spencer, *supra* note 23, for a thoughtful analysis of personal jurisdiction based on Internet contacts.

26. See Mirrer-Singer, *supra* note 21, at 213 (citing New York's long-arm statute, at N.Y. C.P.L.R. 302(a)(1), (a)(3)(i) (McKinney 2001 & Supp. 2007)); Kerrie S. Howze, Note, *Medical Tourism: Symptom or Cure?*, 41 GA. L. REV. 1013, 1031 (2007).

27. Mirrer-Singer, *supra* note 21, at 213 (citing cases).

28. *Id.* (citing cases).

29. *Id.* at 214 (citing cases).

30. *Id.*

31. *Romah v. Scully*, No. 06-698, 2007 WL 3493943, at *5-*6 (W.D. Pa., Nov. 13, 2007) ("The mere existence of a contract, standing alone, does not confer general jurisdiction over a defendant.").

32. *Id.* Importantly, the patient was not a medical tourist, but was treated while in the custody of Canadian law enforcement.

33. *Id.* at *7.

34. Howze, *supra* note 26, at 1032.

35. Graduate Management Admission Council v. Raju, 241 F. Supp. 2d 589, 599 (E.D. Va. 2003).

36. *Romah*, 2007 WL 3493943, at *8-*9.

personal jurisdiction over a foreign provider.³⁷ Recent critiques of Internet-based jurisdiction suggest ways courts might better balance concerns of fairness and the limits of state sovereignty,³⁸ which are particularly applicable in medical tourist arrangements.

Aggrieved patients might also argue for U.S. jurisdiction under a continuing tort theory if the patient continues to be affected in the forum state by the foreign provider's tortious conduct.³⁹ But U.S. courts may be reluctant to make this leap unless the patient has some sort of continuing relationship with the provider,⁴⁰ which is less likely in medical tourist arrangements.

Notwithstanding these hurdles, patients might be comforted to know that U.S. courts often provide remedies when Americans are tortiously injured in Mexico.⁴¹ In fact, U.S. courts decide far more tort cases arising in Mexico than Mexican courts do.⁴² One study found that Americans can sue in U.S. courts if the injury is egregious enough. For example, if a company with U.S. ties books a vacationer's travel and strongly recommends a particular hotel in Mexico, a hotel guest injured in the hotel can often sue in the United States.⁴³ This scenario suggests that U.S. courts might find ways to exercise jurisdiction in egregious medical tourism cases as well.

2. Venue and Forum Non Conveniens

Even if a patient can establish jurisdiction in the United States, most foreign defendants would move to dismiss under *forum non conveniens*—a doctrine that allows courts to dismiss cases that would excessively burden the defendant and when a more appropriate forum exists elsewhere.⁴⁴ For example, if the defendant resides overseas along with most of the witnesses and evidence, a court would likely dismiss the case. In *Jeha v. Arabian American Oil Co.*, a U.S. court dismissed a medical malpractice suit filed by an employee's wife against a Saudi Arabian-based employer because the critical evidence and witnesses were all located in Lebanon.⁴⁵ Courts considering a *forum non conveniens* motion must

37. Howze, *supra* note 26, at 1031-32.

38. See, e.g., Spencer, *supra* note 23.

39. Mirrer-Singer, *supra* note 21, at 214 (citing cases).

40. *Id.* (citing cases explaining that refilling a prescription or receiving "incidental" phone calls from a resident of the forum state did not establish personal jurisdiction over the out-of-state doctor).

41. Vargas, *supra* note 12, at 477.

42. *Id.* at 478.

43. *Id.* at 505.

44. Piper Aircraft Co. v. Reyno, 454 U.S. 235, 241 (1981).

45. 751 F. Supp. 122, 126-28 (S.D. Tex. 1990). Note that *Jeha* involved a particularly complicated fact pattern. The plaintiff was the wife of the employee and was treated by the employer's doctors in Saudi Arabia. Both the employee and his wife were Lebanese citizens, who

also consider which country's laws to apply and, more importantly, whether there is an adequate alternative forum.⁴⁶ Courts commonly invoke *forum non conveniens* if foreign rather than domestic law governs the conduct at issue.⁴⁷ Thus, for example, a U.S. court might be reluctant to accept venue and be forced to apply Thai law to malpractice allegedly committed in Bangkok.

Courts typically recognize *forum non conveniens* if an alternative forum can provide adequate legal redress, even if the remedies available are "substantially less than provided by U.S. laws."⁴⁸ Though courts are reluctant to find that a foreign forum is inadequate, some have.⁴⁹ For example, in *Bhatnagar v. Surrendra Overseas Ltd.*, the Third Circuit denied a motion to dismiss a personal injury case against an Indian shipping company on *forum non conveniens* grounds because the alternative forum in India (the Calcutta High Court) was beset by "extreme delays," lasting possibly even a quarter century.⁵⁰ The court held that the severe backlog in Indian courts rendered them inadequate.⁵¹ Testimony in the *Bhatnagar* case suggested that an "average" case before the Calcutta High Court would take fifteen to twenty years to resolve.⁵² Thus, the delayed remedies provided by Indian courts may be "so clearly inadequate or unsatisfactory" that they are "no remedy at all."⁵³ However, the availability of India's consumer forums for malpractice complaints might complicate this analysis, as consumer forums were designed to resolve cases much more expediently.⁵⁴ Nevertheless, medical tourists should know that plaintiffs have had difficulty convincing U.S. courts that even extremely small recoveries overseas amount to "no remedy at all."⁵⁵ For example, in *Gonzalez v. Chrysler Corp.*, the Fifth Circuit held that a \$2500 maximum recovery in Mexico did not prove that

sued in federal district court in Texas in part because she traveled to the United States for treatment, in part because the Saudi company had a Houston-based subsidiary, and most likely in part because Saudi law does not recognize vicarious liability. A U.S. court might be more sympathetic to a U.S. medical tourist injured overseas.

46. Mirrer-Singer, *supra* note 21, at 223-24.

47. *Id.* at 223 (citing cases).

48. *Sector Navigation Co. v. M/V Captain P*, No. 06-1788, 2006 WL 2946356, at *4 (E.D. La. Oct. 13, 2006); Mirrer-Singer, *supra* note 21, at 223-24; Howze, *supra* note 26, at 1033.

49. Mirrer-Singer, *supra* note 21, at 223-24.

50. *Bhatnagar v. Surrendra Overseas Ltd.*, 52 F.3d 1220, 1226-29 (3d Cir. 1995) (noting that the experts "provided both statistical and anecdotal evidence documenting litigation delays" in India); Mirrer-Singer, *supra* note 21, at 224.

51. *Bhatnagar*, 52 F.3d at 1227.

52. *Id.* at 1228.

53. *Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 254 (1981). *But see id.* at 265 n.22 (noting that alternative forums would be inadequate only in "rare circumstances"); Howze, *supra* note 26, at 1034.

54. See Section II.B, *infra*, for a description of India's consumer dispute redressal forums.

55. Howze, *supra* note 26, at 1035.

the Mexican court was inadequate under *forum non conveniens*.⁵⁶ Thus, although concerns about lengthy judicial delays abroad may be sufficient for medical tourists to gain access to U.S. courts, those same courts may not be sympathetic to patients' complaints about the meager damage awards available overseas.

3. Choice of Law

Patients that sue foreign providers in U.S. courts must establish not only jurisdiction and venue, but also may have to litigate complicated choice of law questions. Defendants no doubt will argue that the laws where the treatment was provided govern because, as I demonstrate in Part II, these laws tend to favor providers.

Choice of law questions could be dispositive in medical tourism disputes. Defeating a motion to dismiss for *forum non conveniens* may represent a Pyrrhic victory, as U.S. courts will frequently be obliged to follow the defendant-friendly laws of major medical tourism destinations. For example, in *Chadwick v. Arabian American Oil Co.*, a U.S. plaintiff sued a Saudi Arabian company incorporated in Delaware, arguing that the company was vicariously liable for medical malpractice committed by the company's physician in Saudi Arabia.⁵⁷ The court followed Delaware's conflict of law principles, governed by *lex loci delicti* (a choice of law rule that applies the law of the place where the tort was committed), and applied Saudi law because the physician allegedly misdiagnosed the plaintiff in Saudi Arabia.⁵⁸ But because Saudi law does not recognize vicarious liability, the court dismissed the case.⁵⁹ Similarly, a U.S. court applying the law of India to a malpractice case might leave the patient with very little compensation, yielding the same outcome as if the plaintiff had sued in India.⁶⁰

But the *Chadwick* case may be an unrepresentative and relatively simplistic example of how courts might resolve choice of law questions in medical tourism cases. First, very few American jurisdictions use *lex loci delicti*.⁶¹ Instead, modern choice of law approaches tend to rely on a multitude of "contacts, factors, and policies" that would require courts not only to examine the content of foreign laws, but their underlying policies as well.⁶² Second, choice of law

56. 301 F.3d 377, 383 (5th Cir. 2002); see also Howze, *supra* note 26, at 1035.

57. *Chadwick v. Arabian Am. Oil Co.*, 656 F. Supp. 857, 858 (D. Del. 1987).

58. *Id.*

59. *Id.*

60. Howze, *supra* note 26, at 1038.

61. Symeon C. Symeonides, Choice of Law in Cross-Border Torts 8 (Jan. 14, 2009), available at <http://ssrn.com/abstract=1328191> (unpublished manuscript) (noting how forty-two out of fifty-two U.S. jurisdictions have abandoned the more straightforward *lex loci delicti* rule, which applies the law of the place of injury). Note, however, that in Symeonides's article, "cross-border tort" refers to conduct that causes an injury in a different state. *Id.* at 3 n.1.

62. *Id.* at 9.

disputes will be challenging because medical tourism complicates the traditional analyses. U.S. patients might argue that because foreign providers market themselves as meeting Western standards of medical care, they should be held to those standards in court. Otherwise, divergent standards of care between jurisdictions can affect the choice of law analysis.⁶³ Moreover, courts assessing choice of law might consider patients' expectations and role in choosing the foreign provider.⁶⁴ For example, in a domestic cross-border malpractice case, a Pennsylvania court declined to apply Pennsylvania law and applied the more pro-defendant law of Delaware, noting that patients who travel out-of-state for care cannot carry with them the more protective laws of their domiciles, because such a rule would require providers to comply with the laws of all states that send them patients.⁶⁵ In a medical tourism case, the foreign provider could similarly argue that patients knowingly choose to receive health care in a foreign jurisdiction and that providers cannot be expected to comply with the laws of all of their patients' home countries.

Thus, although suing a foreign provider seems to be the most straightforward avenue for redress, it could be anything but. Patients not only would struggle to establish jurisdiction and venue in U.S. courts, but they may find that courts would apply foreign law. Moreover, these legal obstacles are only compounded by practical ones, such as the burden of properly serving process to a defendant overseas.⁶⁶ Combined, these obstacles could insulate foreign providers from liability in U.S. courts. But until courts are confronted with such cases, we are left to speculate.

B. Suing Intermediaries in the United States

Although medical facilitators located overseas can use many of the same defenses as foreign providers, facilitators located in the United States are not similarly shielded by questions of jurisdiction, venue, or choice of law, making

63. *Id.* at 30 (discussing *Kuehn v. Childrens Hospital, L.A.*, 119 F.3d 1296 (7th Cir. 1997), in which Judge Richard Posner held that a medical malpractice claim brought by a Wisconsin plaintiff against a California hospital was governed by Wisconsin law in part because the state laws differed primarily "in the scope of liability for negligence, not in the standard of care." 119 F.3d. at 1302).

64. Symeonides, *supra* note 61, at 31-32 (citing *Pietrantonio v. United States*, 827 F. Supp. 458 (W.D. Mich. 1993)). In *Pietrantonio*, the court held that a Michigan patient could sue a Wisconsin hospital under Michigan law because the patient "did not go to Wisconsin except by referral from his Michigan doctor" and thus "did not choose Wisconsin as the source of his medical care and . . . would not have expected Wisconsin law to determine [his and his family's] rights." *Pietrantonio*, 827 F. Supp. at 462.

65. *Troxel v. A.I. duPont Inst.*, 636 A.2d 1179, 1181-82 (Pa. Super. Ct. 1994).

66. *Romah v. Scully*, No. 06-698, 2007 WL 3493943 (W.D. Pa. Nov. 13, 2007) (noting difficulty plaintiff had serving process on a Toronto-based hospital defendant); Edelstein, *supra* note 20, at Slide 11.

them more convenient defendants.⁶⁷ U.S. facilitators could be liable under any of the following theories: corporate negligence, failure to obtain informed consent, and vicarious liability.

1. Corporate Negligence

Aggrieved patients may sue medical tourism facilitators for corporate negligence, just as hospitals have been held liable for negligently hiring, retaining, or supervising unfit or incompetent physicians.⁶⁸ However, courts might be reluctant to extend corporate negligence beyond hospitals, as shown by decisions absolving HMOs for torts committed by network physicians.⁶⁹

Moreover, medical tourists could encounter difficulty proving corporate negligence. For example, proving negligent retention would require demonstrating not only that the foreign physician was unfit or incompetent, but also that the U.S. company knew or should have known this based on some pattern of misconduct.⁷⁰ Patients might find it difficult to muster evidence that a foreign provider was unfit or incompetent, especially if the standards for credentialing and practice depart from U.S. standards. Further, courts may be reluctant to pass judgment on such matters.

2. Informed Consent

Patients may also sue medical tourism facilitators for failure to obtain informed consent if the company misrepresents the quality or qualifications of its foreign providers.⁷¹ Facilitators often boast about the quality of foreign providers, and it is not difficult to find marketing hyperbole on their websites.⁷² Of course, patients will face several hurdles proving not only that a facilitator had a duty to obtain informed consent, but that the facilitator also had failed to do so. Courts remain wary of extending informed consent liability beyond the treating physician.⁷³ And it would be difficult to prove that the misrepresentation was material because it must be shown to have caused the patient's injuries.⁷⁴ Most importantly, it would be difficult for U.S. courts to ascertain whether the statements were in fact misrepresentations, because this determination requires

67. Cortez, *supra* note 6, at 113-20; Mirrer-Singer, *supra* note 21, at 215-16.

68. Cortez, *supra* note 6, at 120; Mirrer-Singer, *supra* note 21, at 216.

69. Mirrer-Singer, *supra* note 21, at 216.

70. *Id.* at 216-17 (proving negligent hiring or supervision requires similar steps).

71. *Id.* at 217-19.

72. See, e.g., Global Med Network, Quality, <http://www.globalmednetwork.com/html/quality.html> ("All our network hospitals have success rates that are in many cases equal to or higher than their American counterparts.").

73. Mirrer-Singer, *supra* note 21, at 217.

74. *Id.* at 217-18 (citing cases).

courts to assess the quality and credentials of foreign health care providers—a thorny proposition.⁷⁵

3. *Vicarious Liability*

Finally, patients may argue that a medical tourism facilitator should be vicariously liable for malpractice committed overseas.⁷⁶ However, courts generally refuse to hold HMOs and similar entities vicariously liable for malpractice by a physician unless the physician is an employee or the agent of the company.⁷⁷ Even then, most medical tourism facilitators can safeguard against liability through a well-worded disclaimer.⁷⁸

C. *Suing Employers and Insurers in the United States*

Today, many patients venture overseas not on their own planning, but because an employer or insurer encourages it. In such cases, patients might assert yet additional theories of liability. In fact, patients sent overseas by an employer or insurer may have an easier path to redress in the United States than patients venturing overseas independently.⁷⁹ Some legal theories available to patients suing employers or insurers overlap with those that would hold facilitators liable. For example, patients might argue that an employer or insurer failed to obtain informed consent or exerted some control over a negligent foreign provider and should be vicariously liable.⁸⁰ If an HMO physician recommends a foreign surgeon, the U.S. physician would probably have some duty to disclose the risks of the procedure and obtain preliminary informed consent; at least one court has imposed such a duty on the referring physician in a domestic case.⁸¹ In spite of this domestic precedent, courts in medical tourism cases would still need to resolve complicated questions regarding the scope of the risks, disclosures, and consent required.⁸²

Like hospitals, insurers could be responsible for negligent credentialing if

75. *Id.* at 218-19.

76. Cortez, *supra* note 6, at 120; Mirrer-Singer, *supra* note 21, at 219-21.

77. Mirrer-Singer, *supra* note 21, at 219-20.

78. *Id.* at 221-22.

79. BOOKMAN & BOOKMAN, *supra* note 6, at 157.

80. Howze, *supra* note 26, at 1039-40, 1043-44. Note, however, that the Supreme Court's recent decision in *Aetna v. Davila*, 542 U.S. 200, 209 (2004), held that ERISA preempts state tort claims against covered HMOs.

81. Howze, *supra* note 26, at 1046-48 (citing *Kashkin v. Mount Sinai Med. Ctr.*, 538 N.Y.S.2d 686 (Sup. Ct. 1989), which held the referring physician liable for failure to obtain informed consent because the physician not only referred the patient to a second physician for a specific procedure rather than a second opinion, but also made hospital arrangements through the referrer's office).

82. Howze, *supra* note 26, at 1049-50.

the insurer negligently approved a foreign physician for treating its customers.⁸³ Some observers argue that if HMOs and other employer-sponsored health plans outsource surgeries to foreign providers, they may violate their fiduciary duties under the Employee Retirement Income Security Act of 1974 (ERISA).⁸⁴ Health plans covered by ERISA must act “solely in the interest” of plan beneficiaries and must at minimum avoid making any material misrepresentations about the plan.⁸⁵ Health plans that outsource surgeries risk violating both duties.⁸⁶ Even though an ERISA claim would not compensate victims of malpractice, it might encourage health plans to be more careful about the financial incentives they offer and perhaps the representations they make about foreign providers. Otherwise, insurers might be liable for civil damages as a result of the breach.⁸⁷

Overall, employers and insurers that send patients overseas may be the least sympathetic defendants because they generally save a significant amount of money without accepting much risk in return.⁸⁸ Some authors even suggest that offering financial incentives to patients may increase an insurer’s risk of liability.⁸⁹

But as with other defendants, there are real obstacles to proving these claims against employers and insurers. For example, a court would have to resolve several knotty questions outlined above to hold a U.S. employer or insurer liable for failing to obtain informed consent from medical tourists.⁹⁰ Vicarious liability is unlikely unless the employer or insurer exerted some control over the foreign provider,⁹¹ which would be relatively unusual. A complaint based on negligent credentialing may have some teeth but would require courts to scrutinize the credentials of foreign providers operating in vastly different environments.

D. Inoculating Against Liability

The medical tourism industry is well aware of its potential legal liabilities. Companies have identified these risks and are taking steps to minimize them.⁹² Lawyers are busy formulating ways to avoid liability, particularly in U.S.

83. *Id.* at 1040-42.

84. *See, e.g.*, Christopher J. Brady, *Offshore Gambling: Medical Outsourcing Versus ERISA’s Fiduciary Duty Requirement*, 64 WASH. & LEE L. REV. 1073 (2007); *see also* Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001-1461 (2006).

85. Brady, *supra* note 84, at 1081-87 (citing cases).

86. *See generally id.*

87. *Id.* at 1078-79; 29 U.S.C. § 1109(a) (2006) (describing the remedies available).

88. *See, e.g.*, Cortez, *supra* note 6, at 121-23; Wagner, *supra* note 6, at 7.

89. BOOKMAN & BOOKMAN, *supra* note 6, at 157.

90. Howze, *supra* note 26, at 1048-49.

91. *Id.* at 1039-40, 1043-44.

92. *See generally* Edelstein, *supra* note 20.

courts.⁹³ In fact, companies may be able to limit their exposure (or at least discourage lawsuits) by asking patients to acknowledge disclaimers or sign releases or waivers. For example, companies can try to use contracts to limit the remedies available, to cap damages, to allocate liability between suppliers, to require indemnification, to shift jurisdiction to foreign courts, and to designate alternative dispute resolution or other non-judicial methods of settling disputes.⁹⁴

As a practical matter, medical tourism companies can also reduce their exposure by limiting the representations they make about foreign providers, including any claims about surgical success rates or express comparisons to U.S. hospitals.⁹⁵ The industry might also discourage litigation by informing customers of medical malpractice accident insurance and other forms of protection,⁹⁶ which I explore further in Section III.A. Together, these safeguards may inoculate the industry against liability, particularly in U.S. courts.

Nevertheless, the unsettled legal questions raised by medical tourism introduce pervasive uncertainty for patients, providers, and facilitators in the market. These issues will be litigated eventually, and the first reported opinions will quickly set standards for the industry. Patients undoubtedly will assert creative legal theories, and defendants will devise even more creative defenses. Until then, we are left to speculate. In the meantime, companies that outsource health care to less expensive jurisdictions will continue to try to outsource potential legal disputes as well.

II. SEEKING REDRESS IN FOREIGN JURISDICTIONS

Medical tourists who do not have legal recourse in the United States will have to look elsewhere. In this Part, I evaluate the legal redress provided by four common destinations—India, Thailand, Singapore, and Mexico. I assess whether these countries provide adequate recourse to U.S. patients and the obstacles patients might face navigating various complaint mechanisms in each country.

To date, no scholars or policymakers have tackled these issues, even as employers and insurers increasingly outsource medical treatments. The current literature assumes, without scrutiny, that medical tourist destinations provide lesser remedies or even no remedies at all. In fact, most assume patients will be on their own. For example, the United Kingdom's National Health Service (NHS) warns that if patients seek treatment abroad and need to sue a treating provider, they must rely on the legal system in that country.⁹⁷ Industry

93. *Id.*

94. *Id.* Part III discusses the extent to which waivers of liability might be enforceable in medical tourist arrangements.

95. *Id.*

96. *Id.*

97. Cara Guthrie & Hannah Volpé, *Overseas Treatment for NHS Patients*, 2006 J. PERSONAL

representatives and observers often warn patients not to travel overseas if they are concerned with their potential legal remedies. That is, medical tourists are warned *caveat emptor*.

A. U.S. Expectations

Before scrutinizing malpractice regimes overseas, it is worth taking stock of how U.S. patients fare here. In 2006, the National Practitioner Data Bank (NPDB) received over 12,500 reports of medical malpractice payouts made on behalf of physicians, including both judgments and settlements.⁹⁸ The mean payout was \$311,965 per patient, with a median of \$175,000.⁹⁹ The NPDB also reported that patients waited an average of 4.88 years from the date of the incident to receive compensation.¹⁰⁰

Malpractice litigation in the United States is criticized as being a “lawsuit lottery.”¹⁰¹ The system is blamed for not only awarding windfall damages, but also for awarding damages to meritless claims and denying damages to claims with merit.¹⁰² The Institute of Medicine estimated that anywhere from 44,000 to 98,000 U.S. patients die in hospitals each year from preventable errors.¹⁰³ Yet the vast majority of U.S. patients injured by medical negligence do not sue.¹⁰⁴ Around 70% of those who file claims receive no compensation, and defendants win most cases that proceed to trial.¹⁰⁵ Although several studies conclude that

INJ. L. 12, 15-16; Terry, *supra* note 6, at 464. NHS’s program paying for certain medical treatments in fellow member states is known as E112. National Health Service, Going Abroad for Planned Treatment, Using E112, <http://www.nhs.uk/Treatmentabroad/Pages/E112.aspx> (last visited Nov. 22, 2009).

98. U.S. DEP’T OF HEALTH & HUM. SERVS., NAT’L PRACTITIONER DATA BANK, 2006 ANNUAL REPORT 27, 65 tbl.4 (2006), http://www.npdb-hipdb.hrsa.gov/pubs/stats/2006_NPDB_Annual_Report.pdf [hereinafter NPDB ANNUAL REPORT]. Congress created the NPDB in the Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, 100 Stat. 3784, codified at 42 U.S.C. § 11,101 (2006).

99. NPDB ANNUAL REPORT, *supra* note 98, at 8, 65 tbl.4.

100. *Id.* at 8. Although the NPDB requires reports in various circumstances (e.g., when state boards take disciplinary actions, or when hospitals, HMOs, and similar entities discipline physicians), *id.* at 14-15, the NPDB has been concerned about under-reporting, *id.* at 39-40. Note, however, that very few practitioners dispute reports about them, *id.* at 8, and false reports can trigger criminal punishment, *id.* at 17.

101. David M. Studdert, Michelle M. Mello & Troyen A. Brennan, *Medical Malpractice*, 350 NEW ENG. J. MED. 283 (2004).

102. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2025 (2006); Studdert, *supra* note 101.

103. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH CARE SYSTEM 1 (Linda J. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 1999).

104. Studdert et al., *supra* note 102, at 2024, 2025 (citing research).

105. Studdert et al., *supra* note 101, at 285.

“the tort system does a reasonably good job of directing compensation to plaintiffs with meritorious claims,” compensation can still be indiscriminate.¹⁰⁶ At the same time, stories are legion of U.S. physicians quitting practice due to skyrocketing malpractice insurance premiums.¹⁰⁷ Media reports of “mega awards” in states without damage caps further undercut the public’s faith in our medical malpractice compensation system.¹⁰⁸

Critics of our system are also quick to note that it is expensive and inefficient: “For every dollar spent on compensation, 54 cents went to administrative expenses (including those involving lawyers, experts, and courts).”¹⁰⁹ The consensus in the U.S. health care industry, of course, is that “malpractice litigation has long since surpassed sensible levels and that major tort reform is overdue.”¹¹⁰ Many states have responded by enacting some kind of tort reform, mostly focusing on capping damages.¹¹¹ Critics blame malpractice litigation for encouraging defensive medicine and raising the costs of health care, although “that canard has been exposed,”¹¹² as researchers have found that defending against medical malpractice litigation accounts for less than one percent of all health care spending in the United States.¹¹³ The U.S. Department of Health and Human Services under former President Bush also expressed its concerns with our system, noting that “Americans spend far more per person on the costs of litigation than any other country in the world.”¹¹⁴

106. *Id.* (citing five sources concluding that the system generally compensates valid claims filed, but citing two sources concluding that compensation is indiscriminate). Note also that Studdert et al., reviewing a random sample of closed malpractice claims from five liability insurers, found that 72% of malpractice claims not associated with medical errors did not result in compensation, while 73% of claims associated with medical errors did. Studdert et al., *supra* note 102, at 2028.

107. See U.S. DEP’T OF HEALTH & HUM. SERVS., ADDRESSING THE NEW HEALTH CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM TO IMPROVE THE QUALITY OF HEALTH CARE 3-7 (2003), <http://aspe.hhs.gov/daltcp/reports/medliab.pdf> [hereinafter NEW HEALTH CARE CRISIS].

108. *Id.* at 13-14 (listing awards of \$94 million and \$100 million). Note, however, that appellate courts almost uniformly reduce such awards.

109. Studdert et al., *supra* note 102, at 2024. A separate study found that sixty cents of every dollar is spent on administrative costs. See Studdert et al., *supra* note 101, at 286.

110. Studdert et al., *supra* note 101, at 283.

111. See David A. Hyman et al., *Estimating the Effect of Damages Caps in Medical Malpractice Cases: Evidence from Texas*, 1 J. LEG. ANALYSIS 355, 356 (2009) (noting that thirty states cap non-economic or total damages); Studdert et al., *supra* note 101, at 283.

112. NEW HEALTH CARE CRISIS, *supra* note 107, at 7-8; Studdert et al., *supra* note 101, at 283; Terry, *supra* note 6, at 456-57 (describing the debate over the extent to which malpractice litigation contributes to defensive medicine and rising health care costs).

113. Gerard F. Anderson et al., *Health Spending in the United States and the Rest of the Industrialized World*, 24 HEALTH AFF. 903, 910 (2005).

114. NEW HEALTH CARE CRISIS, *supra* note 107, at 1.

Thus, there are obvious dangers in juxtaposing any malpractice system with ours. Our system has gained international notoriety for being excessive, inefficient, arbitrary, wasteful, and sometimes punitive.¹¹⁵ Virtually any comparison using U.S. awards as a baseline might conclude that the foreign system undercompensates patients. Moreover, scholars cannot say with any certainty that other systems are more or less adept at resisting meritless claims or compensating claims with merit, because these data elude us. The best we can do is to piece together disparate points of information to gauge how patients with legitimate claims fare in each jurisdiction.

Finally, while each of the four countries I examine seems to be struggling to make its malpractice system more efficient and just, each country has expressed grave concerns about the rise of malpractice complaints. Moreover, developing countries in particular worry about more pressing public health issues that might relegate patient compensation down the list of priorities. Needless to say, these tensions may magnify if foreign patients from more litigious jurisdictions begin suing local providers.

B. India

India has quickly become perhaps the leading new destination for foreign patients. In 2007, roughly 450,000 foreign patients visited India, up from roughly 150,000 in 2003 and second only to Thailand.¹¹⁶ By 2012, India may earn over \$2 billion per year from medical tourism.¹¹⁷ India possesses the perfect formula for attracting foreign patients. Its supply of physicians is world renowned,¹¹⁸ and its hospitals are gaining ground.¹¹⁹ India integrates new medical technologies relatively well. Widespread use of English makes its private hospitals and physicians accessible to U.S. patients. Most of all, health care in India is dramatically less expensive than in most countries that offer comparable services.¹²⁰

115. Robert B. Leflar, "Unnatural Deaths," *Criminal Sanctions, and Medical Quality Improvement in Japan*, 9 YALE J. HEALTH POL'Y L. & ETHICS 1, 3 (2009).

116. DELOITTE CTR. FOR HEALTH SOLUTIONS, *supra* note 17, at 6; Aaditya Mattoo & Randeep Rathindran, *Does Health Insurance Impede Trade in Health Care Services?* 2, 12 tbl.2 (World Bank, Policy Research, Working Paper No. 3667, 2005). Many in the industry believe that India will eventually attract more medical tourists than Thailand, although projecting the number of medical tourists that will visit any one country has proven notoriously difficult.

117. Ganapati Mudur, *Hospitals in India Woo Foreign Patients*, 328 BRIT. MED. J. 1338 (2004).

118. See, e.g., Fitzhugh Mullan, *Doctors for the World: Indian Physician Emigration*, 25 HEALTH AFF. 380 (2006).

119. Cortez, *supra* note 6, at 83-85.

120. See, e.g., Aaditya Mattoo & Randeep Rathindran, *How Health Insurance Inhibits Trade in Health Care*, 25 HEALTH AFF. 358, 359 (2006).

The Indian government aggressively promotes its medical tourism industry, following the lead of Thailand and Singapore.¹²¹ The Ministry of Tourism partners with the industry to promote medical tourism, and some state governments have followed suit.¹²² When U.S. health insurers consider outsourcing surgeries, Indian hospitals often top the list of candidates.

But when observers scrutinize India as a destination for U.S. patients, we often generalize about the extent to which its legal and regulatory systems fail to protect patients. In theory, Indian laws attempt not only to punish and deter medical malpractice, but also to compensate patients. Patients can file complaints both in civil courts and in India's Consumer Disputes Redressal Agencies (CDRAs).¹²³ India also relies on familiar mechanisms like criminal prosecution, self-regulation by medical councils, and hospital accreditation to enforce at least some quality standards and accountability.

In reality, India does not impose much accountability. Civil litigation in India is beset by maddening delays.¹²⁴ India's consumer forums were intended to provide a fair and efficient alternative but suffer from several deficiencies.¹²⁵ Criminal prosecution for medical malpractice is rare,¹²⁶ perhaps as it should be. Regulation by the government is virtually non-existent, and self-regulation by medical councils is deeply flawed.¹²⁷ Hospital accreditation is beginning to take hold among private hospitals that attract foreign patients, but the patchwork of accreditation bodies is immature and weak,¹²⁸ and accreditation does not pretend to address negligence. Notably, an executive with the Confederation of Indian

121. Cortez, *supra* note 6, at 91-93.

122. *Id.* at 91.

123. See Subsection II.B.1, *infra*.

124. See Subsection II.B.1, *infra*.

125. See Subsection II.B.1, *infra*.

126. See Subsection II.B.2, *infra*.

127. See Subsection II.B.2, *infra*.

128. There is no national hospital accreditation in India, and at least seven different groups have proposed accreditation systems, including 1) states, 2) the Bureau of Indian Standards, 3) the National Institute for Health and Family Welfare, 4) the Indian Hospital Association, 5) the Confederation of Indian Industry, 6) the National Accreditation Board for Hospitals and Health Care Providers, and 7) the Indian Ministry of Health and Family Welfare. The latter three efforts have emerged with international standards and commerce in mind. See Chandrima B. Chatterjee, *Accreditation of Hospitals: An Overview*, EXPRESS HEALTHCARE MGMT. (India), Sept. 2005, <http://www.expresshealthcaremgmt.com/20050915/accreditation01.shtml>; Rupa Chinai & Rahul Goswami, *Medical Visas Mark Growth of Indian Medical Tourism*, 85 BULL. WORLD HEALTH ORG. 164 (2007), available at <http://www.who.int/bulletin/volumes/85/3/07-010307.pdf>; Varsha Zende, *Dynamics of Accreditation of Private Hospitals*, EXPRESS HEALTHCARE MGMT. (India), Nov. 2006, <http://expresshealthcaremgmt.com/200611/accreditation01.shtml>; National Accreditation Board for Hospitals and Healthcare Providers (NABH), <http://www.qcin.org/nabh> (last visited Nov. 22, 2009).

Industry states that “[a]ny litigation launched against an Indian hospital will expose the poor system of justice that exists here.”¹²⁹

In short, India’s legal and regulatory systems impose few standards on the practice of medicine and do not hold providers accountable in any meaningful way. In fact, some feel the lack of standards and accountability has led the medical profession in India to become increasingly “recalcitrant.”¹³⁰ Finally, there remains a gap in India between several well-intentioned laws and how they operate in reality. As one medical malpractice expert observes, laws exist, but in practice the legal and regulatory systems are beset by delay and apathy.¹³¹ Ironically, the most concrete incentives to avoid injuring foreign patients derive from external sources, such as international accreditation, adverse publicity, and perhaps contracts with foreign payors.

Thus, my research largely confirms our intuition that U.S. patients will struggle to obtain adequate, timely redress in India. But my research also complicates this intuition. Recourse is inadequate in India not because of unreasonable delays or inaccessible tribunals—India’s consumer forums still resolve cases more quickly than most U.S. courts—but because compensation is several magnitudes lower than what U.S. patients might expect. Ironically, compensation is lower in India for largely the same reasons that medical care costs so little: everything is more expensive in the United States.¹³²

1. Redressal Options in India

Victims of medical negligence in India have two primary options: sue in a consumer forum under the Consumer Protection Act or sue in civil court under the tort theory of negligence. Although the government created consumer forums to avoid the burdens of civil litigation, they have come to suffer from some of the same deficiencies that plague civil courts. I discuss both venues and conclude that although consumer forums provide a much more efficient alternative to civil litigation, they present discrete challenges for aggrieved foreign patients, not the least of which is very modest compensation.

a. Consumer Forums

India’s Consumer Disputes Redressal Agencies have become the primary avenue of redress for patients. The forums are a quasi-judicial grievance system intended to create a fair, efficient alternative to civil courts. Although India

129. Chinai & Goswami, *supra* note 128, at 165. The Confederation is a not-for-profit industry organization, much like the U.S. Chamber of Commerce.

130. ANOOP K. KAUSHAL, *MEDICAL NEGLIGENCE AND LEGAL REMEDIES* 2 (2004).

131. *Id.* at 5.

132. See, e.g., Gerard F. Anderson et al., *It’s the Prices, Stupid: Why the United States Is So Different from Other Countries*, 22 *HEALTH AFF.* 89 (2003).

should be commended for creating these forums, in practice, medical negligence suits in consumer forums now impose many of the same burdens as civil litigation: delays, difficulty securing medical records and expert testimony, low success rates, and very modest compensation. In this section, I describe how the consumer forums function and the obstacles U.S. patients might encounter.

i. Creating an Alternative to Civil Litigation

In 1986, the Parliament of India passed the Consumer Protection Act,¹³³ implementing the United Nations' 1985 Consumer Protection Resolution.¹³⁴ The Act was hailed as a "remarkable piece of legislation" because it created an economical, quasi-judicial alternative for resolving consumer grievances in a country that sorely needed it.¹³⁵ Although it took several years to clarify that the Act applied to medical malpractice cases,¹³⁶ it has since become the most well-known law among medical practitioners in India.¹³⁷ Indeed, the Act is a source of anxiety for physicians precisely because it supplants India's notoriously protracted civil litigation system, in which plaintiffs might have to wait well over ten years for a case to be resolved.¹³⁸

The Act established three tiers of consumer forums—district, state, and national.¹³⁹ States have established at least 604 District Forums and 34 State Commissions.¹⁴⁰ The Parliament structured these forums to be "quicker and less costly" alternatives to civil litigation.¹⁴¹ None of the forums utilize juries; decisions are made by panels of "members" and a president. Each tier generally appoints members with both judicial and non-judicial backgrounds, in line with

133. The Consumer Protection Act, 1986, No. 68, Acts of Parliament, 1986.

134. G.A. Res. 39/248, U.N. Doc. A/RES/39/248 (Apr. 16, 1985). This resolution asked signatories, particularly developing countries like India, to improve consumer protection laws, including "measures enabling consumers to obtain redress." *Id.*

135. Bharat Jayaraj, *A Forum for Redressal*, HINDU FOLIO, Oct. 31, 1999, available at <http://www.hinduonnet.com/folio/fo9910/99100100.htm>.

136. Consumer forums began operating in 1987. In 1992, the National Consumer Disputes Redressal Commission announced that the Act applied to medical services, and in 1995 the Indian Supreme Court affirmed. *See Indian Med. Ass'n v. V.P. Shantha*, A.I.R. 1996 S.C. 550.

137. Ramesh Bhat, *Regulation of the Private Health Sector in India*, 11 INT'L J. HEALTH PLAN. & MGMT. 253, 262 (1996).

138. Sanjay Kumar, *India: Doctors Dispute Trader Role*, 340 LANCET 1400 (1992).

139. The Consumer Protection Act, 1986, No. 68, Acts of Parliament, 1986.

140. National Consumer Disputes Redressal Commission, Addresses of the State Consumer Disputes Redressal Commissions, <http://www.ncdrc.nic.in/sDetails.html>; National Consumer Disputes Redressal Commission, District Forums, <http://www.ncdrc.nic.in/districtforums.html> (the database does not include information for the state of Manipur).

141. Bhat, *supra* note 137, at 264.

the forum's quasi-judicial nature.¹⁴² And each tier has original jurisdiction to hear complaints based on the damages claimed.¹⁴³ For example, District Forums may hear complaints claiming compensation up to two million rupees (roughly \$43,500).¹⁴⁴ State Commissions hear complaints seeking compensation between two million and ten million rupees (between \$43,500 and \$217,700).¹⁴⁵ The National Commission hears complaints seeking more than ten million rupees (\$217,700).¹⁴⁶ These ranges were raised significantly in 2002.¹⁴⁷ Both the State and National Commissions also have appellate jurisdiction to hear appeals from subordinate forums.¹⁴⁸

In structuring these forums, the Indian Parliament tried to balance the convenience of non-judicial forums with the legitimacy of courts. For example, the Act vests consumer forums with the power to summon witnesses, receive affidavits, request laboratory tests, and review other documentary and material evidence.¹⁴⁹ In fact, the Act deems each consumer forum to be a "civil court"¹⁵⁰ and every proceeding is a "judicial proceeding" under the Indian Code.¹⁵¹ Despite these grants, National Commission regulations recognize that a consumer forum is "not a regular court."¹⁵²

ii. Causes of Action

The Act empowers consumers in India to bring six different causes of

142. For example, the president of each District Forum must be a current or former District Judge, or someone who is "qualified" to be one. *See* The Consumer Protection Act § 10(1)(a), No. 68 of 1986, *available at* http://ncdrc.nic.in/1_1.html.

143. The Consumer Protection Act §§ 9-27A, No. 68 of 1986, *available at* http://ncdrc.nic.in/1_1.html.

144. *Id.* § 11(1). I calculated the U.S. dollar equivalents using the Federal Reserve Bank's historical foreign exchange rates for the Indian rupee as of September 15, 2008. *See* Federal Reserve Statistical Release H.10, Foreign Exchange Rates (Weekly), Historical Rates for India, http://www.federalreserve.gov/releases/h10/hist/dat00_in.htm.

145. The Consumer Protection Act § 17(1)(a)(i), No. 68 of 1986, *available at* http://ncdrc.nic.in/1_1.html.

146. *Id.* § 21(a)(i).

147. The Consumer Protection (Amendment) Act, 2002, No. 62, Acts of Parliament, 2002.

148. The Consumer Protection Act §§ 17(1)(a)(ii), 21(a)(ii), No. 68 of 1986, *available at* http://ncdrc.nic.in/1_1.html.

149. The Consumer Protection Act § 13(4), No. 68 of 1986, *available at* http://ncdrc.nic.in/1_1.html.

150. *Id.* § 13(5).

151. *Id.*

152. National Consumer Disputes Redressal Commission, Consumer Protection Regulations, 2005, § 3(1), *available at* <http://ncdrc.nic.in/Regulations2005.html> [hereinafter Consumer Protection Regulations].

action.¹⁵³ The most common cause of action used by patients is that medical services “suffer from deficiency in any respect.”¹⁵⁴ The Act defines “deficiency” broadly to mean “any fault, imperfection, shortcoming or inadequacy in the quality, nature and manner of performance.”¹⁵⁵ Of course, the trick for consumer forums is determining whether a physician provided services that were indeed faulty, imperfect, or inadequate. This language is widely considered to be a negligence standard, even though a separate provision in the Act awards damages for any loss or injury due to “negligence.”¹⁵⁶

The Act exempts complaints for services provided “free of charge or under a contract of personal service.”¹⁵⁷ Despite longstanding arguments by physicians that this exemption excluded medical services from the Act, the Indian Supreme Court held that the Act allows consumers to sue private (and sometimes public) physicians.¹⁵⁸ Of course, physicians criticized the Supreme Court’s opinion.¹⁵⁹ In response, one physician castigated his colleagues for their “God complexes” and implored them to embrace the Act for the sake of patients.¹⁶⁰

iii. Truncated Procedures, But Delays

Parliament created truncated procedures so consumer forums could dispose of cases quickly. The Act gives consumers two years to file a complaint from when the cause of action arose.¹⁶¹ Forums must hear complaints “as expeditiously

153. *Id.* § 2(c).

154. *Id.* § 2(c)(iii).

155. *Id.* § 2(g).

156. *Id.* § 14(d); see, e.g., Bhat, *supra* note 137, at 265; K.K.S.R. Murthy, *Medical Negligence and the Law*, INDIAN J. MED. ETHICS, Jul.-Sept. 2007, available at <http://www.issuesinmedicalethics.org/153oa116.html>; Talha Abdul Rahman, *Medical Negligence and Doctors’ Liability*, INDIAN J. MED. ETHICS, Apr.-June 2005, available at <http://www.issuesinmedicalethics.org/132hl060.html>.

157. National Consumer Disputes Redressal Commission, *supra* note 152, § 2(1)(o) (defining “service”); Bhat, *supra* note 137, at 264.

158. *Indian Med. Ass’n v. V.P. Shantha*, A.I.R. 1996 S.C. 550, 567-68 (holding that service rendered to a patient by a doctor qualifies as “service” under the Consumer Protection Act and that patients in Employee State Insurance hospitals and dispensaries could sue under the Act because patients partially pay for treatments); Khomba Singh, *Government Working on Framing Clinical Guidelines for Doctors*, ECON. TIMES (India), May 2, 2008, available at 2008 WLNR 8113374.

159. Bhat, *supra* note 137, at 265.

160. Mangesh Jalgaonkar, *Consumer Protection Act: An Introspection by a General Practitioner*, INDIAN J. MED. ETHICS, Nov. 2007, available at <http://www.issuesinmedicalethics.org/022mi012.html> (“Patients used to consider us as Gods. We still believe ourselves so.”).

161. The Consumer Protection Act § 24A(1), No. 68 of 1986, available at http://ncdr.nic.in/1_1.html. Forums may accept complaints beyond two years if the party shows “sufficient cause.” *Id.* § 24A(2).

as possible” and must attempt to resolve them within three months from receiving the defendant’s response.¹⁶² The Act anticipates that, from start to finish, complaints should be resolved within five-and-a-half to six months of being filed, subject to limited “adjournments.”¹⁶³

In reality, very few cases resolve this quickly. Critics complain that delays cripple India’s consumer forums because forums rarely resolve cases within the recommended deadlines.¹⁶⁴ Although the Act calls for forums to resolve complaints within three months of hearing arguments, “cases are likely to take two or three years.”¹⁶⁵ The Department of Consumer Affairs estimated that only 27% of cases were resolved within the three-month period required by the Act.¹⁶⁶ Although these delays may not be what Parliament envisioned, the timeframes still compare favorably to the 4.88 years it takes on average for payouts in the United States.¹⁶⁷

The forums have tried to mitigate delays, with minimal success. Regulations require each District Forum to resolve “at least 75 to 100 matters every month.”¹⁶⁸ The National Commission boasts that all three tiers of consumer forums have disposed of a large portion of their cases.¹⁶⁹ Yet delays remain a concern in India, as shown by the sheer number of pending cases. For example, in September 2007, there were 723 pending cases in Chennai (North) District Forums and 1,372 in Chennai (South).¹⁷⁰ Karnataka boasted that its State Commission had resolved 95.4% of cases and that its District Forums had resolved 96.9%.¹⁷¹ But these clearance percentages may be misleading because it appears that states and districts are calculating the number of cases resolved against every complaint that the forums have *ever* entertained—meaning that

162. *Id.* § 13(3A). The Act gives a five-month timeframe for cases that require products to be tested by laboratories, but it is not clear if this would apply to many malpractice cases.

163. *Id.* §§ 12-14.

164. Jayaraj, *supra* note 135; *Consumer Laws Implementation*, HINDU (India), Nov. 6, 2007, available at 2007 WLNR 21848658.

165. See Tim Ensor & Sabine Weinzierl, *Regulating Health Care in Low- and Middle-Income Countries: Broadening the Policy Response in Resource Constrained Environments*, 65 SOC. SCI. & MED. 355 (2007) (noting that in the state of Andhra Pradesh, cases typically take three to four years); *Consumer Laws Implementation*, *supra* note 164.

166. K. Srinivasan, *A New Era in Consumerism*, HINDU FOLIO (India), Oct. 31, 1999, available at <http://www.hinduonnet.com/folio/fo9910/99100060.htm>.

167. See NPDB ANNUAL REPORT, *supra* note 98, at 8.

168. Consumer Protection Regulations, *supra* note 152, § 19(1).

169. NCDRC, Total Number of Consumer Complaints Filed/Disposed Since Inception Under Consumer Protection Law, http://ncdrc.nic.in/statistics_files/sheet006.html (posting cases resolved as of Nov. 13, 2009) (last visited Nov. 22, 2009).

170. *Consumer Laws Implementation*, *supra* note 164.

171. *Consumer Forums Clear 95 Per Cent of Cases*, HINDU (India), Dec. 24, 2006, available at 2006 WLNR 23781013.

over time, the clearance rates will naturally inflate. To illustrate, despite 95% to 97% clearance rates in Karnataka, 977 cases were still pending before its State Commission, and 2982 cases were pending in its District Forums.¹⁷² Observers argue that these delays deter consumers from filing complaints in the first place,¹⁷³ though it is not clear whether a three to four year delay would deter U.S. patients.¹⁷⁴

iv. The Obstacles to Proving Negligence

Delays may deter claims, but patients in India might be even more disheartened by other obstacles to proving malpractice in consumer forums. As in most countries, patients in India alleging medical negligence must bear the burden of proving it.¹⁷⁵ This burden does not seem unreasonable until we account for two major obstacles. First, it is extremely difficult for patients to find a qualified medical expert willing to testify that a colleague was negligent. Second, physicians and hospitals make it difficult for patients to obtain medical records and other information about the services in dispute.

First, physician defendants easily find experts to testify on their behalf, but plaintiffs have “faced problems in getting qualified medical practitioners to testify on their behalf,” and most have been “ultimately unable to furnish qualified witnesses to support their claim.”¹⁷⁶ A plaintiff’s lawyer who has tried more than 1,000 consumer forum cases said that malpractice cases often fail because “[i]n most of these cases, the expert opinion provided by the Indian Medical Association are always in favour of doctors and hospitals, even if they have erred.”¹⁷⁷ Thus, patients claiming damages for medical negligence in consumer forums are often unable to prove their allegations because physicians are unwilling to testify against other physicians.¹⁷⁸ One observer notes that “patients are clearly at a disadvantage because of lack of on-the-record testimony

172. *Id.*

173. *Consumer Laws Implementation*, *supra* note 164.

174. American patients suing in U.S. courts might be more patient waiting for judgment or settlement because they anticipate a relatively large recovery; American patients suing in India’s consumer protection forums may be less patient if they anticipate relatively small recoveries by U.S. standards.

175. KAUSHAL, *supra* note 130, at 12, 26.

176. Bhat, *supra* note 137, at 265.

177. *His Brief Is Different*, HINDU (India), Sept. 17, 2005, available at 2005 WLNR 14689221.

178. Ganapati Mudur, *Indian Doctors Not Accountable, Says Consumer Report*, 321 BRIT. MED. J. 588 (2000). Although securing expert medical testimony can be a challenge in most jurisdictions, including the United States, it is especially so in India, where there are many fewer physicians per capita.

by doctors and also a lack of relevant medical documents.”¹⁷⁹ In 2003, the President of the Consumer Information Center said that “it is very difficult to prove an act of negligence” because “[m]ost doctors never speak against their fellow medical practitioners even if they are guilty.”¹⁸⁰

Some observers worry that consumer forums do not have the requisite expertise or resources to handle complex medical cases.¹⁸¹ A State Consumer Affairs Minister agreed that consumer forums need outside medical experts in negligence cases—possibly an independent advisory panel.¹⁸² Currently, civil courts can ask experts from government medical colleges to testify, but consumer courts lack this authority.¹⁸³ Others have echoed this recommendation, proposing that a panel convene monthly to hear all the medical negligence cases on a forum’s docket, or alternatively, proposing that forums assign an additional medical expert to each two-member panel.¹⁸⁴ One malpractice expert in India even suggested that forums could require complaints to append a supporting expert opinion affidavit.¹⁸⁵ Such a recommendation would likely preclude many legitimate complaints, given the widely-acknowledged difficulty that patients have securing expert testimony of any kind. At least one high court has urged courts not to speculate about medical practices, concluding that court opinions must be supported by some expert evidence.¹⁸⁶

Second, patients have difficulty proving medical negligence in India’s consumer forums because hospitals and physicians often refuse to provide medical records or other information about the services in dispute. Providers regularly fail to give patients written records of the diagnoses they receive, the medicines they consume,¹⁸⁷ or their course of treatment.¹⁸⁸ Historically, no laws in India have required medical professionals to provide such information to patients or their families.¹⁸⁹ It was not until 2002 that Indian Medical Council

179. *Id.* at 588.

180. *Straight Answers*, ECON. TIMES (India), Oct. 1, 2003, *available at* 2003 WLNR 4449878.

181. Bhat, *supra* note 137, at 265.

182. Debashis Konar, *Courting Crisis: Medico Cases in the Docks*, TIMES INDIA, Apr. 23, 2005, *available at* 2005 WLNR 6358838.

183. *Id.* Dr. K. Mathiharan doubts that many civil courts actually exercise this option. Letter from K. Mathiharan, Professor, Institute of Legal Medicine (Chennai, India), to Nathan Cortez, Assistant Professor, Southern Methodist University, Dedman School of Law (Jan. 4, 2009) (on file with author).

184. KAUSHAL, *supra* note 130, at 6-7.

185. *Id.* at 66.

186. Dr. C.J. Subramania v. Kumarasamy, I (1994) C.P.J. 509, ¶ 28; KAUSHAL, *supra* note 130, at 67.

187. Bhat, *supra* note 137, at 265.

188. Nayak, *supra* note 7, at 22.

189. *Id.* at 22; KAUSHAL, *supra* note 130, at 24. Note, however, that in 1996, the Bombay High Court held that physicians and hospitals must provide medical records to patients or their close

regulations required physicians to maintain patient records for three years and provide them upon request.¹⁹⁰ However, it is unclear whether the Medical Council has enforced these new requirements. Thus, access to basic information about one's course of treatment remains alien to most patients in India.¹⁹¹

This unfortunate reality only compounds plaintiffs' burden of persuasion, because most patients will find it nearly impossible to convince an expert to testify that a physician was negligent without the benefit of at least some written records describing the procedure and its outcome.¹⁹² Notably, the National Commission has held that a hospital's failure to supply medical records is not actionable as a "deficiency in service" under the Consumer Protection Act because no law in India created a legal duty to provide these records.¹⁹³ However, the 2002 Medical Council regulations that require physicians to keep patient records and provide them upon request might enable such a cause of action.¹⁹⁴ The Medical Council may remove physicians from the Indian Medical Register if a physician refuses to maintain or provide records,¹⁹⁵ but this is a punishment the Council rarely employs.¹⁹⁶ Even though India's Central Consumer Protection Council "has periodically urged the Indian health ministry to make it mandatory for all hospitals to provide medical records to patients," in practice, hospitals still refuse such requests.¹⁹⁷ In 2003, the Medical Council in the state of West Bengal passed its own new Code of Medical Ethics requiring physicians to keep records for every patient for at least three years.¹⁹⁸ Interestingly, one of the putative purposes of the new Code was to speed up decisions in medical negligence

relatives when requested. *Raghunath G. Raheja v. Maharashtra Med. Council*, A.I.R. 1996 Bom. 198, 203; K. Mathiharan, *Medical Records*, INDIAN J. MED. ETHICS, Apr.-Jun. 2004, available at <http://www.issuesinmedicalethics.org/122hl059.html>

190. Medical Council of India, Code of Ethics Regulations, 2002, § 1.3, Apr. 6, 2002, <http://www.mciindia.org/know/rules/ethics.htm> [hereinafter Code of Ethics Regulations].

191. Nayak, *supra* note 7, at 22.

192. KAUSHAL, *supra* note 130, at 27 (citing *Dr. Shyam Kumar v. Rameshbhai, Harmanbhai Kachhiya*, 2002 (1) C.P.R. 320).

193. *Poona Medical Foundation v. Maruttrao Tikare*, 1995 (1) C.P.R. 661 (NC); KAUSHAL, *supra* note 130, at 27; Mathiharan, *supra* note 189.

194. Code of Ethics Regulations, *supra* note 190, § 1.3.

195. *Id.* §§ 7.2, 8.3. The Register is a nationwide registry of physicians with recognized credentials. See The Indian Medical Council Act §§ 21, 23, No. 102 of 1956, available at <http://www.mciindia.org/know/acts/acts.htm>; Medical Council of India, MCI Regulations, 2000, §§ 61-67, Nov. 15, 2000, <http://mciindia.org/know/rules/regulate2000.htm> [hereinafter MCI Regulations].

196. Bhat, *supra* note 137, at 270.

197. Mudur, *supra* note 178, at 588.

198. Aditya Ghosh, *Negligence Cases Pile Up at Medical Council*, ECON. TIMES (India), Feb. 17, 2004, available at 2004 WLNR 7027823.

cases.¹⁹⁹ But the West Bengal Medical Council seemed to be looking out for its own constituents—an officer with the Council said that doctors were disadvantaged in negligence cases because most of the documentary evidence was produced by patients.²⁰⁰ By mandating that doctors keep better records, the West Bengal Medical Council is trying to ensure that physicians control more of the evidence instead of relying on the documentation of patients. There may be a move toward more disclosure in India, but this move is by no means a revolution motivated solely by an interest in protecting patients.

Some patients have sued for alleged manipulation of their medical records,²⁰¹ but these cases seem to be rare. Thus patients in India “are not in a position to build a case with the necessary information and documents as evidence.”²⁰² Although consumer forums recognize the doctrine of *res ipsa loquitur*²⁰³—which allows a forum to presume negligence when the injury could not have occurred otherwise—this does not compensate for the significant hurdles that often preclude patients from accessing expert witnesses and medical records.

v. Limited Compensation

Perhaps the biggest practical obstacle for U.S. patients seeking recourse in India is the very modest compensation awarded. Not only does the Consumer Protection Act not recognize non-economic damages like pain and suffering²⁰⁴ that often amplify recoveries in U.S. courts, but the awards themselves are simply magnitudes lower.

As a structural matter, the Act allows consumer forums to award several forms of compensation. In medical malpractice cases, the most common form is damages “for any loss or injury suffered by the consumer due to the negligence of the opposite party.”²⁰⁵ The Act also allows forums to grant punitive damages “in such circumstances as it deems fit.”²⁰⁶ Finally, the Act empowers forums to “provide adequate costs to parties.”²⁰⁷ It is unclear how often consumer forums actually grant punitive damages or costs. Recently, the Indian Supreme Court

199. *Id.*

200. *Id.*

201. KAUSHAL, *supra* note 130, at 27-28; Mathiharan, *supra* note 189.

202. Bhat, *supra* note 137, at 265.

203. Janak Kantimathi Nathan v. Murlidhar Eknath Masane, 2002 (2) C.P.R. 138, *available at* <http://ncdrc.nic.in/fa7391994.html>.

204. Harjol Ahluwalia v. Spring Meadows Hosp., 1986-1999 Consumer 4457 (NS); Spring Meadows Hosp. v. Harjol Ahluwalia (1998) 4 S.C.C. 39.

205. The Consumer Protection Act § 14(1)(d), No. 68 of 1986, *available at* http://ncdrc.nic.in/1_1.html.

206. *Id.*

207. *Id.* § 14(1)(i).

held that awards in consumer forums should not only compensate patients but should aim to do justice by changing the attitudes of deficient service providers.²⁰⁸ Nevertheless, forums are not explicitly authorized to grant damages for pain and suffering or most other forms of non-economic damages.²⁰⁹ Indian consumer forums have discretion to “serve ends of justice,”²¹⁰ but non-economic damages are not widely accepted.

As a practical matter, India’s consumer forums simply award much lower compensation than U.S. courts do. There is no reliable data of recovery amounts as there is in the United States, but anecdotal evidence in cases and media reports suggest much lower compensation. In fact, major national newspapers in India report malpractice awards that would barely warrant local media coverage here in the United States. For example, the Times of India, the highest circulating English language newspaper in the world,²¹¹ reported that a consumer forum awarded 250,000 rupees (\$5443) to the family of a patient who died during an appendicitis operation.²¹² My review of other media reports shows similarly modest awards making national news: 80,000 rupees for a faulty eye operation (\$1742),²¹³ 100,000 rupees for an eye operation that resulted in death (\$2177),²¹⁴ and 80,000 rupees for leaving a needle inside the body after surgery (\$1742).²¹⁵ Other publications also report awards in these ranges, indicating that payouts of this magnitude are considered newsworthy.²¹⁶ There have been significantly higher awards, but these appear to be the exception rather than the rule.²¹⁷

Importantly, compensation is modest in India compared to the United States for largely the same reasons that medical care costs so little. The basic inputs

208. Charan Singh v. Healing Touch Hosp., A.I.R. 2000 S.C. 3138, 3142.

209. *Id.*

210. *Id.*

211. *Times Now Masthead of the World*, TIMES INDIA, June 27, 2005, available at 2005 WLNR 10154745.

212. *Dead Patient’s Kin Get Rs. 2.5 Lakh*, TIMES INDIA, May 24, 2006, available at <http://timesofindia.indiatimes.com/city/delhi/Dead-patients-kin-get-Rs-25-lakh/articleshow/1549786.cms> (last visited Nov. 22, 2009). For an explanation of how I calculated the U.S. Dollar equivalents, please see note 144, *supra*.

213. Konar, *supra* note 182.

214. *Id.*

215. *His Brief Is Different*, *supra* note 177.

216. See, e.g., KAUSHAL, *supra* note 130, at 71-72 (reporting awards of \$2612 for negligent death, \$2721 for an injury resulting in an amputated leg, and \$2177 for negligent death). Kaushal reports similar awards in a digest of cases. *Id.* at 120-216.

217. For example, in *Harjol Ahluwalia v. Spring Meadows Hospital*, 1986-1999 Consumer 4457 (NS), the National Commission awarded Rs.1,250,000 for medical negligence by a nurse, a physician, and a hospital. The National Commission further awarded Rs.500,000 for mental agony suffered by the parents of the minor. On appeal, the Supreme Court upheld the order. *Spring Meadows Hosp. v. Harjol Ahluwalia*, (1998) 4 S.C.C. 39.

contributing to the cost of medical care are higher in the United States than in other countries.²¹⁸ Thus, it is unrealistic for U.S. patients to expect to pay third world prices for medical care, but receive first world compensation if something goes wrong. The prices of wages and other inputs simply do not support U.S.-like compensation. Yet, even some Indian consumers are not happy with the compensation awarded by consumer forums, ironically in part because they hope to receive a huge, “American-like compensation.”²¹⁹

vi. Few Patients Succeed

There are no reliable, comprehensive, and recent estimates of how medical malpractice complaints fare in India’s consumer forums, but the best available sources suggest they do not fare well. Between 1988 and 1998, only 73 out of 302 cases (24%) reported by the State Commissions, the National Commission, and the Supreme Court awarded compensation.²²⁰ Another report estimated that 71% of malpractice cases resolved by the Gujarat State Commission between 1990 and 1994 were resolved in favor of the physician.²²¹ In 1998, even the Indian Medical Association estimated that district forums dismissed more than 90% of the 10,000 medical malpractice cases filed in a two year period.²²² This data does not, on its face, support the contention by physicians that the Consumer Protection Act treats them unfairly.²²³

The final barrier to efficient and effective recourse as envisioned under the Consumer Protection Act derives from the difficulty of enforcing judgments. Indian consumers used to face “enormous difficulty” enforcing orders by the consumer forums,²²⁴ and recovery could be “tedious.”²²⁵ Even though the original Act empowered forums to enforce judgments as if they were courts,²²⁶ it did not

218. See, e.g., Anderson et al., *supra* note 132 (using OECD data to compare health spending in the United States and twenty-nine other countries, not including India).

219. *His Brief Is Different*, *supra* note 177.

220. Letter from K. Mathiharan, Professor, Institute of Legal Medicine (Chennai, India), to Nathan Cortez, Assistant Professor, Southern Methodist University, Dedman School of Law (Jan. 4, 2009) (on file with author).

221. Ramesh Bhat, *Regulating the Private Health Care Sector in India: The Case of the Indian Consumer Protection Act*, 11 HEALTH POL’Y & PLAN. 266, 275 (1996); Bhat, *supra* note 137, at 265.

222. Ganapati Mudur, *Indian Doctors Call for Protection Against Patients’ Complaints*, 316 BRIT. MED. J. 1558 (1998); see also Howze, *supra* note 26, at 1034 (estimating that 95% of medical malpractice cases are dismissed).

223. Bhat, *supra* note 221, at 269; Bhat, *supra* note 137, at 265.

224. Jayaraj, *supra* note 135.

225. *Id.*

226. The Consumer Protection Act § 25, 1986, No. 68, Acts of Parliament, 1986.

allow forums to attach the property of non-complying parties.²²⁷ To attach a property, consumer forums had to transfer the case to civil court, creating another procedural hurdle.²²⁸ However, recent amendments vest consumer forums with new enforcement powers. For example, the forums may attach the property of non-complying parties or may even impose criminal penalties, such as imprisonment up to three years or a fine up to ten thousand rupees (\$217).²²⁹ Nevertheless, it remains to be seen whether consumer forums will use these new powers or if the gap between the well-intentioned language of the Act and reality will persist. One physician summarized the recent atmosphere in India as “absolute chaos.”²³⁰

In summary, India’s consumer forums serve as an efficient alternative to civil litigation, although medical malpractice cases can bog down as they do in civil courts. Nevertheless, they still provide a crucial alternative to India’s notoriously protracted civil litigation system. And though both domestic and foreign patients may struggle to secure expert testimony or access their own medical records, the biggest impediment to U.S. patients recovering satisfactory compensation in India’s consumer forums is the comparatively small recoveries they award. Thus, patients visiting India should know that although consumer forums provide a palatable alternative to civil litigation, this alternative provides understandably modest compensation.

b. Civil Courts

Civil courts in India have morphed into a depository for malpractice cases that cannot or will not be entertained by consumer forums. For example, tort law in India allows patients to sue for medical negligence even if the service was provided free of charge, which would disqualify it from consumer forum jurisdiction.²³¹ More importantly, consumer forums sometimes transfer complex medical negligence cases to civil courts.²³² In *Herambalal Das v. Dr. Ajoy Paul*, a consumer forum declined to hear a complaint arising from an allegedly

227. *Id.*; Jayaraj, *supra* note 135.

228. The Consumer Protection Act § 25, 1986, No. 68, Acts of Parliament, 1986; Jayaraj, *supra* note 135.

229. Consumer Protection Act § 27(1). For the methodology I used to calculate exchange rates, see *supra* note 144.

230. George Thomas, *Consummate Justice or Complete Folly? Doctors and Consumer Protection Act*, ISSUES MED. ETHICS, Apr.-June 2002, at 28, available at <http://www.issuesinmedicalethics.org/102le028.html>.

231. Rahman, *supra* note 156.

232. See *Herambalal Das v. Dr. Ajoy Paul*, 2001 (2) C.P.R. 498, 498 (dismissing medical malpractice claim while granting liberty to complainant “to seek remedy before the appropriate Forum”).

deficient cataract surgery,²³³ referring the case to civil court because the physicians may have manipulated and fabricated the medical records, which required the consumer forum to take elaborate oral and documentary evidence beyond the forum's expertise.²³⁴ Another consumer forum referred a case to civil court because the dispute would have taken too long to resolve.²³⁵ There does not appear to be any predictable doctrinal framework that guides the decisions of consumer forums to transfer cases to civil courts.

Liability for medical negligence in civil courts derives in part from India's Fatal Accidents Act, which compensates the heirs of those killed by an actionable wrong.²³⁶ Liability also derives from the common law. Indian courts seem to use the same formula that U.S. courts generally use in malpractice cases, looking at duty, breach, causation, and damages.²³⁷ But India's legal system derives from the English system, and as a result, Indian courts generally follow the decisions of English courts.²³⁸ In medical negligence cases, Indian courts adhere to the controversial *Bolam* and *Bolitho* decisions.²³⁹ *Bolam v. Friern Hospital Management Committee*, a 1957 English trial court opinion, and *Bolitho v. City & Hackney Health Authority*, a 1998 House of Lords opinion, altered the standards for proving medical negligence, requiring a judgment for the defendant if any "expert" concludes the physician's actions were appropriate. These rulings have been criticized for making courts overly reliant on medical testimony and permitting negligent doctors to escape liability if they can find one expert to testify on their behalf.²⁴⁰

Perhaps the most significant hurdle for patients in civil courts is their infamous delays. Plaintiffs may wait well over ten years for a case to conclude.²⁴¹

233. *Id.*; KAUSHAL, *supra* note 130, at 27-28.

234. *Herambalal Das*, 2001 (2) C.P.R. at 498-99.

235. *See* Basudev Goswami v. Dr. Bhaskar Das, 2001 (2) C.P.R. 501, 503 (agreeing with decision of Consumer Forum to dismiss case where "adjudication of the dispute in hand cannot be done within a time frame"); KAUSHAL, *supra* note 130, at 28.

236. The Fatal Accidents Act § 1A, No. 13 of 1855, available at <http://indiacode.nic.in/fullact1.asp?tfnm=185513>. The Act does not specify that it applies to medical negligence cases, but courts have interpreted the statute broadly and have awarded damages to the heirs of deceased patients. *See* Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole, A.I.R. 1969 S.C. 128; *Amalgamated Coal Fields Ltd. v. Mst. Chhotibai*, (1973) 18 M.P.L.J. 389.

237. KAUSHAL, *supra* note 130, at 11-12; *see* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS (5th ed. 1984); Nayak, *supra* note 7, at 22.

238. Nayak, *supra* note 7, at 20; Sidhartha Satpathy & Sujata Satapathy, *Medical Negligence or Diagnostic Conundrum? – A Medico-Legal Case Study*, 21 MED. & L. 427, 428 (2002).

239. *Bolitho v. City & Hackney Health Auth.*, [1998] A.C. 232 (H.L.); *Bolam v. Friern Hosp. Mgmt. Comm.*, [1957] 1 W.L.R. 582 (Eng.).

240. *See* Section II.D, *infra*, for a fuller discussion of the criticisms of *Bolam* and its progeny.

241. Kumar, *supra* note 138.

In fact, as noted above, a U.S. court refused to dismiss a case on *forum non conveniens* grounds because the courts in India have such severe delays, possibly even “up to a quarter century.”²⁴² Testimony in that case revealed that an “average” case before the Calcutta High Court would take fifteen to twenty years.²⁴³

Aside from the burdens of civil litigation, there are other reasons patients might prefer India’s consumer forums to its civil courts. First, when litigating a complaint in civil court, the plaintiff cannot file a parallel claim in a consumer forum.²⁴⁴ Thus, the choice to litigate in civil court effectively precludes a consumer complaint, given the two-year statute of limitations under the Consumer Protection Act. Perhaps more importantly, some Indian courts have expressed unabashed hostility toward medical negligence cases. In 2004, a justice of the Calcutta High Court criticized the rise in medical negligence cases, claiming that the entire medical system would collapse if physicians were harassed by lawsuits.²⁴⁵ Though such hostility certainly is not limited to judges, criticisms of medical negligence claims by judicial officers indicates the type of legal environment medical tourists must be prepared to encounter.

c. Self-Regulation by Medical Councils

India’s medical councils ostensibly govern medical practice in India. The primary professional organization for physicians is the Medical Council of India.²⁴⁶ On several occasions, the Indian Parliament has granted more statutory powers to the Medical Council to “make it an effective regulatory body.”²⁴⁷ The Medical Council sets and maintains standards for medical education and credentialing²⁴⁸ and runs the Indian Medical Register of physicians with recognized credentials.²⁴⁹ As health regulation is decentralized in India, several

242. *Bhatnagar v. Surrendra Overseas Ltd.*, 52 F.3d 1220, 1226-27 (3d Cir. 1995) (reporting that experts who testified about India’s legal system “provided both statistical and anecdotal evidence documenting litigation delays” there); *Mirr-Singer*, *supra* note 21, at 224.

243. *Bhatnagar*, 52 F.3d at 1228.

244. KAUSHAL, *supra* note 130, at 69.

245. *Hasty Negligence Pleas Annoy High Court*, *ECON. TIMES* (India), Jan. 23, 2004, available at 2004 WLNR 6999762.

246. The Indian Medical Council Act, 1933, No. 27, Acts of Parliament, 1933, *repealed by* Indian Medical Council Act, 1956, No. 102, Acts of Parliament 1956 (amended by the Indian Medical Council (Amendment) Acts of 1964, 1993, and 2001).

247. Bhat, *supra* note 137, at 269.

248. Medical Council of India, Introduction, http://www.mciindia.org/know/mci/mci_intro.htm (last visited Nov. 22, 2009).

249. *Id.*; The Indian Medical Council Act §§ 21, 23, 1956, No. 102, Acts of Parliament, 1956; MCI Regulations, *supra* note 195, §§ 61-67.

states have parallel state medical councils that also register physicians.²⁵⁰ However, India's medical councils are more useful in theory than in practice. The councils have lost their influence because few physicians are active members, and most ignore the councils' guidelines.²⁵¹ Unsurprisingly, Indian patients do not trust the medical councils to regulate physicians.²⁵²

First, the councils are intended to regulate members and promote compliance,²⁵³ but the Medical Council of India is often criticized for protecting its members rather than the public.²⁵⁴ Critics note that "the Medical Council of India has a poor record in dealing with malpractice, and it cannot award compensation or pass criminal sentences."²⁵⁵ Council regulations identify forms of misconduct that can trigger disciplinary action.²⁵⁶ For example, the Council can punish physicians by removing their names from the register.²⁵⁷ Nevertheless, the list of actionable offenses is generally incomplete, outdated, and does not identify a range of punishments to fit offenses of vastly different severity.²⁵⁸

Of course, the most glaring weakness with self-regulation by medical councils is the conflict of interest created when the foxes guard the henhouse. The Council's Code of Ethics Regulations requires disciplinary cases to be judged by "peers."²⁵⁹ One critic of the Medical Council's oversight explains:

There have been few instances of medical councils intervening and initiating disciplinary action against members of their profession even when there is a formal complaint of negligence. Informal discussions with one of the council members revealed that not many councils have suspended the registration of any member even though many complaints are received by the council. In the case of one council, inquiry was initiated in only three cases and, in those, no disciplinary action has been taken."²⁶⁰

In 1996, the Supreme Court handed down its landmark decision, *Indian Medical Ass'n v. V.P. Shantha*, which ruled in favor of those who had criticized the self-regulation of the medical profession by clarifying that the Consumer

250. Bhat, *supra* note 137, at 269.

251. *Id.* at 264.

252. Ensor & Weinzierl, *supra* note 165, at 359.

253. Bhat, *supra* note 137, at 269.

254. *Id.* at 270.

255. Kumar, *supra* note 138; Bhat, *supra* note 223, at 269.

256. Code of Ethics Regulations, *supra* note 190, § 7.

257. Indian Medical Council Act § 24(1), 1956, No. 102, Acts of Parliament, 1956.

258. Code of Ethics Regulations, *supra* note 190; Bhat, *supra* note 137, at 270.

259. Code of Ethics Regulations, *supra* note 190, § 8.6.

260. Bhat, *supra* note 137, at 270.

Protection Act applies to medical services.²⁶¹ The Medical Council of India has been castigated by consumer groups, the Supreme Court, and even physicians for being corrupt and for not punishing its own members.²⁶² A neurosurgeon declared at a public meeting on medical ethics that the national and state councils “are inefficient and corrupt.”²⁶³ The medical councils in India are subject to minimal, if any, government oversight,²⁶⁴ and the government will intervene only if the councils do not follow the Medical Council Act.²⁶⁵

In short, the medical councils of India do not regulate the practice of medicine in any meaningful way.²⁶⁶ The councils may fail patients more than anyone, given their unique position to influence practice standards and ethics.²⁶⁷

d. Criminal Prosecution

Physicians in India may be prosecuted criminally, though it is doubtful this deters ordinary negligence. The most common provision used against physicians is section 304A of the Indian Penal Code, which prohibits “causing death by negligence.”²⁶⁸ The Code punishes “[w]hoever causes the death of any person by doing any rash or negligent act” with imprisonment up to two years, or a fine, or both.²⁶⁹ Although this appears to create culpability from simple negligence, the Indian Supreme Court has held that physicians committing a mere error of judgment are not criminally liable under section 304A.²⁷⁰ Rather, the Supreme Court read into section 304A a standard of gross negligence or recklessness.²⁷¹ The Court found a heightened standard in light of two other sections in the Penal Code that absolve accidents resulting from lawful activities performed in good faith, which would cover most medical care.²⁷² Physicians in India obviously

261. *Indian Med. Ass’n v. V.P. Shantha*, A.I.R. 1996 S.C. 550, 567-68. Note that this case originated in part from consumer frustration with the Medical Council’s poor record in disciplining its members. See Lilani Kumaranayake, *The Role of Regulation: Influencing Private Sector Activity Within Health Sector Reform*, 9 J. INT’L DEV. 641, 647 (1997) (noting that consumer groups initiated the litigation in response to the Medical Council’s failures to discipline its members).

262. *Straight Answers*, *supra* note 180; Thomas, *supra* note 230.

263. *Lack of Medical Ethics Deplored*, ECON. TIMES (India), June 25, 2003, available at 2003 WLNR 4399683.

264. Bhat, *supra* note 137, at 270.

265. *Id.*

266. *Id.*

267. *Id.*

268. Indian Penal Code § 304A, 1860, No. 45, Acts of Parliament, 1860.

269. *Id.*

270. *Dr. Suresh Gupta v. Government of N.C.T. of Delhi*, A.I.R. 2004 S.C. 4091; *Mahadev Prasad Kaushik v. State of Uttar Pradesh*, 2008 Criminal Appeal No. 1625.

271. *Dr. Suresh Gupta*, A.I.R. 2004 S.C. 4091.

272. *Id.* Indian Penal Code section 80 absolves any “accident” that results from a lawful act.

were relieved by the Court's opinion.²⁷³

Other provisions in the Indian Penal Code may also punish medical malpractice that does not result in death.²⁷⁴ Although it is not immediately clear how frequently physicians are prosecuted under these latter provisions, they have been invoked in some cases.²⁷⁵

Of course, proving criminal negligence against medical professionals is difficult. In 2005, the Supreme Court held that courts should not hear criminal complaints against physicians without *prima facie* evidence supporting the charge from a competent medical expert.²⁷⁶ As noted earlier, finding such an expert is difficult. The Court also encouraged investigators, often police, to secure an independent medical opinion, preferably from a government physician.²⁷⁷ Most importantly, Indian law departs from most jurisdictions in placing the burden to *collect* evidence of criminal liability on the complainant, even though prosecutors must still prove the case.²⁷⁸ Given weak access to medical records, this evidentiary demand may preclude many prosecutions.²⁷⁹

2. Foreign Patients in India

Although India ostensibly regulates medical practice through consumer forums, civil and criminal liability, and self-regulation by medical councils, each of these systems is flawed. Civil litigation is fraught with delay. Consumer forums present several obstacles. Government regulation is virtually non-existent, and self-regulation by medical councils is inherently problematic. In

Section 88 absolves actions that were not intended to cause death and were performed with consent in good faith for the person's benefit. No. 45 of 1860, INDIAN PEN. CODE §§ 80, 88 (2002); Murthy, *supra* note 156, at 117.

273. Nayak, *supra* note 7, at 21; *Docs Can't Be Culpable*, ECON. TIMES (India), Aug. 6, 2004, available at 2004 WL 7387190.

274. No. 45 of 1860, INDIAN PEN. CODE § 337 (2002) (punishing those who cause "hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others"); *id.* § 338 (punishing those who cause "grievous hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others").

275. M.R. Hariharan Nair, *Supreme Court Judgment on Criminal Medical Negligence: A Challenge to the Profession*, INDIAN J. MED. ETHICS, Oct.-Dec. 2005, available at <http://www.issuesinmedicalethics.org/134ed110.html>.

276. Jacob Mathew v. State of Punjab, A.I.R. 2005 S.C. 3180; Murthy, *supra* note 156; Nair, *supra* note 275.

277. Nair, *supra* note 275.

278. *Id.*

279. Overall, my research did not reveal much interplay between criminal actions and civil or consumer forum actions. Physicians acquitted in criminal cases may not use the acquittal as evidence in a consumer forum, because the standard in consumer forums is mere negligence rather than gross negligence or recklessness. *Dead Patient's Kin Get Rs. 2.5 Lakh*, *supra* note 212.

short, India's legal and regulatory systems impose few standards on medical practice and generally fail to hold health care providers accountable in any meaningful way.

Notably, the best mechanisms for regulating Indian providers that treat foreign patients may be external sources, such as international accreditation, adverse publicity that might encourage foreign patients to go elsewhere, and contracts with foreign payors that might impose some accountability. That said, all patients in India would benefit from locally-grown oversight. India's state and local governments could do much more to regulate medical practice. However, increased regulation does not seem to be a high priority. India is plagued by extremely pressing public health issues like HIV/AIDS, malaria, a severe shortage of resources, and extreme poverty.²⁸⁰ In a country where someone dies every minute from tuberculosis,²⁸¹ other health priorities obviously loom.

C. Thailand

Thailand is a primary destination for foreign patients. In 2006, it treated an estimated 1.2 million foreigners, more than any other developing country.²⁸² Thailand's Bumrungrad International Hospital itself claims to host some 500,000 foreign patients annually,²⁸³ and the country boasts at least 450 hospitals with internationally trained health care professionals.²⁸⁴ In 2006, Thailand generated roughly \$2.3 billion from treating foreign patients, and revenues grow 40% each year.²⁸⁵ Thailand has also been one of the more aggressive countries courting foreign patients. After the 1997 Asian economic crisis, the Ministries of Public Health and Commerce began coordinating with the Private Hospitals Association to promote Thai hospitals overseas.²⁸⁶ More recently, the government has planned to develop and promote health care centers in Bangkok, Phuket, and

280. WORLD HEALTH ORG., INDIA: NATIONAL HEALTH SYSTEM PROFILE 10, 13 (2002), available at http://www.searo.who.int/LinkFiles/India_CHP_india.pdf.

281. Reuben Granich et al., *Tuberculosis Control in India*, 3 LANCET INFECTIOUS DISEASES 595, 595 (2003).

282. DELOITTE CTR. FOR HEALTH SOLUTIONS, *supra* note 17, at 6 (defining this population as anyone "traveling to another country to seek specialized or economical medical care" as distinct from emergency or unplanned services provided to foreign tourists or expatriates).

283. *Bumrungrad Keeps on Target*, NATION (Thail.), Jan. 14, 2009, available at 2009 WLNR 775459.

284. Arthur Saniotis, *Changing Ethics in Medical Practice: A Thai Perspective*, 4 INDIAN J. MED. ETHICS 24, 24 (2007), available at <http://www.issuesinmedicalethics.org/151ie24.html>.

285. *Id.*

286. Cha-aim Pachanee & Suwit Wibulpolprasert, *Incoherent Policies on Universal Coverage of Health Insurance and Promotion of International Trade in Health Services in Thailand*, 21 HEALTH POL'Y & PLAN. 310, 311-12 (2006).

Chiang Mai.²⁸⁷

But Thailand struggles with an emergent dichotomy, part of which embraces medical tourism and part of which remains uneasy with the drive toward more commercialized, profit-driven medicine.²⁸⁸ Though medical tourism draws new revenues to Thailand, critics argue that it crowds out the medical care available to ordinary Thais.²⁸⁹ There is widespread fear of both a brain and resource drain from the public to the private sector,²⁹⁰ although some dispute the severity of the drain.²⁹¹ Indeed, officials from the Ministry of Public Health have estimated that “the resources needed to provide services to one foreigner may be equivalent to those used to provide services to 4-5 Thais.”²⁹² While the medical tourism industry booms, several provincial public hospitals have closed from lack of resources.²⁹³ There remains a severe shortage of physicians in public hospitals²⁹⁴ because physicians can earn five to ten times as much in private ones.²⁹⁵

287. Joan C. Henderson, *Healthcare Tourism in Southeast Asia*, 7 TOURISM REV. INT’L 115 (2004).

288. Saniotis, *supra* note 284.

289. *See id.* at 25.

290. *Id.*

291. Professor Eungprabhanth notes that the brain drain from the public to the private health care sector in Thailand is not as severe as reported. He offers two possible reasons: first, public hospitals receive a steady stream of new medical graduates who are obligated to work in public hospitals for three years (with very few opting to pay a hefty fine to exempt themselves); and second, provisions in Thai law exempt public but not private hospital physicians from legal liability, allowing public patients to sue the government instead of individual physicians. Memorandum from Prof. Vithoon Eungprabhanth, Consultant for Health Laws and Ethics Ctr., Thammasat Univ., Thailand to Prof. Nathan Cortez, Assist. Prof. of Law, SMU Dedman School of Law (June 14, 2009) (on file with author) [hereinafter Memorandum from Prof. Eungprabhanth].

292. Suwit Wibulpolprasert et al., *International Service Trade and Its Implications for Human Resources for Health: A Case Study of Thailand*, HUM. RESOURCES FOR HEALTH, June 2004, <http://www.human-resources-health.com/content/2/1/10>. Note, however, contrary data from Australian officials, who claim that revenue from one foreign patient can be used to treat two or three Australian patients on waiting lists. *See* David D. Benavides, *Trade Policies and Export of Health Services: A Development Perspective*, in TRADE IN HEALTH SERVICES: GLOBAL, REGIONAL, AND COUNTRY PERSPECTIVES 65 (Nick Drager & Cesar Vieira eds., 2002). Note also that according to Professor Eungprabhanth, many of the large, private hospitals that cater to foreign patients have chosen not to participate in Thailand’s universal health insurance system. *See* Memorandum from Prof. Eungprabhanth, *supra* note 291.

293. Saniotis, *supra* note 284. Note, however, that Professor Eungprabhanth disputes that provincial public hospitals have had to close because of resource constraints. *See* Memorandum from Prof. Eungprabhanth, *supra* note 291.

294. *Id.*; Songphan Singkaew & Songyot Chaichana, *The Case of Thailand*, in INTERNATIONAL TRADE IN HEALTH SERVICES: A DEVELOPMENT PERSPECTIVE 237, 238 (Simonetta Zarrilli & Colette Kinnon eds., 1998).

295. Wibulpolprasert et al., *supra* note 292.

Meanwhile, Thailand recently created a universal health care system by extending coverage to 18.5 million previously uninsured Thais,²⁹⁶ and researchers report that the system “has greatly increased demand for health care.”²⁹⁷ As in other developing countries, Thailand’s public and private sectors wrestle for finite health care resources.

What do these domestic challenges mean for foreign patients? First, the struggle for finite resources exacerbates Thailand’s two-tiered health care system, and Thais may view foreign patients as a drain on health care resources rather than as a source that might replenish them. Second, Thai courts and the legislature might be more concerned about local public health issues and could have little sympathy for foreign patients seeking relatively large malpractice awards. As in India, other health priorities beckon. In short, Thailand’s health care system remains in flux. Not only is there tension between the public and private sectors, but several legislative proposals may dramatically change the way Thailand’s legal and regulatory systems resolve medical malpractice cases. In this section, I explain the avenues of redress in Thailand, how those avenues may change, and what these changes could mean for foreign patients.

1. Avenues of Redress in Thailand

Bumrungrad International, perhaps Thailand’s most famous hospital, explains on its website that Thailand protects patients in several ways:

All patients in Thailand are protected by Thai law, codes of medical conduct, and a Patient Bill of Rights enforced by the Kingdom’s Medical Council Patients may complain directly to the Thai Medical Council, or the Ministry of Public Health You may also complain to the Thai Consumer Protection Agency or the police, or take legal action in a Thai court.

When considering any overseas treatment it is important to understand that any legal disputes . . . will be decided in the country of treatment, not your country of origin or citizenship.²⁹⁸

Bumrungrad International assures foreign patients that they are protected by several legal and regulatory authorities in Thailand. Although Bumrungrad warns

296. David Hughes & Songkramchai Leethongdee, *Universal Coverage in the Land of Smiles: Lessons from Thailand’s 30 Baht Health Reforms*, 26 HEALTH AFF. 999, 1000 (2007); Pachanee & Wibulpolprasert, *supra* note 286, at 310; Adrian Towse et al., *Learning from Thailand’s Health Reforms*, 328 BRIT. MED. J. 103, 103 (2004). Thailand’s reform was called the “30 baht treats all diseases project” because it provided a generous benefit package for a 30 baht copayment (around \$0.80) per chargeable episode. Hughes & Leethongdee, *supra*, at 999-1000.

297. Pachanee & Wibulpolprasert, *supra* note 286, at 311-12.

298. Bumrungrad International, FAQs, <http://www.bumrungrad.com/overseas-medical-care/faq-s.aspx#Q10> (last visited Nov. 22, 2009).

that complaints will be governed by Thai rather than foreign law, the hospital conveys the unmistakable message that Thai authorities protect foreign patients and give them adequate legal recourse. But a fuller understanding of Thailand's legal and regulatory systems calls these claims into question.

a. Civil Litigation in Thailand

Aggrieved patients in Thailand may sue health care providers in trial court and may appeal unfavorable decisions to appellate courts and ultimately to Thailand's Supreme Court.²⁹⁹ Although Thailand is a civil code country, no Thai statutes specifically address medical malpractice. Thus, patients most frequently claim damages under Section 420 of Thailand's Civil and Commercial Code, which requires any "person who, willfully or negligently, unlawfully injures the life, body, health, liberty, property, or any right of another person" to pay remuneration.³⁰⁰ Thus, health care providers in Thailand may be sued for simple negligence, though the plain language of the statute allows plaintiffs to allege more creative grounds. As in most countries, medical negligence in Thailand is defined as deviating from "a degree of care and skill that could reasonably be expected of a normal, prudent practitioner of the same experience and standing."³⁰¹ Patients bear the burden of proving negligence in Thai courts.³⁰² As in India, patients face enormous practical difficulties proving negligence and recovering meaningful compensation.³⁰³ These burdens are magnified for foreign patients.

First, aggrieved patients frequently fail to recover satisfactory compensation for medical negligence because Thai malpractice law is underdeveloped. No significant body of jurisprudence exists governing medical malpractice cases, and there are few standards to guide courts in granting remuneration.³⁰⁴ In addition to the lack of malpractice statutes, there are very few reported cases, legal periodical articles, and books that discuss malpractice law there.³⁰⁵

Second, Thais perceive that medical negligence suits languish in courts,

299. S. Saithanu et al., *Management of Medical Liability in Thailand*, 12 J. HEALTH SCI. 876 (2003) (Thail.).

300. THAIL. CIVIL & COMMERCIAL CODE § 420.

301. Sukhit Phaosavasdi et al., *Physician's Weak Points at Court*, 89 J. MED. ASS'N THAIL... 401, 401 (2006).

302. Saithanu et al., *supra* note 299.

303. *Id.*

304. *Id.*

305. Yot Teerawattananon et al., *Health Sector Regulation in Thailand: Recent Progress and the Future Agenda*, 63 HEALTH POL'Y 323 (2003). Two well-known books are DR. VITHOON EUNGPRABHATH, *MEDICAL LAW: LIABILITY OF MEDICAL AND HEALTH SERVICE PROVIDERS* (2004); and SAWANG BOONCHALERMVIPAS, *LAWS AND CAUTIONS FOR MEDICAL PRACTITIONERS* (2002), both in Thai.

bogged down in procedure.³⁰⁶ Malpractice suits generally take five to seven years to resolve,³⁰⁷ although like India, this timeframe does not necessarily compare unfavorably to the United States.³⁰⁸ However, there are no official, comprehensive estimates of how long the average malpractice case in Thailand takes to resolve, and it is unclear whether these delays would deter U.S. patients.

Third, as in India, patients face enormous difficulty proving medical negligence because many cannot access their own medical records. Some in Thailand worry that “patients are systematically being denied access to hospital medical records” when preparing malpractice complaints.³⁰⁹ Preeyanan Lorsermvattana, director of the Thai Iatrogenic Disease Network and herself a malpractice plaintiff on behalf of her son, says that “[i]n many cases, the hospitals simply claim that the records have disappeared.”³¹⁰ Although Thailand’s professional councils helped promulgate a Declaration of Patients Rights in 1998, physicians are still reluctant to provide patients with information, even before treatment.³¹¹ Thus, as in India, lack of access to medical records may effectively preclude many legitimate complaints.

Fourth, even if plaintiffs can prove negligence, compensation is modest both in judgment and in settlement.³¹² For example, one author suggests that the largest award ever issued was around \$100,000.³¹³ A Thai newspaper reported that “about 36.5 million baht in total was paid to 443 victims of medical malpractice between 2005-2006”³¹⁴—about 82,393 baht (\$2463) per person.³¹⁵ Thus, as in India, compensation in Thailand is dwarfed by the mean (\$311,965) and median (\$175,000) payouts in the United States.³¹⁶

Fifth, of immediate practical significance to foreign patients is the Thai court system itself, which utilizes judges rather than lay juries, and is conducted

306. Saithanu et al., *supra* note 299.

307. *Health Forum To Debate Medical Malpractice Law*, NATION (Thail.), Feb. 21, 2008, available at 2008 WLNR 3415529.

308. See NPDB ANNUAL REPORT, *supra* note 98.

309. Tunya Sukpanich, *The ‘Doctor’s Devil,’* BANGKOK POST, Jan. 6, 2008, available at 2008 WLNR 297194.

310. *Id.*

311. Teerawattananon et al., *supra* note 305, at 336.

312. Saithanu et al., *supra* note 299.

313. Mark Roth, *A Cheaper Medical Alternative; For Those with Minimal Health Insurance, Getting Surgery Abroad May Be a Sound Option*, PITTSBURGH POST-GAZETTE, Sept. 10, 2006, at G1.

314. *Thailand: The Public Health Ministry Drafts New Laws on Compensation for Victims of Medical Malpractice*, THAI PRESS REPS., Apr. 26, 2007, available at 2007 WLNR 7811849.

315. See Federal Reserve Statistical Release H.10 (Thailand) (calculated exchange rate on January 1, 2006), available at http://federalreserve.gov/RELEASES/H10/Hist/dat00_th.htm.

316. NPDB ANNUAL REPORT, *supra* note 98, at 8, 65 tbl.4.

exclusively in Thai.³¹⁷ All oral and documentary evidence in foreign languages must be translated into Thai.³¹⁸ Moreover, Thai courts do not permit pre-trial discovery of documents; instead, courts subpoena parties to present documents at trial,³¹⁹ which disadvantages plaintiffs. Consequentially, navigating the Thai legal system may present an incredible challenge for a foreign plaintiff.³²⁰

Finally, as in India, there is some hostility in Thailand toward medical malpractice lawsuits and the legal system in general. New malpractice cases still make national news in Thailand.³²¹ And as in most jurisdictions, physicians openly lament malpractice litigation. The Medical Association of Thailand decries litigation as “a win at all costs game that we [find] dishonorable,” and has called for a national discussion “to restore sanity to a system that right now severely inhibits physicians’ efforts to learn from mistakes and make health care safer for everyone.”³²² Physicians complain that litigation can last “many years” and that they often have no choice but to settle.³²³ These lamentations are sometimes published as invective toward patients.³²⁴ On the other hand, some physicians in Thailand believe that a small minority of “egotistic,” “selfish,” and “merciless” physicians ruin the profession’s reputation.³²⁵

On a more basic level, Thais generally distrust the legal system and rarely

317. Interview with Yuthana Srisavat and Pongwut Bamrungsuksawat, L.L.M. Candidates, Southern Methodist University, Dedman School of Law, in Dallas, Tx (Mar. 18, 2009) (citing Civil Procedure Code, Articles 13, 46, procedural rules that require the translation of court documents into Thai). The Thai Constitution does not mention a right to jury trials, and section 197 ascribes judicial powers to judges. Constitution of the Kingdom of Thailand, B.E. 2550 (2007).

318. *Id.*

319. *Id.*

320. The U.S. Embassy in Bangkok maintains a list of attorney referrals should Americans need legal assistance. Email from American Citizen Services (ACS), U.S. Embassy Bangkok, to Prof. Nathan Cortez (Dec. 22, 2008, 09:46 p.m. CST) (on file with author). Because the Embassy does not ask why U.S. citizens are asking for attorney referrals, it was unable to estimate how many seek an attorney to handle medical malpractice cases.

321. *See, e.g., Couple May Sue Hospitals*, THE NATION (Thail.), Dec. 29, 2007, available at 2007 WLNR 25643974.

322. Phaosavasdi et al., *supra* note 301, at 401.

323. *Id.*

324. Members of the Medical Association of Thailand complained that physicians “must always remain calm even when the other party’s temper[s] flair, they do not listen to reason, they always complain about the doctor’s privilege, they question everything but do not listen to the answers and they keep talking nonsense, even when they are wrong.” *Id.* at 402. Despite such public condescension, the authors recommend that Thailand “actively pursue patient safety initiatives that prevent medical injury, promote open communication between patients and doctors and create a just compensation system without hindering the doctor’s ability.” *Id.*

325. Sukhit Phaosavasdi et al., *Medical Ethics and the Survival of the Medical Profession*, 88 J. MED. ASS’N THAIL. 563 (2005).

pursue formal recourse in part because of Buddhist principles like karma, which warn that “the assertion of [legal] rights may ultimately prolong conflict and may in the long run contribute to suffering, misfortune, and distress.”³²⁶ In surveying Thai citizens over several years, Professor David Engel found “diminished regard for and use of law and legal institutions,”³²⁷ quoting a Thai aphorism that “It is better to eat dog shit than to go to court.”³²⁸ Although litigation rates have always been low in Thailand,³²⁹ rates of tort litigation in certain provinces have dramatically decreased per capita over the last twenty-five to thirty years,³³⁰ which may suggest an unfriendly atmosphere for plaintiffs.

Perhaps reflecting these aggregate difficulties, malpractice complaints in Thailand seem to be extremely rare,³³¹ and those that exist are not often successful. Roughly half of the 2726 complaints submitted to the Medical Council between 1988 and 2006 alleged medical malpractice, but only twenty-two of those cases went to court.³³² At the same time, some researchers have found a decisive uptick in malpractice complaints in various forums.³³³ The Ministry of Public Health found that the rate of malpractice complaints submitted to the Thai Medical Council increased sevenfold between 1980 and 2004.³³⁴ The

326. See generally David M. Engel, *Globalization and the Decline of Legal Consciousness: Torts, Ghosts, and Karma in Thailand*, 30 LAW & SOC. INQUIRY 469, 506 (2005).

327. *Id.* at 471-72.

328. *Id.* at 493.

329. *Id.* at 502, n.22.

330. *Id.* at 497. Note that this seems to counter the assertion by the National Health Commission Office that Thai patients increasingly assert legal rights. NAT'L HEALTH COMM'N OFFICE OF THAIL., DOCTOR-PATIENT RELATIONSHIPS: A CHRONIC PROBLEM WHICH MUST BE “CURED” WITHOUT PREJUDICE 2 (2008), http://www.nhcthailand.com/admin/data/Factsheet_D-P.pdf.

331. *Id.*; Kumaranayake, *supra* note 261, at 644.

332. *Thailand: Public Health Minister Wants Doctors To Contribute to Fund To Help Patients Affected by Medical Malpractice*, THAI PRESS REP., Dec. 21, 2007, available at 2007 WLNR 25204659. Patients may sue directly in civil courts, but most Thais prefer to avoid court and attempt to resolve the dispute via the Medical Council.

333. NAT'L HEALTH COMM'N OFFICE OF THAIL., *supra* note 330, at 1-2; Phaosavasdi et al., *supra* note 301, at 401; Saithan et al., *supra* note 299; Teerawattananon et al., *supra* note 305, at 323; *Groups Divided over Bill on Compensation for Medical Errors*, NATION (Thail.), May 26, 2008, available at 2008 WLNR 9951397; *President of Thailand Medical Council Works To Stop Malpractice Lawsuits*, THAI PRESS REP., Jan. 17, 2006; Pongphon Sarnsamak, *New Panel To Resolve Medical Disputes*, NATION (Thail.), Dec. 15, 2007, available at 2007 WLNR 24808537. Note, however, that Professor Eungprabhanth believes that the Thai press sometimes overestimates the number of complaints, and he believes that the number of malpractice complaints made against private facilities has definitely not increased. See Memorandum from Prof. Eungprabhanth, *supra* note 291.

334. Wibulpolprasert et al., *supra* note 292. The Thai Medical Council claims that negligence suits jumped from 250 in 2004 to more than 300 in 2005. *President of Thailand Medical Council*

Thai Medical Association claims that from 1973 to 2003, medical malpractice lawsuits rose from 250 per year to over 500 per year,³³⁵ although, proportionally, the amount of medical services provided during that period has probably risen at least as much. The National Health Commission Office observed sharper rises in complaints to the Medical Council in 1999 and 2005 but reported fewer complaints in 2006 and 2007.³³⁶ There are caveats, however, when attempting to extract any conclusions from these data. There are no official, reliable, and comprehensive estimates of the number of medical malpractice complaints filed in Thailand,³³⁷ and many sources conflate separate complaint venues, for example by failing to distinguish lawsuits filed in civil courts from complaints made to the Medical Council.³³⁸ Nevertheless, even if the Medical Association is correct that malpractice suits have risen to 500 per year, this seems like a relatively minuscule number for a population of over 66 million.³³⁹

One anecdote demonstrates the difficulties aggrieved patients might face in Thailand. Preeyanan Lorsermvattana, director of the Thai Iatrogenic Disease Network, filed suit on behalf of her son, who suffered injuries after being born at “a famous private hospital.”³⁴⁰ In January 1996, she sued the hospital for 57 million baht (\$1.5 million).³⁴¹ In 2000, the trial court dismissed the case because she filed it past the one-year statute of limitations.³⁴² Moreover, the court ordered her to pay the hospital 200,000 baht (\$5420) in court fees and 100,000 baht (\$2710) in lawyers’ fees.³⁴³ In 2002, Lorsermvattana sought help from the National Human Rights Commission, which asked the hospital to compensate her family and pay for future medical treatments.³⁴⁴ The Commission also asked the

Works To Stop Malpractice Lawsuits, supra note 333.

335. Phaosavasdi et al., *supra* note 301, at 401.

336. NAT’L HEALTH COMM’N OFFICE OF THAIL., *supra* note 330, at 2.

337. Professor Eungprabhanth explains that it is extremely difficult to quantify the number of medical malpractice cases filed in civil courts each year in Thailand. However, he estimates that the number of cases filed is “not more than 100 cases per year.” See Memorandum from Prof. Eungprabhanth, *supra* note 291.

338. See, e.g., Phaosavasdi et al., *supra* note 301, at 401; *Thailand: Public Health Minister Wants Doctors To Contribute to Fund To Help Patients Affected by Medical Malpractice, supra* note 332. The Medical Council governs only professional disciplinary rules, not tort claims. See Memorandum from Prof. Eungprabhanth, *supra* note 291.

339. U.S. Department of State, Background Note: Thailand, July 2009, <http://www.state.gov/r/pa/ei/bgn/2814.htm>.

340. Sukpanich, *supra* note 309.

341. *Id.*; see Federal Reserve Statistical Release H.10 (Thailand), available at http://federalreserve.gov/RELEASES/H10/Hist/dat00_th.htm (using the earliest exchange rate available, January 3, 2000).

342. Sukpanich, *supra* note 309.

343. *Id.* (using the exchange rate on January 3, 2000).

344. *Id.*

Medical Council of Thailand to reconsider her son's case and requested that the Ministry of Public Health set better standards for medical care, though these requests were not legally binding.³⁴⁵ Meanwhile, the hospital sued Lorsermvattana for 100 million baht (\$3.1 million) for defamation, though the Supreme Court dismissed this claim.³⁴⁶

In sum, aggrieved patients face obstacles to securing compensation nearly everywhere, but there are significant obstacles in Thailand. Foreign patients may find Thailand's redressal system to be an unrealistic option. Malpractice suits are rare. Compensation is meager, especially by Western standards. Litigation is long and expensive, and generally disfavors patients in fundamental ways. Proving negligence is exceedingly difficult with lack of access to medical records. Court proceedings are conducted exclusively in Thai. And the general atmosphere is hostile to medical malpractice complaints. There have even been reports of violence—both real and threatened—against those who have brought malpractice complaints.³⁴⁷ A medical tourism company in the United States states bluntly: "If someone is considering suing someone, for whatever reason, don't [seek treatment abroad] . . . That's all we have to say."³⁴⁸

b. Pending Reforms in Thailand?

Aware of these hurdles, the government is considering several legislative proposals that may fundamentally change how Thailand handles medical malpractice complaints. Policymakers are considering no-fault compensation and mediation committees, and they may amend legal burdens of proof, criminal liability, and other devices that can hold health care providers accountable.

Currently, Thai law provides a limited safety net for some malpractice victims. The National Health Security Fund compensates victims of medical errors if the patient does not receive any compensation from the health care provider within a reasonable time frame.³⁴⁹ Although the National Health

345. *Id.*

346. *Id.* (using the exchange rate on October 1, 2007).

347. A member of the Thai Iatrogenic Disease Network was shot dead in front of her house in 2007 after suing a physician who allegedly left her face disfigured after cosmetic surgery. The police suspect her murder might have been related to her complaint. Sukpanich, *supra* note 309. Moreover, the father of a 23 year-old American who died during surgery at Bumrungrad International hospital has reported receiving death threats after publicizing the death on a website. See Bumrungrad Hospital Death 2006, <http://www.bumrungraddeath.com> (last visited Nov. 22, 2009).

348. Manthey, *supra* note 10 (quoting a MedRetreat spokesperson) (internal quotation marks omitted).

349. National Health Security Act B.E. 2545, § 41 (2002) (Thail.), available at http://www.nhso.go.th/eng/content/uploads/files/Thailand_NHS_Act.pdf; Saithanu et al., *supra* note 300. A committee of five to seven reviewers determines whether an application for

Security Act caps medical malpractice compensation provided under the Fund to 200,000 baht (\$5764), legislation may raise the cap to two million baht (\$57,636).³⁵⁰ The National Health Security Office can then seek indemnification from the health care provider.³⁵¹ The Committee of National Health Security replenishes the Fund by withholding 1% or less from hospital budgets.³⁵² Article 38 of the Act suggests that the Fund applies to both public and private hospitals,³⁵³ but it is not clear how often patients treated at private hospitals turn to the Fund for compensation.

In 2008, the Ministry of Health proposed legislation to handle malpractice complaints through a “no fault” system, utilizing a national fund to compensate victims of medical errors.³⁵⁴ Former Health Minister Mongkol na Songkhla wanted state physicians to contribute 3000 to 5000 baht to the fund each year, but some doubt physicians would willingly do so.³⁵⁵ Others have called for the government to standardize criteria for awarding compensation.³⁵⁶

Whatever reforms materialize, Thailand seems to be following the recommendation of health policy researchers who urge it to move further away from the U.S. medical malpractice system:

There is a risk of creating the environment of the US where fear of litigation generates unnecessary investigations, overdiagnosis and overtreatment and hence higher health care costs, and there is a vicious cycle of rising insurance premia and rising health-care costs.³⁵⁷

The researchers support a “no fault” compensation system not only because it removes the time and expense spent proving fault, but because it should

compensation complies with the criteria in the regulations, the most important of which is that the patient suffered damages that would not normally occur and has not yet received compensation. *See* Regulation of National Health Security Office on Criteria, Methods and Conditions for Primary Compensation for Damages from Medical Services, B.E. 2549 (2007).

350. Regulation of National Health Security Office on Criteria, Methods and Conditions for Primary Compensation for Damages from Medical Services, B.E. 2549 (2007); Samsamak, *supra* note 333. For exchange rate methodology, see Federal Reserve Statistical Release H.10, Foreign Exchange Rates (Weekly), Historical Rates for Thailand, http://www.federalreserve.gov/releases/h10/Hist/dat00_th.htm.

351. National Health Security Act B.E. 2545, § 42.

352. National Health Security Act B.E. 2545, § 41.

353. National Health Security Act B.E. 2545, § 38.

354. Pongphon Samsamak, *A Challenge To Improve Quality of Life*, NATION (Thail.), Jan. 1, 2008, available at 2008 WLN 49326.

355. Thailand: Public Health Minister Wants Doctors To Contribute to Fund To Help Patients Affected by Medical Malpractice, *supra* note 332.

356. Saithanu et al., *supra* note 299.

357. Teerawattananon et al., *supra* note 305, at 336.

improve physician-patient relationships.³⁵⁸

Thailand may be moving precisely in this direction. In early 2008, Thailand's Health System Research Institute (HSRI) reignited earlier efforts by proposing more expansive legislation to establish a "Medical Malpractice Victim Fund,"³⁵⁹ which would compensate patients within one month of suffering "damage" from medical malpractice and provide additional compensation shortly thereafter depending on the type and severity of damages.³⁶⁰ The bill would compensate only "serious cases,"³⁶¹ although it is not clear how the government would distinguish serious cases from minor ones. The legislation aims to compensate patients quickly—within five months of being injured.³⁶² To build support for the bill, HSRI noted that five months compared very favorably to civil litigation, which generally takes between five and seven years.³⁶³

Of course, establishing a convenient compensation system comes with a price. The legislation has hit some political snags, and the Ministry of Public Health is trying to reconcile several conflicts.³⁶⁴ First, an early analysis of the bill predicts that the Thai government might spend one billion baht per year (\$28.8 million) to compensate malpractice in public hospitals.³⁶⁵ Private hospitals would have to contribute to the fund separately to be covered.³⁶⁶ The bill would effectively render the system a form of government-sponsored malpractice insurance.

Second, a proposal would require patients to forego suing in civil court once they pursue compensation through the fund.³⁶⁷ This provision has become an obvious point of contention. Previously, Thailand's Iatrogenic Disease Network supported the legislation, but it later opposed this new wrinkle and proposed its own reformulation.³⁶⁸ A separate proposal by the National Health Commission would require patients and providers to negotiate before patients could receive compensation.³⁶⁹

Finally, physicians groups have used these legislative efforts as an

358. *Id.*

359. *Health Forum To Debate Medical Malpractice Law*, *supra* note 307.

360. *Id.*

361. *Id.*

362. *Id.*

363. *Id.*

364. *Groups Divided Over Bill on Compensation for Medical Errors*, *supra* note 333.

365. *Health Forum To Debate Medical Malpractice Law*, *supra* note 307 (using exchange rates on Dec. 31, 2008).

366. *Id.*

367. *Id.*; *Groups Divided Over Bill on Compensation for Medical Errors*, *supra* note 333.

368. *Groups Council Urged to Seek Outside Help*, BANGKOK POST, Mar. 12, 2008, available at 2008 WLNR 4790095; *Divided Over Bill on Compensation for Medical Errors*, *supra* note 333.

369. *Groups Divided Over Bill on Compensation for Medical Errors*, *supra* note 333.

opportunity to limit criminal and possibly even civil liability for malpractice. The Medical Council has asked the National Legislative Assembly to revise the Criminal Code to limit criminal punishment for physicians unless they intentionally injure a patient.³⁷⁰ The Council has even proposed eliminating both criminal and civil liability unless the plaintiff proved that the malpractice was intentional or grossly negligent.³⁷¹ Though some recommended that the legislature focus on amending the National Health Security Act rather than the Criminal Code,³⁷² it seems likely that the Medical Council will achieve at least some concessions on this point.

There have been separate but related efforts in Thailand to enhance the medical expertise available to tribunals that hear malpractice cases. Former Health Minister Mongkol na Songkhla proposed establishing a mediation committee to help patients and physicians negotiate settlements.³⁷³ As noted above, the legislation would have increased the maximum medical malpractice compensation from 200,000 baht to two million baht (from roughly \$5700 to \$57,000).³⁷⁴ Although the mediation committee would decide compensation in each case, the legislation would still give victims the chance to sue in court.³⁷⁵ It was not clear whether or when the legislation would be considered formally,³⁷⁶ but the mediation idea seems to be gaining support.³⁷⁷

In a similar vein, the Thai Medical Council proposed legislation to ensure that judges hearing malpractice cases would have access to medical experts.³⁷⁸ But the Council again combined this proposal with a provision that would eliminate both civil and criminal liability for physicians unless the malpractice was intentional or grossly negligent.³⁷⁹

Thus, the medical malpractice system in Thailand remains very much in transition. The government is considering several different legislative proposals, and even with ongoing political upheaval, the compensation system available to patients may look very different, very soon. Of course, this change could be a

370. Sarnsamak, *supra* note 333; *Medical Council Wants New Law To Protect Doctors*, BANGKOK POST (Thail.), Dec. 15, 2007, available at 2007 WLNR 24755523; *Thailand: The Public Health Ministry Drafts New Laws on Compensation for Victims of Medical Malpractice*, *supra* note 314.

371. Sarnsamak, *supra* note 354.

372. *Jarun: Plan to Protect Doctors Needs Review*, BANGKOK POST, Dec. 20, 2007, available at 2007 WLNR 25050574.

373. Sarnsamak, *supra* note 354.

374. Sarnsamak, *supra* note 333.

375. *Id.*

376. *Id.*

377. *Calls for Law To Protect Doctors*, BANGKOK POST, Feb. 12, 2008, available at 2008 WLNR 2651367.

378. Sarnsamak, *supra* note 354.

379. *Id.*

good thing. But it also compounds the uncertainty for foreign patients traveling to Thailand.

c. Consumer Complaints

In February 2008, the Thai government enacted the Consumer Case Procedure Act, B.E. 2551, which creates a streamlined procedure for “consumers” to file complaints against “business operators,”³⁸⁰ which presumably includes private hospitals.³⁸¹ Like India’s consumer forums, the intent seems to be to offer a less costly and more convenient alternative forum to resolve consumer complaints. In fact, the new procedures resemble those in India’s consumer forums, particularly their informality (consumers do not need to be represented by counsel), their quasi-judicial nature (judges are supported by judicial officers who try to mediate), and their truncated procedures (cases are meant to be resolved much more quickly than civil litigation).³⁸² However, because the law took effect in August 2008, it remains unclear what impact it will have on medical malpractice cases.³⁸³

d. Thai Ministry of Public Health

Thailand’s Ministry of Public Health is the Prime Minister’s central cabinet-level department responsible for regulating health care.³⁸⁴ The Ministry not only registers and licenses medical professionals³⁸⁵ but also investigates and reviews patient complaints.³⁸⁶ Most importantly, Thai law authorizes the Ministry to act as a safety net for aggrieved patients by allowing it to order compensation for any damages resulting from inappropriate medical services,³⁸⁷ although it is not clear the Ministry actively exercises this authority.

In spite of its authority, researchers found that the Ministry plays virtually “no role” in regulating the quality or safety of medical services as a practical

380. Consumer Case Procedure Act B.E. 2551 (2008) (English translation on file with author).

381. See Memorandum from Prof. Eungprabhanth, *supra* note 291.

382. *Id.*

383. *Id.* Professor Eungprabhanth predicts that medical malpractice complaints will increase through these new consumer procedures. Memorandum from Prof. Eungprabhanth, *supra* note 291. But to date, the most notable complaint involved the failure of an airport to use a metal detector. See *Airport Fined for Lack of Metal Detector*, NATION (Thail.), Dec. 18, 2008, available at 2008 WLNR 25048009.

384. See Ministry of Public Health: Thailand, <http://eng.moph.go.th> (last visited Nov. 22, 2009).

385. Singkaew & Chaichana, *supra* note 294, at 241.

386. National Health Security Act B.E. 2545, § 50 (2002) (Thail.), available at http://www.nhso.go.th/eng/content/uploads/files/Thailand_NHS_Act.pdf.

387. National Health Security Act B.E. 2545, §§ 50(5), 50(8), 59.

matter.³⁸⁸ Although the Ministry's laws seem to be comprehensive, reviews of discipline in the 1990s show that "enforcement is poor" and "few severe penalties were awarded."³⁸⁹ This comports with a recent analysis of health care regulation in low- and middle-income countries, which found that "traditional methods such as licensing and certification frequently fail to control behavior because of the limited resources available to government [for enforcement] in low- and middle-income countries, and because of the powerful countervailing incentives that encourage deviant behavior to continue."³⁹⁰ Thus, even in more prosperous low- and middle-income countries like Thailand, enforcement lags due to lack of resources.³⁹¹

e. Thai Medical Council

The Thai government entrusts the Medical Council, a quasi-governmental self-regulatory body, to oversee medical professionals by licensing them and enforcing rules of professionalism and ethics.³⁹² The Council may also sanction members, for example by placing them under probation for mild violations or by suspending or revoking licenses for more severe ones.³⁹³ The Council uses an Ethical Committee to handle medical malpractice and ethical complaints against members.³⁹⁴ The Committee investigates each complaint and then recommends penalties.³⁹⁵

Complaints to the Council seem to be rising. Between 1990 and 2006, around 2800 patients filed complaints, more than half alleging malpractice.³⁹⁶ Council records claim that malpractice complaints jumped from 250 in 2004 to more than 300 in 2005.³⁹⁷ Also, the ratio of claims seems to be rising, from 88 complaints per 100,000 physicians in 1975³⁹⁸ to 869 complaints per 100,000

388. Teerawattananon et al., *supra* note 305, at 331 tbl.3.

389. *Id.* at 332.

390. Ensor & Weinzierl, *supra* note 165, at 355.

391. Kumaranayake, *supra* note 261, at 645.

392. Teerawattananon et al., *supra* note 305, at 325.

393. *Id.*

394. *Id.* at 334.

395. *Id.* at 330.

396. Media reports conflict on the precise time frame and number of complaints. *See Thailand: Public Health Minister Wants Doctors To Contribute to Fund To Help Patients Affected by Medical Malpractice*, *supra* note 332 (reporting that between 1988 and 2006, 2726 complaints were filed with the Council). *But see Thailand: The Public Health Ministry Drafts New Laws on Compensation for Victims of Medical Malpractice*, *supra* note 314 ("More than 2,800 complaints were submitted to the Medical Council between 1990 and 2006 . . .").

397. *President of Thailand Medical Council Works To Stop Malpractice Lawsuits*, *supra* note 333.

398. Note again that media reports differ on the precise number. *Compare* Teerawattananon et

physicians in 2003.³⁹⁹ Nonetheless, researchers report that despite widespread problems with physicians in Thailand, the Medical Council still receives relatively few complaints.⁴⁰⁰

Of course, the Medical Council is vulnerable to the same criticisms that plague other professional medical organizations responsible for regulating their own members. For example, a study found that the Council and other professional medical organizations in Thailand “react passively to complaints made directly by consumers and to reports of ethical misconduct from fellow professionals,” even though most complaints allege negligent or substandard care.⁴⁰¹ The same study found that “punishments of the guilty were mostly mild with 53% being reprimanded, 23% placed on probation, 22% ha[ving] their licenses suspended, and 1% ha[ving] their licenses revoked.”⁴⁰² As in India, professional medical organizations in Thailand seem to lack any real incentive to actively investigate their members and resolve complaints.⁴⁰³ One study concluded that the Council only disciplined its members when the Thai media publicized potential violations.⁴⁰⁴

The Medical Council receives many more complaints than it is able or perhaps willing to handle.⁴⁰⁵ In 1999, it resolved only thirty-eight of the 173 complaints filed, and the gap grows over time.⁴⁰⁶ The backlog has provoked even more public criticism of the Council and has raised questions whether the Council is more concerned with protecting patients or its members.⁴⁰⁷

Unsurprisingly, there is widespread public distrust of the Council.⁴⁰⁸ As noted above, plaintiffs criticize it for protecting its members in complaints.⁴⁰⁹ Its investigations are slow and operate under no deadlines.⁴¹⁰ One study notes that “plaintiffs have little confidence that their cases will be handled fairly.”⁴¹¹ Observers have urged the Council to seek assistance from neutral, outside experts

al., *supra* note 305, at 330, 332 (identifying 687 complaints per 100,000 physicians in 1999), with Wibulpolprasert et al., *supra* note 292 (identifying 114.6 complaints per 10,000 physicians in 1999, which is equivalent to 1146 complaints per 100,000 physicians).

399. Wibulpolprasert et al., *supra* note 292 (identifying 86.9 complaints per 10,000 physicians in 2003, is equivalent to 869 complaints per 100,000 physicians).

400. Kumaranayake, *supra* note 261, at 644.

401. Teerawattananon et al., *supra* note 305, at 335.

402. *Id.* at 327 (based on records from the Medical Council between 1995 and 1999).

403. *Id.* at 334.

404. Ensor & Weinzierl, *supra* note 165, at 359.

405. Teerawattananon et al., *supra* note 305, at 335.

406. *Id.* at 333 fig.4.

407. *Id.* at 330.

408. *Council Urged To Seek Outside Help*, *supra* note 368.

409. Saithanu et al., *supra* note 299.

410. *Id.*

411. Teerawattananon et al., *supra* note 305, at 335.

to handle malpractice complaints.⁴¹² One respected scholar recommended that the Council avoid handling any malpractice complaints to avoid conflicts of interest and to restore the public's faith in the profession.⁴¹³ Of course, the Council's president claims that the Council already asks neutral experts to help investigate complaints, noting skeptically that some patients file complaints simply because "they want to get money and take revenge."⁴¹⁴

Meanwhile, it is becoming even more crucial that the Medical Council and other regulators hold physicians in Thailand accountable. In 2004, the Ministry of Public Health wrote that "[w]ith more international trade in health services, professional ethics may erode," and "[m]ore malpractice lawsuits can be envisaged if professional councils are not strong enough."⁴¹⁵ The Ministry thus recommended that the government strengthen regulatory oversight by professional councils and associations.⁴¹⁶

In short, as in India, foreign patients visiting Thailand cannot rely on physician self-regulation to provide any meaningful constraints on medical practice.

f. Criminal Prosecution in Thailand

Physicians in Thailand can also be prosecuted for extreme cases of medical malpractice, but as in most countries, such prosecutions are quite rare. In fact, only one physician has been sentenced to prison for malpractice in Thailand, and this case ignited a firestorm of debate.⁴¹⁷ A rural doctor was sentenced to three years in prison after injecting anesthetic into a patient during a fatal appendicitis operation.⁴¹⁸ According to press reports, the case has intensified tensions between physicians and patients in Thailand, and many surgeons have expressed more reluctance to operate.⁴¹⁹ For example, in response to the case, the Rural Doctors Society threatened to stop operating at rural hospitals.⁴²⁰ The Ministry of Public

412. Sukpanich, *supra* note 309.

413. *Calls for Law To Protect Doctors*, *supra* note 377.

414. Sukpanich, *supra* note 309.

415. Wibulpolprasert et al., *supra* note 292.

416. *Id.*

417. *Medical Council Wants New Law To Protect Doctors*, *supra* note 370; Sarnsamak, *supra* note 354; *Thailand: Public Health Minister Wants Doctors To Contribute to Fund To Help Patients Affected by Medical Malpractice*, *supra* note 332; see also Engel, *supra* note 326, at 500 (noting the drop in private criminal cases arising out of personal injuries). Note, however, that physicians and nurses have been convicted for non-malpractice-related offenses. NAT'L HEALTH COMM'N OFFICE OF THAIL., *supra* note 330, at 1 (reporting what appears to be a case of physician-assisted suicide).

418. *Medical Council Wants New Law To Protect Doctors*, *supra* note 370.

419. Sarnsamak, *supra* note 354.

420. *Medical Council Wants New Law To Protect Doctors*, *supra* note 370.

Health paid the patient's family 600,000 baht (\$15,267) after a civil court ordered the remuneration.⁴²¹ However, the Ministry is appealing the three-year sentence.⁴²² This example might suggest that criminal prosecution in Thailand incites more anger than self-reflection by physicians.

2. Foreign Patients in Thailand

Thailand remains a popular destination for patients, and as in India, most patients visiting will receive competent medical care. Health care regulation in Thailand is fairly comprehensive,⁴²³ but enforcement lags because Thai regulators dedicate insufficient personnel and resources to monitor and enforce compliance.⁴²⁴ A study by the World Health Organization and the United Nations Conference on Trade and Development found that Thailand uses "a passive regulatory system for health-care."⁴²⁵ The study concluded that "[a]lthough some mechanisms for health care supervision and monitoring in public facilities are implemented, there is a lack of continuous, formal appraisal of the quality and appropriateness of care in public and private hospitals as well as private clinics."⁴²⁶ In general, researchers have found that middle-income countries like Thailand lack the resources to adequately regulate health care.⁴²⁷ Even the scholars that praise Thailand's relatively comprehensive regulatory system recommended several fundamental reforms.⁴²⁸ Thus, as in India, lawmakers have the best intentions, but their efforts thus far have been mostly cosmetic due to lax enforcement.

Moreover, medical malpractice is a matter of *when*, not *if*. Foreign patients unlucky enough to be injured by malpractice will not, as a practical matter, have much recourse if left to navigate Thailand's many redressal systems. And though Thailand's health care regulatory system is fairly broad, it does not promote much accountability.

As a complicating factor, many in Thailand are uneasy with the growth of medical tourism and private, commercialized health care. Citizens distrust the private health care sector,⁴²⁹ and "[s]ocial attitudes towards the medical

421. *Id.* (using the exchange rate on Dec. 14, 2007).

422. *Thailand: Public Health Minister Wants Doctors To Contribute to Fund To Help Patients Affected by Medical Malpractice*, *supra* note 332.

423. Teerawattananon et al., *supra* note 305, at 323.

424. Kumaranayake, *supra* note 261, at 644.

425. Singkaew & Chaichana, *supra* note 294, at 240.

426. *Id.*

427. Ensor & Weinzierl, *supra* note 165, at 355; Kumaranayake, *supra* note 261, at 645.

428. Teerawattananon et al., *supra* note 305, at 335-37.

429. *Id.* at 292. Note, however, that Professor Vithoon Eungprabhanth suggests that Thais generally trust the private sector more than the public sector, except for university hospitals. See Memorandum from Prof. Eungprabhanth, *supra* note 291.

profession have changed drastically since much of the health care service is now done by the private sector and it has become a business.”⁴³⁰ As a result, aggrieved foreign patients treated in private hospitals may not find much sympathy in Thailand.

D. Singapore

Singapore has long been a regional hub for patients, and like India and Thailand, it has grand ambitions for its medical tourism industry. Roughly 348,000 foreign patients visited Singaporean hospitals in 2007, up from 200,000 just four years earlier.⁴³¹ Singapore is being pressured by competition from less expensive destinations like Malaysia, Thailand, and India.⁴³² And, perhaps as only Singapore can do, its government has mustered a coordinated, centralized effort to promote its medical tourism industry and retain its status as Asia’s health care hub.⁴³³ Indeed, the government announced that it hopes to attract one million foreign patients annually by 2012.⁴³⁴

Singapore as a medical destination is a study in contrasts. On one hand, Singapore is far and away the richest, most developed country I examine in this Article.⁴³⁵ Its average income resembles the United States more than India, Thailand, or Mexico.⁴³⁶

But similarities with the United States do not extend much further. Unlike the United States, Singapore’s system for compensating patients is much more limited, veering more toward India and Thailand. Medical malpractice lawsuits

430. *Jarun: Plan to Protect Doctors Needs Review*, *supra* note 372.

431. Maria Almenoar, *Stats at Odds: More or Fewer Medical Tourists?*, STRAITS TIMES (Sing.), Jan. 23, 2009, available at 2009 WLNR 1270475; Mattoo & Rathindran, *supra* note 116, at 2, 12 tbl.2; Singapore Ministry of Health, Medical Travelers Update, Jan. 22, 2009, <http://www.moh.gov.sg/mohcorp/parliamentaryqa.aspx?id=20836>. Note, however, that the Singapore Tourism Board estimates elsewhere that 571,000 medical tourists visited in 2007. See Wong Mei Ling, *Medical Tourism Hit by Global Downturn*, STRAITS TIMES (Sing.), Jan. 11, 2009, available at 2009 WLNR 527972.

432. See Cortez, *supra* note 6, at 89-93.

433. See *id.* at 92-93; SingaporeMedicine, Welcome to SingaporeMedicine, <http://www.singaporemedicine.com> (last visited Nov. 22, 2009).

434. Mattoo & Rathindran, *supra* note 116, at 2, 12 tbl.2.

435. In 2006, the gross national income per capita was \$2460 in India, \$7440 in Thailand, \$11,990 in Mexico, \$43,300 in Singapore, and \$44,070 in the United States. See WHO, WHO Statistical Information System (WHOSIS), <http://www.who.int/whosis/en/index.html> (last visited Nov. 22, 2009) (perform a “Customized Search,” selecting India, Mexico, Singapore, Thailand, and United States, then select “Gross national income per capita (PPP international \$),” then select “2006,” the latest date for which data is available).

436. *Id.*

are rare.⁴³⁷ Awards are modest not only by U.S. standards but by standards appropriate for a country with Singapore's wealth.⁴³⁸ Patients in Singapore remain reluctant to file suit, partly due to a cultural aversion to challenging medical authority, partly due to modest awards, and partly due to the risks of unsuccessful litigation in a system that imposes costs on the losing party and does not allow contingency fee arrangements.⁴³⁹ As in India and Thailand, patients have trouble finding medical experts willing to testify against colleagues.⁴⁴⁰ And like India, Singapore is one of the former British colonies saddled with the *Bolam* decision, the 1957 English trial court opinion that has made proving medical negligence exceptionally difficult.⁴⁴¹ Finally, Singapore is a relatively non-litigious society, and the medical profession is winning the public relations battle against malpractice suits, warning the country that it is sliding further toward a medical malpractice crisis like that in the United States.⁴⁴² All these factors create a general atmosphere that both discourages malpractice suits and makes them unlikely to achieve much.

My goal in this section is to describe this atmosphere and explain how Singapore's redressal system operates. Allegations of medical malpractice in Singapore can trigger several distinct legal procedures, including criminal sanctions, actions by the Singapore Medical Council, and civil liability. Here I outline these procedures and assess whether they might provide adequate recourse to foreign patients.

1. Civil Liability in Singapore

Physicians in Singapore may be civilly liable for medical malpractice under theories of both contract and tort—though the most common allegation is simple

437. See, e.g., Kumaralingam Amirthalingam, Book Review, 2005 SING. J. LEG. STUD. 471, 472 (reviewing YEO KHEE QUAN ET AL., *ESSENTIALS OF MEDICAL LAW* (2004)) (noting that Singapore cases "account for well below 10% of the cases mentioned in the book").

438. See Kumaralingam Amirthalingam, *Judging Doctors and Diagnosing the Law: Bolam Rules in Singapore and Malaysia*, 2003 SING. J. LEG. STUD. 125, 143-44.

439. See Terry Kaan, *Singapore*, in INTERNATIONAL ENCYCLOPAEDIA OF LAWS: MEDICAL LAW 89-90 (Herman Nys ed., 1994 & Supp. 1998); D. Kandiah, *Comparisons of the Interactions of Health Care Delivery and Medico-Legal Practice Between Australia and Singapore*, 25 MED. & L. 463, 467 (2006). Of course the decision to file a complaint is complex. Physicians and patients in Singapore often prefer to use mediation and arbitration—or simply prefer to settle—to avoid legal confrontations. Letter from Kumaralingam Amirthalingam, Professor, National University of Singapore Faculty of Law, to Nathan Cortez, Assistant Professor, Southern Methodist University, Dedman School of Law (Jan. 27, 2009) (on file with author).

440. See Liu Chun Fai, *A Functional Review of Medical Negligence Law*, 6 SING. L. REV. 188, 195 (1985).

441. *Bolam v. Friern Hosp. Mgmt. Comm.*, [1957] 1 W.L.R. 583 (Eng.).

442. See Amirthalingam, *supra* note 438, at 143-44.

negligence in tort.⁴⁴³

As a foundational matter, Singapore inherits its common law from England, and to this day, Singaporean courts often apply judicial precedents from English courts.⁴⁴⁴ Courts tend to treat English decisions as “highly persuasive if not practically binding,” although the Singapore High Court has held that courts need not follow English common law.⁴⁴⁵ In addition, a 1993 statute allows courts to reject English precedents if applying them would be inappropriate.⁴⁴⁶ Thus, courts in Singapore have shown increased willingness to depart from English common law and follow more patient-friendly precedents from Australian or Canadian courts (though Singaporean courts remain reluctant to adopt U.S. precedents).⁴⁴⁷ The Parliament of Singapore has grown more assertive in regulating medical professionals, but medical practice remains governed almost exclusively by the common law of contract and tort.⁴⁴⁸

Courts in Singapore continue to adhere to the infamous *Bolam* rule, the standard for finding medical negligence that has been widely criticized for unduly favoring physicians.⁴⁴⁹ In *Bolam v. Friern Hospital Management Committee*,⁴⁵⁰ the court explained that it would not find medical professionals to be negligent if they “acted in accordance with a practice accepted by a responsible body of medical men skilled in that particular art.”⁴⁵¹ This famous test simply states that the standard of care for physicians is not that of the ubiquitous “reasonable man,” but of a reasonable physician possessing roughly the same special skills and competencies.⁴⁵²

On its face, the *Bolam* rule seems to be innocuous, even bland. But most courts have interpreted *Bolam* to create almost insurmountable hurdles for patients. First, if the standard of care is that of “a responsible body of medical men skilled in that particular art,”⁴⁵³ who else but those same “medical men”

443. Kaan, *supra* note 439, at 70. As with most common law jurisdictions, Singaporean courts apply the familiar duty-breach-causation formula in medical negligence claims at tort. Fai, *supra* note 440, at 195; Margaret Fordham, Singapore Academy of Law, The Law of Negligence § 20.1.3, <http://www.singaporelaw.sg/content/Negligence1.html> (last visited Nov. 22, 2009).

444. Kaan, *supra* note 439, at 15-18.

445. *Id.* at 88 (citing *Pang Koi Fa v. Lim Djoe Phing*, [1993] 3 S.L.R. 317, 323D-E (Sing.)).

446. Application of English Law Act, Ch. 7A, Act 35 of 1993 (Sing.), *available at* <http://policy.mofcom.gov.cn/resource/flaw/f970eb0f-21ba-46d2-9014-025ef1ab5d09.pdf>; *see also* Kaan, *supra* note 439, at 18.

447. Kaan, *supra* note 439, at 18.

448. *Id.* at 16-18.

449. *See, e.g.*, Amirthalingam, *supra* note 438; Fai, *supra* note 440; Fordham, *supra* note 443, § 20.4.10.

450. *Bolam v. Friern Hosp. Mgmt. Comm.*, [1957] 1 W.L.R. 582 (Eng.).

451. *Id.* at 587.

452. *Id.*

453. *Id.*

could identify what practices were appropriate in each case? *Bolam* requires courts to refer to expert testimony to help determine the standard of care—as do courts in most common law jurisdictions—but courts in Singapore rely overwhelmingly on such testimony with very little independent, critical assessment.⁴⁵⁴ In fact, courts applying *Bolam* do not grant themselves much leeway to decide between conflicting medical experts.⁴⁵⁵ Most courts applying *Bolam* prohibit non-experts like judges from independently determining whether the physician was negligent as long as *some* evidence supports the defendant's conduct.⁴⁵⁶ Courts have even held that the testimony of a single expert defense witness can represent a “responsible body” of medical opinion, even if it contradicts a larger body of opinion.⁴⁵⁷ Thus, courts applying *Bolam* often refrain from finding negligence if only one expert finds the defendant's conduct reasonable—even if multiple competent experts find it unreasonable.⁴⁵⁸

As a practical matter, therefore, medical negligence under *Bolam* is often “determined by the lowest standard of care (accepted by the medical profession) rather than reasonable contemporary standards.”⁴⁵⁹ One lawyer notes that “barring a truly exceptional case, there will invariably be a body of medical opinion that supports the allegedly negligent physician's practice.”⁴⁶⁰ Essentially, courts in Singapore enforce standards that the medical profession set for itself without independently assessing those standards.⁴⁶¹ Scholars in Singapore bemoan that courts have forgotten the normative interpretation required when determining whether a physician acted in accordance with a “responsible body” of professional medical opinion.⁴⁶² Indeed, courts in Singapore seem quicker to chastise themselves than physicians. For example, in one highly-publicized case, the Singapore Court of Appeal fumed that:

It would be pure humbug for a judge, in the rarified atmosphere of the courtroom and with the benefit of hindsight, to substitute his opinion for that of the doctor in the consultation room or operating chamber. We often enough tell doctors not to play God; it seems only fair that, similarly, judges and lawyers

454. See Amirthalingam, *supra* note 438, at 129.

455. See, e.g., *Dr. Khoo James v. Gunapathy d/o Muniandy*, [2002] 2 S.L.R. 414 (Sing.); Amirthalingam, *supra* note 438, at 129.

456. Amirthalingam, *supra* note 438, at 129.

457. *Id.* at 129 (citing *Gerrard v. Royal Infirmary of Edinburgh NHS Trust* [2002] ScotCS 11 ¶ 89).

458. *Id.* at 129-30 (citing cases).

459. *Id.* at 129.

460. Paul Tan, *The Doctrine of Informed Consent – When Experts and Non-Experts Collide*, 2006 SING. J. LEG. STUD. 148, 153.

461. Fai, *supra* note 440, at 189.

462. Amirthalingam, *supra* note 438, at 129.

should not play at being doctors.⁴⁶³

A recent trend suggested that courts might retreat from *Bolam* or at least domesticate it, but this proved not to be much of a revolution. In 1998, the English House of Lords left room for courts to depart from *Bolam* in its well-known *Bolitho* opinion,⁴⁶⁴ where it held that courts should depart from *Bolam* when the professional medical opinion “is not capable of withstanding logical analysis.”⁴⁶⁵ *Bolitho* seemed to give judges an opportunity—albeit a narrow one—to reassert themselves and critically weigh expert opinions in medical negligence cases.⁴⁶⁶ Although several courts did use *Bolitho* to appraise expert medical testimony more critically, Lord Browne-Wilkinson warned lower courts in his House of Lords opinion in *Bolitho* to apply the case only in exceptional circumstances.⁴⁶⁷ Thus, many observers view *Bolitho* as only slightly altering *Bolam*’s status quo.⁴⁶⁸

In 2002, in the case of *Dr. Khoo James v. Gunapathy d/o Muniandy*, the Singapore Court of Appeal systematically reviewed the common law in this area.⁴⁶⁹ Reacting to public backlash against a S\$1.4 million trial court award, the Court of Appeal announced that judges should not determine the reasonableness of medical opinions but should merely determine whether the expert medical testimony is logically defensible.⁴⁷⁰ Indeed, the Singapore High Court noted in a 2002 case predating *Gunapathy* that *Bolam* and its progeny prevent courts from finding negligence “even if the diagnosis or treatment were wrong.”⁴⁷¹ As such, the *Gunapathy* opinion represents the current law in Singapore,⁴⁷² cementing the near sancrostat status of the *Bolam* rule. One scholar has interpreted *Gunapathy* as rendering malpractice cases more hostile to plaintiffs in Singapore than in England.⁴⁷³

Professor Amirthalingam has called for courts to “reassert their role as the

463. *Dr. Khoo James v. Gunapathy d/o Muniandy* [2002] 2 S.L.R. 414, ¶ 3 (Sing.), available at <http://www.singaporelaw.sg/rss/judg/8318.html> (English translation).

464. *Bolitho v. City & Hackney Health Auth.*, [1998] A.C. 232 (H.L.).

465. *Id.* at 243.

466. Amirthalingam, *supra* note 438, at 132-33.

467. *Bolitho*, [1998] A.C. at 243.

468. *See, e.g.*, Amirthalingam, *supra* note 438, at 132-33.

469. *Dr. Khoo James v. Gunapathy d/o Muniandy* [2002] 2 S.L.R. 414, ¶ 52 (Sing.), available at <http://www.singaporelaw.sg/rss/judg/8318.html> (English translation); Amirthalingam, *supra* note 438, at 135.

470. *Gunapathy*, [2002] 2 S.L.R. ¶ 63, 65; Amirthalingam, *supra* note 438, at 137.

471. Amirthalingam, *supra* note 438, at 137 (quoting an unreported opinion from 2002).

472. *Id.* at 137.

473. *See* Margaret Fordham, *A Life Without Value? JV and Another v. See Tho Kai Yin*, 2005 SING. J. LEGAL STUD. 395, 404.

final arbiters in determining medical negligence.”⁴⁷⁴ He criticizes *Bolam* for allowing the medical profession to self-regulate and for allowing judges to abdicate their responsibility to determine the *legal* standards of care and negligence.⁴⁷⁵ Professor Amirthalingam also recommends that Singaporean courts abandon the English approach in *Bolam* and embrace the more neutral Australian approach enunciated in *Rogers v. Whitaker*, which reasserted the role of courts in determining the standard of care.⁴⁷⁶ As it is under *Bolam* in India and Thailand, expert medical testimony in Singapore enjoys almost talismanic power, which of course lowers the chance that patients will successfully recover damages.⁴⁷⁷

But *Bolam* is only one part of the medical malpractice atmosphere in Singapore. As in India and Thailand, patients in Singapore face other obstacles in proving negligence.⁴⁷⁸ Indeed, a full assessment of Singapore’s medical malpractice system shows why patients remain so reluctant to sue.

First, lawyers in Singapore cannot accept contingency fees, thus guaranteeing that litigation will be a sunk cost for patients.⁴⁷⁹ And those brave enough to file suit have a strong incentive to settle because a court can impose costs if the case goes to trial and the court finds that an original settlement offer was reasonable.⁴⁸⁰ Perhaps more importantly, patients are deterred from filing all but the strongest medical negligence claims because a court may order the plaintiff to pay the defendant’s costs if the patient fails to prove negligence.⁴⁸¹ Singapore also does not provide jury trials in medical malpractice cases,⁴⁸² which may further disadvantage patients.⁴⁸³

Perhaps unsurprisingly, patients in Singapore seem to be among the least litigious of wealthy, industrialized countries.⁴⁸⁴ Patients there historically have

474. Amirthalingam, *supra* note 438, at 125.

475. *See id.* at 130.

476. [1992] 175 C.L.R. 479 (Austl.); *see* Amirthalingam, *supra* note 438, at 127, 136; Margaret Fordham, *Doctor Does Not Always Know Best: Foo Fio Na v. Dr. Soo Fook Mun*, 2007 SING. J. LEGAL STUD. 128, 132.

477. Fai, *supra* note 440, at 189; Fordham, *supra* note 473, at 406.

478. *See* Kaan, *supra* note 439, at 89; *supra* Sections II.A-B.

479. Kaan, *supra* note 439, at 89-90.

480. *Id.* at 89.

481. *Id.* at 90; Kandiah, *supra* note 439, at 467.

482. Kandiah, *supra* note 439, at 468 tbl.1.

483. For a look at the complicated role of juries in medical malpractice cases, *see*, for example, Nancy S. Marder, *The Medical Malpractice Debate: The Jury as Scapegoat*, 38 LOY. L.A. L. REV. 1267 (2005).

484. *See, e.g.*, M.K. Lim, *Quest for Quality Care and Patient Safety: The Case of Singapore*, 13 QUALITY & SAFETY HEALTH CARE 71, 74 (2004), available at <http://www.who.int/management/questqualitysingapore.pdf>.

been very reluctant to sue,⁴⁸⁵ and very few medical negligence cases in Singapore proceed to trial.⁴⁸⁶ Court records in Singapore show that the number of medical negligence lawsuits has been trivial: three in 1998, seven in 1999, and ten in 2000.⁴⁸⁷ In 2007, medical malpractice cases in the public health sector had fallen from roughly fifteen cases per year in the late 1990s to around eleven per year, counter to the international trend.⁴⁸⁸ In a comprehensive review of initiatives to improve health care quality in Singapore, Professor Lim emphasizes that most of these quality initiatives were pressed by the government rather than the public, “and certainly not the medical profession.”⁴⁸⁹ By attracting patients from the United States and other more litigious societies, Singapore may be inviting a group of patients that is more aware of and ready to assert its legal rights.

Second, as in other jurisdictions, patients may encounter resistance securing an expert medical witness to testify against a colleague—the so-called “conspiracy of silence.”⁴⁹⁰ One possible solution would be for courts to rely more liberally on the doctrine of *res ipsa loquitur*, which allows a plaintiff to establish prima facie evidence of negligence without relying heavily or exclusively on expert medical testimony.⁴⁹¹ However, courts in Singapore historically have been less willing to apply this doctrine than courts in the United States,⁴⁹² and it logically applies only in the most unequivocal cases.

Third, as in most jurisdictions, physicians are winning the public relations battle against medical malpractice suits, which generally creates a more hostile atmosphere for aggrieved patients. Many countries claim to be on the cusp of a malpractice litigation crisis that will drive up health care spending. *The Straits Times* reported that malpractice insurance premiums rose almost 300% for cosmetic and aesthetic surgeons in Singapore between 2002 and 2007.⁴⁹³ Some medical practitioners have used litigation statistics from the United States, the United Kingdom, and Australia to warn that there is a crisis in Singapore.⁴⁹⁴

485. See Fai, *supra* note 440, at 199.

486. Amirthalingam, *supra* note 438 (noting that most cases settle and the details are kept confidential, which precludes public scrutiny of the merits of the claims); Kaan, *supra* note 439, at 70.

487. Lim, *supra* note 484, at 74 (citing the 2002 Singapore High Court Registry).

488. Salma Khalik, *Fewer Suits Filed Against Public Hospitals; S'pore Bucks Rising Global Trend; Yearly Figures Here Fall from 15 Cases to About 11*, STRAITS TIMES (Sing.), Oct. 20, 2007, available at 2007 WLNR 20585394.

489. Lim, *supra* note 484, at 74.

490. Fai, *supra* note 440, at 195.

491. The doctrine was first enunciated in the 1863 English case, *Byrne v. Boadle*, [1863] 159 Eng. Rep. 299, in which the court presumed that a barrel of flour falling out of a second-story window was prima facie evidence of negligence.

492. Fai, *supra* note 492, at 197-99.

493. Khalik, *supra* note 488.

494. Amirthalingam, *supra* note 438, at 143.

Physicians groups like the Singapore Medical Association publish critiques of patient complaints and malpractice litigation.⁴⁹⁵ Medical commentators propagate these claims, contributing to the general atmosphere.⁴⁹⁶

This public relations campaign has driven a fear of a pending medical malpractice crisis that has probably contributed to courts' reluctance to relax the *Bolam* rule.⁴⁹⁷ Indeed, Professor Amirthalingam criticizes these tactics and argues that providers in Singapore already enjoy low malpractice costs:

All first world countries have far higher medical indemnity and general insurance costs, as well as higher compensatory awards. We cannot have our cake and eat it; the move to first world status also means embracing an advanced citizenry that is aware of its rights and desires to assert them.⁴⁹⁸

Fourth, even though Singapore enjoys a relatively high standard of living and is the most developed among major medical tourist destinations,⁴⁹⁹ malpractice awards can still be quite modest. For example, in 2001 *The Straits Times* published an article describing a S\$2.55 million medical negligence judgment by the Singapore High Court (\$1.4 million).⁵⁰⁰ The full-page article describing this “astronomical sum” triggered a “torrent of letters to the newspaper” and “terrified” local physicians.⁵⁰¹ The Court of Appeal swiftly overturned the decision and reaffirmed *Bolam*'s highly deferential standard.⁵⁰² Before this record award, the previous record in a medical negligence case in Singapore appears to have been only S\$356,000 (\$200,000).⁵⁰³ However, in 2007, *The Straits Times* reported a medical malpractice award of S\$2 million

495. P.Y. Cheong, *Handling of Patients' Complaints*, 39 SING. MED. J. 386 (1998), available at <http://www.sma.org.sg/smj/3909/articles/3909e1.html>. To be fair, some physicians do publish honest self-assessments of their role in malpractice. See, e.g., S.Y. Tan, *Blame the Pilots, Blame the Doctors: Lessons from SQ 006*, 43 SING. MED. J. 276 (2002), available at <http://www.sma.org.sg/smj/4306/4306e2.pdf>.

496. See, e.g., Amirthalingam, *supra* note 437, at 471 (noting that the authors of the book he is reviewing show “almost reverent support” for the negligence test in *Bolam* and issue “dire warnings against any dilution of it”).

497. See Amirthalingam, *supra* note 438, at 143-144.

498. *Id.* at 144-45.

499. Lim, *supra* note 484, at 71.

500. H.T. Liang, *When Medical Experts No Longer Hold Sway*, STRAITS TIMES (Sing.), July 21, 2001, at H12. Using the exchange rate on July 2, 2001, this calculates to \$1.37 million. See Federal Reserve Statistical Release H.10, Foreign Exchange Rates, Historical Rates for Singapore, http://www.federalreserve.gov/releases/h10/hist/dat00_si.htm (last visited Nov. 22, 2009).

501. Amirthalingam, *supra* note 438, at 125.

502. *Id.* at 125 (citing *Dr. Khoo James v. Gunapathy d/o Muniandy* [2002] 2 S.L.R. 414, 419 (Sing.)).

503. See Amirthalingam, *supra* note 438, at 143.

(\$1.3 million)⁵⁰⁴ and the resulting increase in malpractice insurance rates.⁵⁰⁵ Thus, aggrieved patients in Singapore may be faring better than they have historically, which could signal a better legal atmosphere for foreign patients.

2. The Singapore Medical Council

All physicians in Singapore must register with the Medical Council, a component of the Ministry of Health.⁵⁰⁶ The Council has statutory authority to discipline physicians for unprofessional conduct or other ethical transgressions, usually by removing them from the registry, restricting their practice, levying fines up to S\$10,000, or censuring them.⁵⁰⁷ Although more severe cases of medical malpractice may rise to the level of an ethical transgression, this is rare. Further, the Council cannot compensate patients, nor can it compel physicians to provide patients their medical records, which are necessary to support a malpractice suit.⁵⁰⁸

The overall number of complaints made to the Council is rising, from 84 in 2004 to 138 in 2008,⁵⁰⁹ although there has been no upward trend in the number of complaints filed per physician.⁵¹⁰ Around 20% of complaints allege medical negligence, though a higher number could be categorized as such.⁵¹¹ The Council's complaint form notes that investigations may take between six and nine months, if not longer.⁵¹²

The Ministry of Health is considering proposals to amend the Council's

504. Khalik, *supra* note 488. I used the exchange rate on January 2, 2007. See Federal Reserve Statistical Release H.10, *supra* note 503.

505. Khalik, *supra* note 488.

506. Kaan, *supra* note 439, at 43, 47-49; Singapore Medical Council, Home, http://www.smc.gov.sg/html/SMC_Home.html (last visited Nov. 22, 2009).

507. See Medical Registration Act § 40, Ch. 174 (Sing.); Kaan, *supra* note 439, at 43, 47-49, 51-52.

508. Singapore Medical Council, Frequently Asked Questions, http://www.ifaq.gov.sg/smc/apps/fcd_faqlmain.aspx (last visited Nov. 22, 2009).

509. Jessica Jaganathan, *Quicker Action on Complaints: Higher Maximum Fines Proposed in Changes to Medical Registration Act*, STRAITS TIMES (Sing.), Jan. 15, 2009, available at http://www.straitstimes.com/Breaking%2BNews/Singapore/Story/STISStory_326369.html.

510. SING. MED. COUNCIL, ANNUAL REPORT 2007, at 16 tbl.1, available at <http://www.smc.gov.sg/html/MungoBlobs/629/548/Annual%20Report%20v06.pdf>.

511. *Id.* at 16-17 tbl.2. The Council categorized the "nature" of each complaint. In addition to "professional negligence/incompetence," other categories could qualify as negligence as a legal matter, including for example "excessive/inappropriate prescription of drugs," "misdiagnosis," and "over/unnecessary/inappropriate treatment."

512. Singapore Medical Council, Instructions on Putting Up a Statutory Declaration, http://www.smc.gov.sg/html/SMC_DownloadForms.html (follow link for "complaints/disciplinary proceedings forms") (last visited Nov. 22, 2009).

grievance procedures.⁵¹³ For example, the proposals would 1) increase maximum fines from S\$10,000 to S\$100,000, 2) speed up the complaint process, 3) broaden the Council's powers to recommend outside mediation, and 4) allow patients to appeal decisions to the Singapore High Court.⁵¹⁴ Currently, patients can appeal decisions by the Council's complaints committee to the Health Minister, but only physicians can further appeal those decisions to the High Court.⁵¹⁵ Singapore may try to use these proposed reforms to shift complaints away from civil tort litigation.

3. *Criminal Sanctions in Singapore*

When a patient dies, Singapore's Criminal Procedure Code requires a public coroner's inquiry to determine the precise cause of death.⁵¹⁶ The coroner does not initiate formal charges or recommend sanctions, but the coroner may identify specific medical professionals as defendants for potential prosecution.⁵¹⁷ Yet the coroner's inquiry does not obligate the Attorney General to prosecute, nor can plaintiffs use it as evidence in civil suits.⁵¹⁸ Given that only a patient's death can trigger criminal action as well as the limited impact of coroners' reports, criminal proceedings against physicians remain exceedingly rare.⁵¹⁹

4. *Foreign Patients in Singapore*

Singapore is an established medical destination whose hospitals have experience handling foreign patients. However, Singapore's medical malpractice system generally favors providers and disfavors patients, and the few patients that win judgments receive compensation that is modest not only by U.S. standards, but by standards appropriate for a country with Singapore's wealth. Scholars have called for courts in Singapore to reassert themselves in medical negligence cases, but the common law remains a significant obstacle. The general atmosphere also tends to encourage mediation and settlement over full-blown litigation.

The bright spot for patients is that, overall, Singapore's health care system

513. See Medical Registration Amendment Bill, 2009 (Sing.), available at [http://www.moh.gov.sg/mohcorp/data/EConsult/752/draft_mra%20\(amendment\)_bill140109.pdf](http://www.moh.gov.sg/mohcorp/data/EConsult/752/draft_mra%20(amendment)_bill140109.pdf); Jaganathan, *supra* note 509; Singapore Ministry of Health, Legislation: E-Consultation, <http://www.moh.gov.sg/mohcorp/econsultationpast.aspx?ecid=752>.

514. Jaganathan, *supra* note 509.

515. *Id.*

516. Singapore Criminal Procedure Code, §§ 273-277, Ch. 68, Rev. Ed. 1985 (Sing.); see also Kaan, *supra* note 439, at 68-69.

517. Kaan, *supra* note 439, at 69.

518. *Id.* at 69.

519. *Id.* at 70-71.

enjoys a relatively strong regulatory environment,⁵²⁰ contrary to many other medical tourist destinations. The Ministry of Health and the Singapore Medical Association have initiated programs to study the incidence of medical errors and reduce them.⁵²¹ Moreover, practitioners have embraced evidence-based medicine to guide clinical practice, which some believe may frame standards of care in more concrete terms.⁵²² These developments should only help patients.

E. Mexico

Mexico has long been a medical destination for U.S. residents,⁵²³ and thousands on both sides of the border cross each day to purchase medical care, dental care, or pharmaceuticals.⁵²⁴ More recently, Mexican hospitals in cities like Monterrey are earning stellar reviews from U.S. patients,⁵²⁵ and health care providers in Mexico now actively compete for medical tourists.⁵²⁶ Private medicine is one of Mexico's most profitable industries,⁵²⁷ and cross-border health care between the United States and Mexico is a ripe market. At least 11.5 million people reside along the border.⁵²⁸ Many U.S. residents seek health care in Mexico because they are uninsured, have low incomes, or might prefer Spanish-speaking providers.⁵²⁹ Though prices may not be as low as in some Asian countries, Mexico's competitive advantage is its proximity to the United States.⁵³⁰

520. See Lim, *supra* note 484, at 72-75.

521. See *id.* at 74 (noting that "no one knows what the true incidence of medical errors is, but everyone knows it is certainly not zero").

522. See Kandiah, *supra* note 439, at 476-77 (noting, however, the complications of relying on evidence-based medicine both in guiding clinical practice and in determining legal standards of care).

523. BOOKMAN & BOOKMAN, *supra* note 6, at 49.

524. *Id.* at 49; Núria Homedes, *Globalization and Health at the United States-Mexico Border*, 93 AM. J. PUB. HEALTH 2016, 2017 (2003); David C. Warner & Pablo G. Schneider, *Cross-Border Health Insurance: Options for Texas*, at xxiv, xxv (2004) (unpublished manuscript, on file with author).

525. See, e.g., Alfredo Corchado & Laurence Iliff, *Good Care, Low Prices Lure Patients to Mexico*, DALLAS MORNING NEWS, July 28, 2007, at 1A.

526. *Id.*

527. BOOKMAN & BOOKMAN, *supra* note 6, at 3 (citing Jorge Augusto Arredondo Vega, *The Case of the Mexico-United States Border Area*, in INTERNATIONAL TRADE IN HEALTH SERVICES: A DEVELOPMENT PERSPECTIVE, *supra* note 294, at 161, 166).

528. Homedes, *supra* note 524, at 2016.

529. Cortez, *supra* note 6, at 101; Marissa Paul Walker & Robert Guerrero, *Cross-Border Health Insurance Initiatives in California, Texas and Arizona* 5, 8 (Jan. 30, 2003), available at <http://econdev.web.arizona.edu/pubs/az-mexico/pubs/Cross-BorderInsurance.pdf> (slides only).

530. BOOKMAN & BOOKMAN, *supra* note 6, at 58 (noting that proximity is an important factor for elderly and ill patients traveling from the United States and Canada to Mexico); Corchado & Iliff, *supra* note 525 (noting that surgeries are 40% less expensive in Mexico than in the United

Providers are using a combination of proximity, improved quality, and comparatively low prices to target not only individual patients, but also U.S. employers and insurers willing to outsource expensive surgeries or even routine checkups.⁵³¹

But Mexico's geographic proximity, shared demography, and cross-border commerce with the United States do not translate into many similarities between the countries' health care systems.⁵³² Providers along the border collaborate much less than we might expect, which some attribute to dramatically different systems for organizing, financing, delivering, and regulating health care.⁵³³

Moreover, although Mexico is geographically closer to the United States than India, Thailand, or Singapore, its malpractice compensation system may be the most distant. Like Thailand, Mexico is a civil law country, and its courts do not utilize juries or *stare decisis*.⁵³⁴ Tort litigation in Mexico is virtually non-existent, and medical malpractice cases are even rarer.⁵³⁵ Mexican law does not allow non-economic damages like pain and suffering, and its economic damages are deflated from being pegged to Mexico's workers' compensation statute.⁵³⁶ Mexican tort law is perhaps the most arcane, alien, and "contrastingly different" body of law between Mexico and the United States.⁵³⁷ As with India's consumer forums, Mexico's new National Commission for Medical Arbitration provides a more efficient alternative to civil litigation, but the compensation it awards would probably not satisfy most U.S. plaintiffs.

In short, U.S. patients traveling to Mexico for medical care should not assume that its legal or arbitration systems will provide satisfactory recourse. On the bright side, U.S. courts have demonstrated a willingness to hear complaints by U.S. residents arising in Mexico,⁵³⁸ which may be the best option for most American patients. In this section, I evaluate how Mexico handles malpractice

States); Kelly Arthur Garrett, *Prices of Medical Services Are at Least 30% Lower in Mexico than in U.S.*, EL UNIVERSAL (Mex.), Dec. 27, 2004, available at 2004 WLNR 14869899.

531. Jason Beaubien, *Mexican Hospitals Aim to Attract More Americans*, NPR WEEKEND EDITION SATURDAY, Jan. 3, 2009, available at 2009 WLNR 135025; Corchado & Iliff, *supra* note 525; Gabriela Rico, *U.S. Patients Turn for Care to Mexico*, ARIZ. DAILY STAR, Apr. 13, 2008, at A1.

532. See Homedes, *supra* note 524, at 2017.

533. *Id.*

534. Vargas, *supra* note 12, at 486.

535. Jorge A. Vargas, *Tort Law in Mexico*, in 2 MEXICAN LAW: A TREATISE FOR LEGAL PRACTITIONERS AND INTERNATIONAL INVESTORS § 21.5 (West 1998) [hereinafter Vargas, *Tort Law in Mexico*] (noting that very few Mexican attorneys handle tort cases, partly due to cultural preferences for resolving these disputes informally, and partly due to Mexico's relatively simple and limited compensation system); Garrett, *supra* note 530; Vargas, *supra* note 12, at 488.

536. Vargas, *supra* note 12, at 479, 484.

537. *Id.* at 484.

538. *Id.* at 476.

complaints, beginning with a brief case study evaluating how cross-border health insurers have handled the legal risks of relying on providers in Mexico.

1. The New Market for Cross-Border Health Insurance

Cross-border health insurance covering treatments in Mexico is becoming increasingly popular. In California, HMOs offer less expensive insurance plans to California residents willing to be treated in Mexico.⁵³⁹ For example, HealthNet, Blue Shield, and SIMNSA are selling plans with lower premiums and deductibles to U.S. citizens in California,⁵⁴⁰ and SIMNSA is selling similar plans to Mexican nationals residing in California.⁵⁴¹ These cross-border health plans generally cost 40-50% less than those that utilize U.S. providers only.⁵⁴²

The cross-border insurance trend emerged primarily after legislation in California legitimized these plans by establishing specific requirements to regulate them.⁵⁴³ Texas and Arizona have considered similar legislation, but concerns remain over legal liabilities and other practical impediments.⁵⁴⁴ Interestingly, California decided to regulate cross-border health plans in substantial part to protect consumers already using unregulated plans and to provide legal recourse in the United States should patients need to sue.⁵⁴⁵ California was concerned that U.S. nationals would find it difficult to seek redress in Mexican courts. In fact, California's statute prevents cross-border HMOs from forcing U.S. residents to rely on the unfamiliar Mexican legal

539. David Warner and Pablo Schneider have published a comprehensive analysis of these plans. See Warner & Schneider, *supra* note 524; see also Cortez, *supra* note 6, at 99-100; Ly Tran, *Sick and Tired of the Knox-Keene Act: The Equal Protection Right of Non-Mexican Californians to Enroll in Mexico-Based HMO Plans*, 14 SW. J.L. & TRADE AM. 357, 357-63 (2008).

540. Cortez, *supra* note 6, at 100.

541. Tran, *supra* note 539.

542. Sonya Geis, *Passport to Health Care at Lower Cost to Patient; California HMOs Send Some Enrollees to Mexico*, WASH. POST, Nov. 6, 2005, at A3; Tran, *supra* note 539, at 358.

543. Knox-Keene Act Health Care Service Plan Act of 1975, CAL. HEALTH & SAFETY CODE §§ 1340-1399 (West 2008) (regulating cross-border health plans sold to U.S. nationals); Warner & Schneider, *supra* note 524, at xix.

544. The Texas legislature considered several bills that would legalize cross-border health insurance. A 1999 bill would have legalized cross-border insurance, but the legislature instead only monitors the trend and has created an Interim Committee on Binational Health Benefit Plan Coverage to study the issue. Additionally, the Texas Department of Insurance studies cross-border insurance but remains concerned about the outstanding legal issues. Warner & Schneider, *supra* note 524, at xxi, 83-87, 89, 117-118 (citing various Texas House and Senate bills); see also Corchado & Iliff, *supra* note 525 (describing proposed legislation in Texas introduced in 2007 that "would have allowed U.S.-based insurers to cover health services in Mexico"); Walker & Guerrero, *supra* note 529.

545. See Tran, *supra* note 539, at 361.

system, even if care was provided in Mexico.⁵⁴⁶

The California statute protects U.S. residents in other ways. First, HMOs offering cross-border plans not only must establish grievance procedures in the United States but also must submit to California's jurisdiction.⁵⁴⁷ For example, SIMNSA maintains offices in San Diego to receive member complaints.⁵⁴⁸ Licensure by the California Department of Managed Health Care (DMHC) also triggers jurisdiction by U.S. courts.⁵⁴⁹ The DMHC has received very few complaints about cross-border health plans to date,⁵⁵⁰ though these grievance procedures may be a poor proxy for measuring the frequency of medical errors by Mexican providers.

Second, HMOs offering cross-border plans in California must regularly review the quality of Mexican providers⁵⁵¹ and must publish an advisory statement on health care in Mexico.⁵⁵² For example, Blue Shield's "Access Baja" plan states that both legal and medical standards differ in Mexico:

Legal requirements for and generally accepted practice standards of medical care in Mexico are different than those of California or elsewhere in the United States. . . . Any member who is not completely comfortable with the standards of care for the practice of medicine in Mexico should not enroll in the Access Baja HMO Health Plan.⁵⁵³

Unsurprisingly, Blue Shield disclaims liability for negligence committed by physicians, hospitals, or other providers in Mexico and classifies them as independent contractors.⁵⁵⁴ Blue Shield's plan also requires Mexican physicians to have their own malpractice insurance.⁵⁵⁵

In short, California addressed the problem of U.S. patients having to sue in Mexican courts by requiring health insurers to submit to U.S. jurisdiction.

546. Tran, *supra* note 539, at 365; Warner & Schneider, *supra* note 524, at 23.

547. CAL. HEALTH & SAFETY CODE § 1351.2(a)(10) (West 2008); Tran, *supra* note 539, at 371-72.

548. Warner & Schneider, *supra* note 524, at 54-55.

549. CAL. HEALTH & SAFETY CODE § 1351 (West 2008); Warner & Schneider, *supra* note 524, at 20, 23.

550. Tran, *supra* note 539, at 364 (citing Sarah Skidmore, *The Mexico Option: Cross-Border Health Insurance Is a Hit with Employers and Workers*, SAN DIEGO UNION-TRIBUNE, Oct. 16, 2005, at H1).

551. CAL. HEALTH & SAFETY CODE § 1370 (West 2008).

552. TEX. INTERIM COMM. ON BINATIONAL HEALTH BENEFIT PLAN COVERAGE, BINATIONAL HEALTH BENEFIT PLAN REPORT PURSUANT TO HB 2498 AND SB 496, at 7, 53 (2003), *available at* <http://www.senate.state.tx.us/75r/senate/commit/c1000/downloads/binational.pdf>.

553. *Id.*

554. *Id.* at 57.

555. Warner & Schneider, *supra* note 524, at 37.

Nevertheless, as in Blue Shield's case, insurers have shielded themselves from liability for malpractice committed by Mexican providers. Patients may still be able to sue these providers in U.S. courts, but they will have to establish personal jurisdiction, which is by no means certain. Otherwise, patients will be left to navigate Mexico's civil courts.

2. Civil Litigation in Mexico

Patients injured by medical malpractice in Mexico may sue in Mexico's civil courts. Some contend that U.S. citizens have adequate legal recourse in Mexico because patients are not only free to sue in Mexican courts but also to file claims with Conamed, Mexico's new medical arbitration board.⁵⁵⁶ However, as in India, Thailand, and Singapore, U.S. patients are likely to find these avenues of redress to be inadequate. There are serious concerns that Mexican courts do not provide any real recourse to victims of medical malpractice. First, most U.S. patients will find the Mexican legal system to be unfamiliar, and Mexican tort law is perhaps the most arcane and distinctive body of law between Mexico and the United States.⁵⁵⁷ Mexico's tort cases are governed primarily by the Federal Civil Code or a corresponding state code.⁵⁵⁸ Mexico's Civil Code has been described as "scant," "skeletal," "obsolete," and "simplistic"—and remains so because the Mexican legislature has not modernized it.⁵⁵⁹ In fact, tort law does not really exist in Mexico;⁵⁶⁰ instead, Mexico characterizes tort law as extra-contractual liability,⁵⁶¹ based on obligations arising from illegal acts.⁵⁶² The legislature has

556. Tran, *supra* note 539, at 371; Warner & Schneider, *supra* note 524, at 24. Note, however, that Tran acknowledges that the Mexican legal system differs from the U.S. legal system and suggests that U.S. citizens try to avoid Mexican courts. Tran, *supra* note 539, at 374-76.

557. Ryan G. Anderson, *Transnational Litigation Involving Mexican Parties*, 25 ST. MARY'S L.J. 1059, 1060 (1994); Vargas, *supra* note 12, at 484.

558. Vargas, *Tort Law in Mexico*, *supra* note 535, § 21.2; Vargas, *supra* note 12, at 478 (citing Articles 1910-1934 of the Federal Civil Code and noting that the thirty-one state codes overwhelmingly adopt these articles).

559. Vargas, *supra* note 12, at 478, 487-88, 499 ("[T]he legal principles that control personal bodily injuries and wrongful deaths in [Mexico] have been kept in isolation and virtually untouched in a legal time capsule that is today legally obsolete and completely out of sync with Mexico's economic and industrial realities."); *see also* Vargas, *Tort Law in Mexico*, *supra* note 535, § 21.41.

560. Vargas, *Tort Law in Mexico*, *supra* note 538, § 21.2.

561. Código Civil Federal [C.C.F.] [Federal Civil Code], *unamended*, Art. 1910, Diario Oficial de la Federación [D.O.], 26 de Mayo de 1928 (Mex.).

562. Jorge Mario Magallón Ibarra, *La Responsabilidad Profesional De Los Medicos*, 1 MEXICAN L. REV. 46, 54 (2004) ("[L]a conducta del que obrando ilícitamente o contra las buenas costumbres cause daño a otro, resulta obligado a repararlo, a menos que demuestre que el daño se produjo como consecuencia de culpa o negligencia inexcusable de la víctima."), *available at* <http://www.juridicas.unam.mx/publica/librev/rev/derpriv/cont/1/dtr/dtr4.pdf>; Vargas, *Tort Law in Mexico*, *supra* note 535, §§ 21.11-21.13; Vargas, *supra* note 12, at 496-98.

not clarified when courts should find fault, negligence, or causation.⁵⁶³ As a result, such questions are left almost entirely to the discretion of individual judges.⁵⁶⁴ Tort law and its attendant concepts are “alien to Mexican legal thinking.”⁵⁶⁵ Mexican courts do not use juries, nor do they use *stare decisis* to establish binding judicial precedents.⁵⁶⁶ Moreover, Mexican courts do not utilize pretrial discovery, instead relying on courts to conduct discovery during trial.⁵⁶⁷ Together, these features suggest that medical malpractice litigation in Mexico’s civil courts will present foreign patients with significant burdens.

Second, and perhaps most importantly, foreign patients will be underwhelmed with malpractice awards in Mexico. Mexican law does not award punitive or exemplary damages, damages for pain and suffering, or damages for loss of consortium.⁵⁶⁸ Even tort actions involving death only generate an amount around \$17,880 pursuant to the Civil Code’s formula for calculating damages.⁵⁶⁹ Such paltry compensation undoubtedly encourages Americans injured in Mexico to sue in U.S. courts.⁵⁷⁰

Courts in Mexico calculate tort compensation by referring to the workers’ compensation formula.⁵⁷¹ Mexico’s Federal Civil Code directs courts to calculate economic recoveries in tort under the Federal Labor Act, as if the victim were a Mexican laborer injured at work.⁵⁷² Courts may award patients the costs of medical care and rehabilitation, but economic losses are limited to four-times the prevailing minimum wage in the state, multiplied by the number of days assigned to the specific disability claimed under the Federal Labor Act.⁵⁷³ As a result, tort damages have been described as “outdated and less than frugal,”⁵⁷⁴ and very few attorneys even handle—let alone specialize in—personal injury cases.⁵⁷⁵

Third, tort cases are extremely rare in Mexican courts. Americans injured

563. Vargas, *supra* note 12, at 499-500. The Mexican Supreme Court refers briefly to negligence and custom in its *Jurisprudencias*, but merely to emphasize that judges should use their discretion. Vargas, *Tort Law in Mexico*, *supra* note 538, § 21.23.

564. Vargas, *supra* note 12, at 499-500.

565. Vargas, *Tort Law in Mexico*, *supra* note 535, § 21.7.

566. Vargas, *supra* note 12, at 486.

567. Anderson, *supra* note 557, at 1060.

568. Vargas, *supra* note 12, at 484; Vargas, *Tort Law in Mexico*, *supra* note 535, § 21.2.

569. Vargas, *supra* note 12, at 503.

570. Vargas, *Tort Law in Mexico*, *supra* note 535, § 21.2; Vargas, *supra* note 12, at 503. *See generally* Anderson, *supra* note 557, at 1100-03, Kozolchik & Ziontz, *supra* note 566.

571. Vargas, *supra* note 12, at 479.

572. Vargas, *supra* note 12, at 478 (citing Ley Federal del Trabajo [L.F.T.] [Federal Labor Law], *as amended*, Diario Oficial de la Federación [D.O.], Title IX, arts. 477-80, 487, 491-93, 495-97, 500-02, 1 de Agosto de 1971 (Mex.)).

573. Vargas, *supra* note 12, at 479.

574. *Id.* at 488.

575. *Id.* at 501-02; Vargas, *Tort Law in Mexico*, *supra* note 535, § 21.5.

while visiting Mexico greatly prefer to sue in the United States.⁵⁷⁶ In fact, U.S. courts decide a far larger number of tort cases arising in Mexico than Mexican courts do.⁵⁷⁷ Professor Vargas states bluntly that “the practice of tort law in Mexico is simply non-existent” and proposes modernizing the framework by borrowing principles from Europe and the United States.⁵⁷⁸ Adding to the danger for patients, there is almost no product liability law in Mexico,⁵⁷⁹ leaving patients exposed should they be injured by faulty pharmaceuticals or medical devices.

Fourth, as in India, Thailand, and Singapore, Mexican culture fundamentally differs from U.S. culture on its desire and tolerance for adversarial litigation.⁵⁸⁰ Mexicans remain pointedly distrustful that courts will resolve disputes fairly.⁵⁸¹ Of course, as in the other countries I examine, observers in Mexico firmly believe that more and more tort cases are being filed, spurred in part by growing consumer awareness.⁵⁸² Mexico claims to be beset by a surge of medical malpractice suits, which observers attribute to “poor personal communication, unrealistic expectations of performance, the high costs of medical attention, and better informed and more critical patients.”⁵⁸³ Some lament that the growing number of lawsuits creates a “vicious circle” of rising insurance premiums, defensive medicine, and rising health care costs.⁵⁸⁴ Unfortunately, as is common in other jurisdictions, the critics decry the situation in Mexico but only cite as support articles describing malpractice litigation in the United States and the United Kingdom.⁵⁸⁵

Thus, foreign patients will likely find that Mexico’s civil litigation system provides inadequate redress for medical negligence. Tort litigation is almost non-existent; damages are modest by U.S. standards and are limited by law. Further, the legal system is arcane, costly, and not trusted by its own citizens.

3. Mexico’s New National Commission for Medical Arbitration

As in India, the Mexican government confronted its flawed civil litigation system by creating an alternative. Malpractice victims in Mexico now have access to a new medical arbitration system, formed to provide a less formal and

576. Vargas, *supra* note 12, at 477.

577. *Id.* at 478.

578. *Id.* at 488.

579. *Id.* at 494-96.

580. *Id.* at 502.

581. *Id.* at 502.

582. *Id.* at 506-07, 519.

583. See, e.g., Carlos Tena-Tamayo & Julio Sotelo, *Malpractice in Mexico: Arbitration Not Litigation*, 331 BRITISH MED. J. 448 (2005).

584. *Id.* at 448.

585. *Id.* at 448 (citing five articles, none of which address Mexico).

costly alternative to civil litigation.⁵⁸⁶ In 1996, President Ernesto Zedillo created by decree the National Commission for Medical Arbitration (Comisión Nacional de Arbitraje Médico, or “Conamed”), residing within the Ministry of Health, and composed entirely of government-paid employees.⁵⁸⁷ Zedillo’s decree gave Conamed jurisdiction to advise parties of their legal rights and obligations and to investigate, hear, and resolve complaints concerning medical care.⁵⁸⁸

Conamed has had some success with its efforts to resolve disputes promptly by having a specialized consultant contact the parties. Between 2001 and 2003, Conamed resolved 73% of nearly 15,000 cases within forty-eight hours of being filed.⁵⁸⁹ If the special consultant fails and a complaint is filed, Conamed will assemble the parties to negotiate during an initial, conciliatory phase.⁵⁹⁰ Fourteen percent of cases filed are resolved by conciliation,⁵⁹¹ in an average of three to six months.⁵⁹²

If the parties do not settle, the case continues to a Conamed arbitrator.⁵⁹³ Conamed then gathers expert medical opinions, including the opinion of the treating physician.⁵⁹⁴ Arbitration generally takes an average of fifteen months.⁵⁹⁵ Conamed has a major advantage over courts because it enjoys credibility in medical disputes.⁵⁹⁶ For example, when selecting physicians and lawyers to handle each dispute, Conamed “consider[s] their expertise, academic background, impartiality in the specific case, and up to date knowledge in the particular branch of the medical specialty involved.”⁵⁹⁷

586. Vargas, *supra* note 12, at 519-20.

587. Magallón Ibarra, *supra* note 562, at 47-48 (describing the purposes and promise of Conamed); Tena-Tamayo & Sotelo, *supra* note 583, at 449; Comisión Nacional de Arbitraje Médico, <http://www.conamed.gob.mx/index.php> (last visited Nov. 22, 2009).

588. Magallón Ibarra, *supra* note 562, at 47-48 (“[L]a Comisión Nacional de Arbitraje Médico . . . puedan contribuir de manera imparcial, al análisis, dictamen y resolución de las quejas y controversias que surjan entre ellos, con motivo de lo que se consideren irregularidades en las prestación o negativa a la prestación de los servicios médicos.”); Jorge Fernández Ruiz, *La Comisión Nacional De Arbitraje Médico y La Responsabilidad De Los Servidores Públicos* [*The National Commission of Medical Arbitration and the Responsibility of Civil Servants*], 3 MEXICAN L. REV. 311, available at <http://www.juridicas.unam.mx/publica/librev/rev/boletin/cont/92/art/art1.pdf>; Tena-Tamayo & Sotelo, *supra* note 583, at 449.

589. Tena-Tamayo & Sotelo, *supra* note 583, at 449, 450.

590. *Id.* at 449.

591. *Id.* at 449, 450.

592. *Id.* at 450.

593. *Id.* at 449 (citing Comisión Nacional de Arbitraje Médico, <http://www.conamed.gob.mx/index.php> (last visited Nov. 22, 2009)).

594. *Id.*

595. *Id.*

596. *Id.*

597. *Id.* at 450.

If Conamed arbitrators find that the physician committed malpractice (usually negligence), then it can award monetary damages under the same criteria used in civil litigation, relying on Mexico's workers' compensation formulas.⁵⁹⁸ However, Conamed's National Commissioner acknowledged that the amount awarded in arbitration is usually lower than that awarded by courts.⁵⁹⁹ In fact, data from Conamed show that cases resolved through conciliation or arbitration typically result in the health care provider solely agreeing to assume responsibility for providing ongoing medical care.⁶⁰⁰ Only 28% of the complaints resolved through conciliation or arbitration resulted in damage awards, paying an average of only \$4841 to each patient.⁶⁰¹

In addition to the limited damages, Conamed has other limitations. Both patients and health care providers must agree to resolve the dispute via Conamed. Although either party may withdraw from Conamed at any time prior to signing the arbitration agreement,⁶⁰² once the arbitration contract has been signed, neither party may take the case to court.⁶⁰³ Similarly, Conamed cannot resolve disputes already being heard by courts.⁶⁰⁴ Moreover, "Conamed is not a judicial authority" and cannot enforce its own judgments,⁶⁰⁵ though it is not clear if lack of enforcement has been a problem.

Conamed maintains comprehensive data of its complaints and resolutions, which aids potential medical tourists in understanding their likelihood of success in Conamed.⁶⁰⁶ As noted above, almost three-quarters of all cases are resolved by special consultants before a formal complaint is filed.⁶⁰⁷ Of the cases that proceeded to conciliation or arbitration, 47% were not resolved, either because a party withdrew or the parties went to court.⁶⁰⁸ Of all the cases filed with Conamed, approximately 12% were left unresolved.⁶⁰⁹

The data also show that of the complaints Conamed resolved through conciliation or arbitration, 66% concluded that no medical malpractice occurred, while 34% found evidence of malpractice.⁶¹⁰ A separate analysis of randomly

598. *Id.* 449, 450.

599. *Id.* at 449.

600. *Id.* at 449-50.

601. *Id.* at 450 (stating that Conamed awarded a total of \$2.9 million to 599 patients).

602. *Id.*

603. *Id.* at 449.

604. *Id.*

605. *Id.*

606. Maria-Eugenia Jimenez-Corona et al., *Epidemiology of Medical Complaints in Mexico: Identifying a General Profile*, 18 INT'L J. QUALITY IN HEALTH CARE 220, 221 (2006).

607. See text accompanying note 588.

608. Tena-Tamayo & Sotelo, *supra* note 583, at 449 box 1, 450.

609. *Id.*

610. *Id.* at 450.

sampled cases found evidence of malpractice in 36.5% of cases.⁶¹¹ Thus, this study corroborated the outcomes reached in Conamed's arbitrations. Additionally, this study found that 67% of the malpractice cases were attributable to the provider's lack of skill rather than negligence.⁶¹²

To date, patients and health care providers seem to be highly satisfied with Conamed. In a survey of over 5500 patients and physicians that used Conamed, 97% of respondents rated the process as good or excellent.⁶¹³

Before Conamed was created, there had been "no systematic review of the annual trends of medical complaints and litigation in Mexico."⁶¹⁴ Thus, Conamed has provided not only an accessible alternative to civil litigation, but also a glimpse into trends surrounding malpractice complaints in Mexico. Unfortunately, even a more efficient, neutral alternative like Conamed is unlikely to provide much recourse to foreign patients if recoveries average only \$4841 per patient.⁶¹⁵

4. Foreign Patients in Mexico

Under almost any scenario, Mexico will continue to compete for U.S. patients. However, patients that visit Mexico to avoid wandering too far from the United States should know that Mexico's legal system does not share the same proximity. As in India, Thailand, and Singapore, seeking recourse in Mexico's civil courts remains fraught with difficulties. And though Conamed provides a relatively neutral, efficient alternative, compensation is still extremely modest by U.S. standards. Moreover, it is telling that California, one of the only legislative bodies to have addressed cross-border health insurance, took several steps to minimize patients' exposure to Mexico's legal system.

Patients should also know that health care in Mexico differs from health care in the United States much more than one might expect, given the countries' shared border, demography, and commerce. The Mexican government approves credentials for physicians and hospitals and provides legal recourse to patients,⁶¹⁶ but these systems are evolving and are in some cases relatively new.⁶¹⁷ Moreover,

611. Jimenez-Corona et al., *supra* note 606, at 221.

612. *Id.* at 221. The authors sorted the "malpractice" cases into lack of skill (67.4% of cases), negligence (30.0%), and deceit (2.6%).

613. Tena-Tamayo & Sotelo, *supra* note 583, at 451 (citing an anonymous Conamed survey conducted in 2002 and 2003).

614. *Id.*

615. *Id.* at 449, 450 (stating that Conamed awarded a total of \$2.9 million to 599 patients, an average of \$4841 per patient).

616. Warner & Schneider, *supra* note 524, at xxv.

617. See TEX. STATE SENATE, REPORT OF THE INTERIM COMM. ON BINATIONAL HEALTH BENEFIT PLAN COVERAGE 8-11 (2003), available at <http://www.senate.state.tx.us/75r/senate/commit/c1000/downloads/binational.pdf>.

Mexico generally does not regulate medical services or impose quality controls to the same extent as the United States.⁶¹⁸ Although these differences may wane as more private hospitals in Mexico cater to foreign patients, Mexican health care providers, insurers, and institutions remain distinct from their U.S. counterparts. For example, researchers have found “profound distrust between decisionmakers and health care workers on both sides of the border.”⁶¹⁹ Patients visiting Mexico should thus consider how they might establish jurisdiction to sue negligent providers in U.S. courts, as U.S. residents have done in other personal injury contexts.

III. REALLOCATING THE LEGAL RISKS OF CROSS-BORDER HEALTH CARE

Medical tourists face real obstacles seeking recourse for medical errors. In Part I, I described how aggrieved patients might struggle in U.S. courts not only to resolve issues of jurisdiction, venue, and choice of law in their favor, but to prove sometimes attenuated theories of liability. In Part II, I explained how patients visiting India, Thailand, Singapore, and Mexico might not recover adequate, timely compensation in those jurisdictions. Two themes join Parts I and II: there are very real obstacles for patients seeking legal recourse for medical errors committed overseas, and patients may not fully appreciate these obstacles. As a result of patients’ lack of understanding, these transactions might not reflect the true risk tolerance of patients. This information deficiency may generate not only inefficient, suboptimal outcomes, but also injustice if patients agree to have surgery overseas based in part on assumptions that foreign legal systems will provide adequate recourse.

It is difficult to predict how destination countries or the medical tourism industry will respond. Some jurisdictions might “race to the top” by shoring up relatively weak systems for regulating local providers and compensating aggrieved patients, recognizing that inadequate legal protections might dissuade patients from visiting.⁶²⁰ Or jurisdictions might “race to the bottom” (or remain there) to keep prices low or offer treatments that are banned elsewhere.⁶²¹ Either way, it is probably unrealistic to expect countries that are strapped for resources and struggling with more pressing public health concerns to bolster legal remedies for patients—and perhaps ignore protectionist impulses.

Thus, in Part III, I evaluate how other parties might respond. First, I evaluate several private sector responses that have emerged, including certification, malpractice insurance, and industry guidelines. After evaluating the promise and weaknesses of these approaches, I suggest several methods the public sector

618. *Id.* at 12.

619. Homedes, *supra* note 524, at 2020.

620. Cortez, *supra* note 6, at 91 n.178; Terry, *supra* note 6, at 466.

621. Cortez, *supra* note 6, at 105; Terry, *supra* note 6, at 466.

might use to reallocate the legal risks of medical travel. I evaluate each response by its ability to both inform patients and improve their chances of obtaining adequate redress.

A. Private Sector Responses

The interests of patients and the medical tourism industry are not necessarily incompatible. Poor quality care and inadequate legal recourse can deter many would-be medical tourists, and defending litigation is burdensome and expensive for providers and insurers. Moreover, legal uncertainties may be discouraging both patients and insurers that would otherwise consider using foreign providers. Thus, companies have some incentives to reallocate the legal risks of medical travel more fairly. In this section, I analyze three different responses by the private sector to date, and I comment on how these responses may not accomplish their stated objectives.

1. Certification

Demand for reassurance in the chaotic medical tourism market has led the industry to respond. A newly-formed industry group, the Medical Tourism Association (MTA), recently began offering a pilot “Medical Tourism Facilitator Certification Program.”⁶²² The MTA intends to use certification to create “best practices” among medical tourism “facilitators” and to assure patients, insurers, and providers that certified facilitators meet certain minimum standards.⁶²³ The form asks applicants to answer over 200 questions regarding how they do business—including how they select foreign providers, handle patients, and earn revenues.⁶²⁴ Approved facilitators receive a renewable, two-year certification for \$2500.⁶²⁵

Because the certification program is new, it is unclear how it will operate, and more importantly, whether it will achieve the MTA’s stated goals. For example, the MTA claims that certification will generate “confidence, trust, and . . . credibility” for medical tourism companies in the eyes of both patients and insurers.⁶²⁶ However, as I have noted, industry self-regulation can be problematic and could be a mediocre substitute for government oversight here.⁶²⁷ Thus, it

622. Medical Tourism Association, Medical Tourism Facilitator Certification Program, 2008-2009, <http://medicaltourismassociation.com/certification.html> (last visited Nov. 22, 2009).

623. *Id.*

624. Medical Tourism Association, Medical Tourism Facilitator Certification 2009-2010, <http://medicaltourismassociation.com/Certification%20Evaluation%20Form.PDF> (last visited Nov. 22, 2009).

625. Medical Tourism Association, *supra* note 622.

626. Medical Tourism Association, *supra* note 622.

627. See Sections II.B (India), II.C (Thailand), II.D (Singapore), *supra*.

remains unclear whether the MTA's certification program will succumb to the same problems that plague the other self-regulatory bodies I discuss in this Article.

The MTA also claims that its certification program can help ensure patient safety.⁶²⁸ For example, the certification form asks whether the applicant: 1) verifies that its foreign providers are accredited and/or certified; 2) personally inspects foreign facilities and meets foreign surgeons; 3) tracks patient outcomes; 4) coordinates follow-up care; 5) validates the need for non-elective surgeries; 6) uses a medical advisor; and 7) uses a process to handle patient complaints.⁶²⁹

However, the MTA does not explain how it will tally or weigh answers to the application, nor does it explain the criteria it will use to grant or deny applications. For example, will the MTA deny applications that answer "no" or "not applicable" to some of these questions? The MTA also does not explain the criteria it will use to revoke certifications or renew applications or whether it would make such decisions public.

Notably, the MTA's application form also asks what information companies convey to patients about their potential legal recourse. For example, the form asks whether the company "adequately explains" the recourse available against the surgeon or hospital, including the "specific legal recourse options for each country" to which it sends patients.⁶³⁰

But what do these companies really know about the medical malpractice systems overseas? As I emphasized in Part II, it is difficult to navigate the medical malpractice systems in these countries, and there are no comprehensive and reliable sources of information. Most intermediaries disclose the legal risks in densely worded legalese, if at all. Moreover, what explanations will the MTA deem "adequate"? For example, must the company explain how Singaporean courts use a strict burden of proof that defers greatly to medical experts? Must companies explain how the civil code in Mexico calculates and caps damages? Do companies have to disclose the limited universe of remedies in India? Or would a general statement listing the possible avenues for recourse in each country suffice, without any analysis of whether the patient might find such recourse difficult to obtain or inadequate? Intermediaries may warn buyers to beware of foreign legal systems without either highlighting specific deficiencies with each system or demonstrating how such systems compare with U.S. courts. Thus, although it appears that the MTA wants facilitators to disclose the legal risks of medical travel, I remain skeptical that facilitators will disclose the critical details that patients may desire to know—such as the average medical malpractice award or the average length of time to recover. Moreover, even if facilitators disclose these details, patients might not fully understand how to

628. Medical Tourism Association, *supra* note 622.

629. Medical Tourism Association, *supra* note 624.

630. *Id.* (Section C, "Legal Recourse").

interpret and use such information.

Notwithstanding these criticisms, the certification program could live up to the MTA's aspirations of creating at least some standards and transparency in a market that currently lacks both. In fact, if the MTA made its data public, the program could achieve many of the objectives I have called for elsewhere, such as: 1) certification or licensure for medical tourism intermediaries, with the threat of decertification; 2) increased transparency in their business practices (to the extent the MTA makes this information public); and 3) gathering more data revealing what types of patients visit which countries for which procedures, including outcomes data.⁶³¹ Moreover, the MTA's certification program seems to encourage companies to think critically and creatively about patient safety, for example, by asking whether facilitators offer patients "complications insurance."⁶³²

Ultimately, however, the MTA is a trade organization, and its certification program—however well-intentioned—may be susceptible to the same pitfalls that plague other self-regulatory bodies. The companies applying for certification are the same companies whose fees fund the program and whose membership dues and advertising dollars fund the MTA itself.⁶³³ Can we trust the industry to regulate itself? At this point, we have no other choice, although elsewhere I have sketched out what government oversight of the industry might look like.⁶³⁴

2. Medical Malpractice Insurance for Patients

Companies that arrange for U.S. patients to travel overseas might consider offering patients insurance that covers any resulting injuries or complications, including the cost of any remedial care required back home.⁶³⁵

To date, there are few such products. Recently, AOS Assurance Company began offering "Patient Medical Malpractice Insurance" to medical tourists.⁶³⁶ Patients can purchase a policy that compensates them for lost wages, medical expenses, rehabilitation expenses, disfigurement, and death from "negligent injury or error" committed during a covered procedure.⁶³⁷ Policy coverage ranges

631. Cortez, *supra* note 6, at 123-27.

632. Medical Tourism Association, *supra* note 624 (Question E3, "Insurance").

633. Note that government regulators sometimes rely on "user fees" by regulated parties and may be criticized for such. See, e.g., James L. Zelenay, Jr., *The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?*, 60 FOOD & DRUG L.J. 261, 288, 330-34 (2005) (noting criticisms of the FDA for relying on user fees paid by pharmaceutical companies).

634. Cortez, *supra* note 6, at 123-27.

635. Terry, *supra* note 6, at 466.

636. AOS Assurance Company Ltd., Patient Medical Malpractice Insurance, <http://www.aosassurance.bb/PublicHtml/readmore.htm> (last visited Nov. 22, 2009).

637. *Id.* at 4; AOS, Patient Medical Malpractice Product Sheet, <http://www.aosassurance.bb/>

from \$100,000 to \$1 million.⁶³⁸ Companies can also purchase group policies.⁶³⁹

The policies cover only certain procedures performed by certain surgeons. The application form requires the patient to select among several dozen procedures and practitioners, though Aos may cover others not specifically listed.⁶⁴⁰ However, Aos does require that all procedures be performed at a facility accredited by Joint Commission International, by a board-certified physician or equivalent.⁶⁴¹

Aos markets this insurance as a way for patients to reduce the legal uncertainty of traveling overseas for surgery. For example, Aos notes in a brochure that “patients face dramatically increased liability exposure if a negligent injury should occur” overseas, because destination countries “have weak malpractice laws resulting in little to no recourse for the patient should something go wrong.”⁶⁴² Aos also advertises that it will settle claims 80% faster than patients would recover in U.S. courts.⁶⁴³ Finally, Aos promises that it will “handle and settle claims in accordance with the norms of the employee[’]s home country with local claim adjusters who understand the particular country customs and standards.”⁶⁴⁴ This could mean, for example, that Aos will provide greater reimbursement to patients from countries with higher standards of living, higher wages, and more expensive remedial care—though Aos does not clarify.

This type of insurance should improve as other companies begin offering competing products. For example, Aos charges policyholders \$1000 simply to file a claim and only refunds the fee if the claim prevails.⁶⁴⁵ Also, the prices quoted on Aos’s website show that purchasing a policy may add significantly to the overall cost of the venture.⁶⁴⁶ Such prices and terms may become more

PublicHtml/Documents/PMMI/PMMI%20Product%20Sheet.pdf (last visited Nov. 22, 2009).

638. *Id.*

639. Aos Assurance Company, *supra* note 636.

640. Aos Assurance Company, *supra* note 636 (Application Step 3).

641. *Id.*

642. AOS, EXECUTIVE SUMMARY: MITIGATING NEGLIGENT INJURY RISK: MEDICAL TOURISM 3, available at <http://www.aosassurance.bb/PublicHtml/Documents/PMMI/Executive%20Summary%20PMMI.pdf>.

643. AOS, Group Medical Malpractice Insurance (GMMI) Coverages, http://www.aosassurance.bb/PublicHtml/GMMI_Coverages.htm (last visited Nov. 22, 2009).

644. *Id.*

645. See AOS, Group Medical Malpractice Insurance (GMMI™) Product Sheet, <http://www.aosassurance.bb/PublicHtml/Documents/GMMI/GMMI%20Product%20Sheet.pdf> (last visited Nov. 22, 2009). Note, however, that Aos does not charge deductibles or copayments.

646. For example, purchasing the median policy with \$500,000 of coverage for arthroscopic surgery on an anterior cruciate ligament (ACL) would cost approximately \$948. See AOS, AOS Quick Quote, <https://www.aosassurance.bb/Reaktor2K7/application/quickquote/quickquote.aspx> (last visited Nov. 22, 2009) (select “Arthroscopic Surgery – Anterior Cruciate Ligament” from the “Procedure” menu and \$500,000 from the “Amount of insurance coverage in

favorable as more companies enter the market. Most importantly, these competition-driven policies are likely to offer peace of mind to patients venturing overseas. Intermediaries might even consider packaging these insurance products into the menu of services they offer.

3. Industry Guidelines

Demand for standards in the medical tourism industry has also prompted a response from the American Medical Association (AMA), which recently published what it calls the “first ever guidance on medical tourism.”⁶⁴⁷ The guidelines implore “employers, insurance companies, and other entities that facilitate or incentivize medical care outside the U.S.” to follow nine principles.⁶⁴⁸ For example, the AMA calls for all travel to be voluntary and instructs that financial incentives for patients “should not inappropriately limit the diagnostic and therapeutic alternatives that are offered to patients, or restrict treatment or referral options.”⁶⁴⁹

Like the MTA’s certification program, the AMA’s guidelines aspire to “ensure the safety of patients considering traveling abroad for medical care.”⁶⁵⁰ The guidelines, of course, bind no one. But the AMA says that it will try to codify these guidelines by introducing model legislation to state legislators.⁶⁵¹

Of course, like the MTA, the AMA is not exactly an objective bystander. U.S. physicians may lose business to foreign providers, and the AMA has publicly cautioned medical tourists about the quality of care overseas.⁶⁵² Nonetheless, the AMA has been a valuable counterpoint to the chorus of industry voices in the media that tend to downplay the risks of medical travel.

Finally, like the MTA’s certification program, the AMA’s guidelines are somewhat aspirational. For example, the AMA calls for companies to inform patients of “their rights and legal recourse prior to agreeing to travel outside the U.S. for medical care.”⁶⁵³ However, as I demonstrate throughout this Article, it is highly doubtful that most U.S. employers, insurers, or intermediaries know much about the medical malpractice systems in destination countries, as this information is elusive. Moreover, companies that try to inform patients of their

US\$” menu).

647. Press Release, Am. Med. Ass’n, *AMA Provides First Ever Guidance on Medical Tourism*, (June 16, 2008), available at <http://www.reuters.com/article/pressRelease/idUS38122+17-Jun-2008+PRN20080617>.

648. American Medical Association, *New AMA Guidelines on Medical Tourism*, <http://www.ama-assn.org/ama1/pub/upload/mm/31/medicaltourism.pdf> (last visited Nov. 22, 2009).

649. *Id.*

650. Press Release, Am. Med. Ass’n, *supra* note 647.

651. *Id.*

652. Edward R. Langston, Letter to the Editor, *CHI. TRIB.*, Apr. 8, 2008, at 20.

653. American Medical Association, *supra* note 648.

legal rights in the United States cannot speak with much authority, given the uncertainty surrounding these issues and the lack of test cases. Nonetheless, as more and better information becomes available, parties should follow the AMA's guidelines and disclose to patients the very real legal risks of having surgery overseas.

4. *Other Responses*

The private sector undoubtedly will conceive more creative ways to introduce standards and certainty to the medical tourism market, including ways for patients to mitigate their legal risks. Hopefully, these attempts move us toward a more equitable allocation of the legal risks and away from the current market allocation that shifts most of the risks to patients.⁶⁵⁴

For example, patients and intermediaries might agree contractually to resolve disputes through alternative dispute resolution, which could assure patients access to at least some realistic forum for redress. Intermediaries might also convince foreign providers to share the burdens of insuring against malpractice, contributing to a patient compensation fund, or perhaps funding alternative grievance procedures. Foreign providers might agree, for example, to compensate for specified losses, such as medical expenses, lost wages, and perhaps even limited payments for pain and suffering that are not available in some jurisdictions. These contributions would obviously raise the cost of medical tourism. But if foreign providers are going to avail themselves of patients from wealthier countries, they should understand that these patients probably expect larger recoveries.

Finally, a powerful tool may be negative publicity. As I have noted, negative publicity generated by medical malpractice suits could be catastrophic for foreign providers,⁶⁵⁵ especially if it jeopardizes contracts with U.S. insurers. In fact, demand for medical tourism services should be sensitive to perceptions of quality. High profile malpractice cases could discourage patients from going overseas.⁶⁵⁶ Unfortunately, there are few incentives in the industry that would encourage companies to publicize substandard quality care.⁶⁵⁷ Currently, we must rely on anecdotal media reporting and academic inquiries.

B. *Public Sector Responses*

Can the government respond to a medical tourism market that

654. Cortez, *supra* note 6, at 119.

655. *Id.* at 101.

656. BOOKMAN & BOOKMAN, *supra* note 6, at 60.

657. Note, however, that medical tourism intermediaries do have a significant incentive to avoid or cease contracting with substandard foreign providers, even if they probably would not publicize substandard care already provided to their customers.

disproportionately allocates legal risks to patients? Before answering, we must note some limits to what the government might reasonably achieve. First, as I note elsewhere, the government would have a difficult time restricting patient travel (an admittedly unlikely option),⁶⁵⁸ or targeting advertising or other commercial speech by medical tourism companies.⁶⁵⁹ Legislatures might consider extending long-arm jurisdiction over providers or intermediaries located overseas, but the federal Due Process clause would limit its reach.

Elsewhere I have called for a variety of government efforts that would provide greater oversight of the employers, insurers, and intermediaries that arrange for patients to travel overseas.⁶⁶⁰ Rather than repeating those recommendations here, I focus solely on fairly reallocating the legal risks. I propose a combination of methods below that would ease legal impediments to suing in the United States and inform patients of the risks of agreeing to assert claims in foreign courts. Importantly, these options need not replace private sector efforts; public and private efforts should operate in tandem.

1. Impose Strict Liability

Governments could create vicarious, strict liability by statute for U.S. employers, insurers, or intermediaries that send patients overseas.⁶⁶¹ For example, a medical tourist injured overseas could receive predetermined compensation based on the injury suffered, without needing to prove whether the provider or the intermediary was somehow negligent.

A vicarious strict liability regime could address several problems. First, vicarious liability would allocate legal responsibility to a U.S. company and thus avoid the burdens of suing in foreign jurisdictions or trying to sue foreign defendants here. Second, imposing strict liability would sidestep thorny legal questions of how to prove that either the provider or intermediary was negligent.⁶⁶² Third, strict liability might also encourage employers, insurers, and intermediaries to choose foreign providers more carefully, monitor quality, and perhaps purchase insurance to cover injuries—these companies are also in a better position to regulate, confront, and negotiate with foreign providers. Thus, vicarious strict liability would not only reallocate the legal risks more fairly, but would more closely align the interests of patients and intermediaries. Currently, employers and insurers save money sending patients overseas without bearing many of the risks.

Though statutory strict liability might appeal here in theory, governments

658. Cortez, *supra* note 6, at 114-18.

659. *Id.* at 119.

660. *Id.* at 118-27.

661. *Id.* at 122.

662. *Id.*

could find the system difficult to create and administer.⁶⁶³ Strict liability would require the government to administer a no-fault compensation system, much like our workers' compensation system or the no-fault system used to compensate for medical errors in New Zealand.⁶⁶⁴ The government would have to assign a range of remedies for a range of injuries, and most governments may be reluctant to devote the time and energy required to do so. Finally, as I have noted elsewhere, such heavy-handed approaches might have the perverse effect of driving medical tourism intermediaries overseas to less regulated jurisdictions.⁶⁶⁵

2. *Mandate or Encourage Insurance*

Governments should consider requiring employers, insurers, or other intermediaries to insure patients against medical errors or other complications arising from surgery overseas. Such insurance might take several forms. First, the government could require intermediaries to purchase (or at least offer) individual insurance policies covering each medical tourist, much like the policies offered by AOs. For example, a U.S. insurer that contracts with a foreign hospital might purchase accident insurance covering each patient sent to that hospital. Patients could even select the precise coverage they desire, similar to the AO policies. The government could mandate minimum coverage just as states mandate minimum automobile insurance. In the United Kingdom, the National Health Service encourages (but does not require) patients that travel to another EU member state for health care services under its E112 program to purchase insurance "to ensure any unforeseen emergencies are covered."⁶⁶⁶ Second, the government could require intermediaries to pay for all pre-screening or post-operative care that might be required in the United States, including any corrective treatments.⁶⁶⁷ This requirement would be a form of de facto insurance for patients injured overseas.

Although a mandate of either kind would increase the overall costs of the venture, it would better approximate the true risk tolerance of patients and would force suppliers of medical tourism services—both providers and intermediaries—to internalize more of the risks inherent in these transactions. Policymakers can require U.S. employers, insurers, or other intermediaries to pay for prescreening and post-operative care in the United States unless the company is able to procure an insurance policy meeting minimum standards.

663. *Id.*

664. Marie Bismark & Ron Paterson, *No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety*, 25 HEALTH AFF. 278 (2006).

665. Cortez, *supra* note 6, at 120.

666. National Health Service, *Going for Planned Treatment, Entitlement*, <http://www.nhs.uk/Treatmentabroad/Pages/Entitlement.aspx> (last visited Nov. 22, 2009).

667. Cortez, *supra* note 6, at 122.

3. Invalidate Liability Waivers

Legislatures might also consider prohibiting releases and waivers of liability, thus allowing courts to iron out complicated questions of duty, fault, and causation raised by medical tourist arrangements. For example, in the clinical research context, Food and Drug Administration regulations prohibit informed consent documents from including “any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights.”⁶⁶⁸ Some state laws also broadly prohibit contracts that exempt one party from responsibility for negligence or violations of law.⁶⁶⁹ Likewise, legislatures may simply decide that courts should resolve liability in medical tourist arrangements by removing the legal obfuscation created by releases and waivers.

Without such legislation, it is not clear whether releases and waivers of liability in medical tourism transactions are valid. In general, liability releases for medical negligence are invalid as being contrary to public policy.⁶⁷⁰ Under the seminal case, *Tunkl v. Regents of the University of California*, the California Supreme Court refused to enforce a release signed by a patient that absolved UCLA Medical Center from liability for negligence, on the basis of a state statute prohibiting such agreements.⁶⁷¹ Releases in California are invalid only if they affect the public interest, and the court applied numerous factors to find that hospital-patient contracts do indeed affect the public interest.⁶⁷² But because the public interest is an amorphous concept, and because the freedom to contract between patients and providers varies by circumstances, several jurisdictions have departed from *Tunkl*.⁶⁷³ Medical tourist arrangements also complicate this analysis because releases and waivers are being sought not only by foreign providers who may not be subject to U.S. jurisdiction, but by intermediaries who do not provide medical care and do not factor neatly into the *Tunkl* criteria.⁶⁷⁴ Legislation could render moot these uncertainties.

Such legislation would also respond to normative arguments that patients

668. 21 C.F.R. § 50.20 (2007).

669. See, e.g., CAL. CIV. CODE § 1668 (West 2009).

670. MARK A. HALL, MARY ANNE BOBINSKI & DAVID ORENTLICHER, MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS 419 (2005).

671. *Tunkl v. Regents of the Univ. of Cal.*, 383 P.2d 441 (Cal. 1963) (striking down the release under CAL. CIV. CODE § 1668).

672. *Id.* at 444-47.

673. See Maxwell J. Mehlman, *Fiduciary Contracting: Limitations on Bargaining Between Patients and Health Care Providers*, 51 U. PITT. L. REV. 365, 401-03 (1989-1990) (discussing alternative approaches adopted by courts).

674. It is not clear whether the factors enunciated in *Tunkl*, 383 P.2d at 445-46, would support invalidating releases of liability in medical tourist arrangements. In fact, application of each of the factors raises interesting policy questions.

should be free to waive legal rights in exchange for less expensive health care. For example, in their new book, *Nudge*, Richard Thaler and Cass Sunstein argue that patients should be allowed to waive the right to sue for medical malpractice, which would free them to negotiate for lower physician fees.⁶⁷⁵ Other scholars have also argued that in lieu of complete waivers, courts should enforce agreements by patients to lower providers' ordinary standard of care.⁶⁷⁶

However, even proponents of more moderate liability standards acknowledge that few courts currently support this position.⁶⁷⁷ And other scholars are poking holes in the wisdom of allowing patients to waive liability for malpractice, and even whether patients can or want to make these complex tradeoffs.⁶⁷⁸ Moreover, medical tourism complicates even this debate. Medical tourists do not exactly accept a lower standard of medical care by going overseas, but the standard might differ in tangible ways. Moreover, medical tourists may not be asked to waive liability completely, but simply agree to resolve disputes in foreign jurisdictions. This choice further complicates the question of whether medical tourists can make fully informed, rational, utility-maximizing decisions to waive legal recourse in the United States in exchange for less costly health care overseas. Again, legislation prohibiting such waivers or imposing strict, vicarious liability could render these difficult questions moot. Combined with a mandatory insurance requirement, the facilitators and suppliers in the medical tourism industry would also have to share the risks.

675. RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS* 207-14 (2008).

676. See, e.g., Clark C. Havighurst, *Private Reform of Tort-Law Dogma: Market Opportunities and Legal Obstacles*, 49 *LAW & CONTEMP. PROBS.* 143 (1986). Note that Thaler, Sunstein, and Havighurst do not contemplate waivers in cross-border medical care arrangements and thus focus on advantages to be gained from bargaining within the U.S. health care system and its web of protective regulations.

677. Mark A. Hall, *Paying for What You Get and Getting What You Pay For: Legal Responses to Consumer-Driven Health Care*, 69 *LAW & CONTEMP. PROBS.* 159, 177 (2006) (noting the distinction between patients agreeing to reduce the level of resources used versus the level of skill used by the provider).

678. See, e.g., TIMOTHY STOLTZFUS JOST, *HEALTH CARE AT RISK: A CRITIQUE OF THE CONSUMER-DRIVEN MOVEMENT* 86-118 (2007) (critiquing the application of traditional neoclassical microeconomic theory to health care and patient decisionmaking); Jennifer Arlen & W. Bentley MacLeod, *Malpractice Liability for Physicians and Managed Care Organizations*, 78 *N.Y.U. L. REV.* 1929, 1998-2005 (2003) (arguing that waivers of liability for medical malpractice are suboptimal even when patients accurately anticipate the risks); Tom Baker & Timothy D. Lytton, *Allowing Patients to Waive the Right To Sue for Medical Malpractice: A Response to Thaler and Sunstein* (Univ. of Pa. Inst. for L. & Econ. Research, Paper No. 09-06, 2009), available at <http://ssrn.com/abstract=1349836>.

4. *Correct Information Asymmetries*

Finally, perhaps the least ambitious but most realistic way to begin to reallocate the legal risks is to correct specific information asymmetries that contribute to the current misallocation of risks. Patients should know what legal recourse they will have under different medical tourism arrangements, particularly those that ask patients to waive various legal rights or litigate in a foreign jurisdiction. Patients should remain free to have surgery overseas—either of their own volition or at the behest of an employer or an insurer—but patients should fully appreciate what legal and regulatory protections they might be sacrificing.

In this spirit, the public sector could try to correct specific information asymmetries in the medical tourism market. For example, a government agency, commission, or perhaps even a multilateral organization like the WHO, might provide information to medical tourists and other payors regarding the legal and regulatory systems in destination countries. These groups could publish country-specific studies comparing foreign legal and regulatory systems and might disseminate the findings through websites, press releases, ad campaigns, targeted announcements, or other methods. For example, some news outlets have provided checklists and answers to frequently asked questions to potential medical tourists.⁶⁷⁹ The government might do the same, except that it could commission more robust data. Governments might even encourage companies that arrange for surgery overseas to disseminate these materials as part of a campaign to encourage full disclosure of the risks.

This method would preserve the status quo that allows patients to forego potential legal recourse in exchange for lower prices, except that it helps patients understand precisely what additional legal risks they are bearing. The current market discloses the legal risks in vague disclaimers loaded with legalese and potentially misleading reassurances that patients, ultimately, do have some legal recourse, somewhere. The government should provide this information because it is doubtful that the market alone will encourage companies to generate or disseminate complete and accurate information.

Under the status quo, some patients may fully appreciate the tradeoffs they are making. However, considering the minimal information available to them, I suspect the majority do not. And those that do not would benefit considerably from the prophylactic measures I propose. The government might supplement these measures with existing regulatory tools, such as consumer protection regulations, bans on unfair or deceptive trade practices, and the like.⁶⁸⁰ Requiring

679. See Greg Allen, *Employers, Insurers Considering Overseas Health Care*, NPR ALL THINGS CONSIDERED, Nov. 14, 2007, available at <http://www.npr.org/templates/story/story.php?storyId=16294182>.

680. Cortez, *supra* note 6, at 119-20.

insurance and banning liability waivers would provide immediate protection for patients in these potentially unbalanced contractual relationships. Collectively, these measures could begin to reallocate more fairly the legal risks of medical travel.

CONCLUSION

This Article began with an ambitious but straightforward goal: to recalibrate the legal risks of cross-border health care by evaluating whether U.S. patients injured overseas have adequate legal recourse, either here or in one of four common destinations: India, Thailand, Singapore, and Mexico. The value, I hope, in covering these four separate jurisdictions is to fill a major void in the literature and give patients a sense of the variety of obstacles they might encounter when seeking legal recourse overseas. The decision to travel for medical care should accurately reflect patients' true risk tolerances, and providers and intermediaries in the industry should share the risks of these transactions. I also hope to encourage the industry to think more critically and creatively about how it might reallocate the legal risks, so they do not fall squarely on patients. In the long run, the industry would benefit from confronting these risks, rather than simply deflecting them to patients. Finally, for the policymakers, I hope to demonstrate how targeted intervention can fairly and efficiently redistribute the legal risks or at least enable patients to make more informed choices about traveling overseas.

Implications of Genetic Testing for Health Policy

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INTRODUCTION

Genetic testing has created both opportunities and dilemmas for personal health care as well as public health systems. The sequencing of the human genome and advances in areas such as genomics and bioinformatics have brought about new diagnostic and therapeutic procedures. These rapidly arising innovations have created policy challenges to providers and other stakeholders, such as employers, insurers, and the legal system.¹ In 1990, the United States National Institutes of Health (NIH) created a taskforce focusing on the ethical, legal, and social implications of human genome research and diagnostic testing.² Similarly, the United States and some European countries have enacted legislation addressing discrimination that genetic testing might cause.³ As genetic testing technologies advance, national and international guidelines attempt to prepare and educate health professionals to prescribe genetic tests and interpret their results.⁴

This paper addresses the apparent divergence between the advances in genetic-based medicine and the guidelines concerning quality standards for genetic tests and the appropriate use of those test results.⁵ The integration of genetic medicine into primary care has spread rapidly thanks to the availability of affordable diagnostic tests for an increasing number of diseases. In this paper, we focus on four aspects of genetic testing that present particular dilemmas for health policymakers both in the United States and abroad:

- 1) The diffusion of genetic testing and its impact on medical practices;
- 2) The tension between confidentiality and transparency related to health insurance;
- 3) The expansion of genetic testing for embryo selection; and
- 4) The evolution of regulatory frameworks for the assurance of quality of genetic tests.

1. Muin J. Khoury, *Genetics and Genomics in Practice: The Continuum from Genetic Disease to Genetic Information in Health and Disease*, 5 GENETICS MED. 261, 261 (2003).

2. National Human Genome Research Institute, The Ethical, Legal and Social Implications (ELSI) Research Program, <http://www.genome.gov/10001618> (last visited Nov. 11, 2009).

3. Stuart Hogarth, Gail Javitt & David Melzer, *The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues*, 9 ANN. REV. GENOMICS & HUM. GENETICS 161, 171 (2008).

4. Jon Emery & Susan Hayflick, *The Challenge of Integrating Genetic Medicine into Primary Care*, 322 BRIT. MED. J. 1027, 1029-30 (2001).

5. Wylie Burke, *Contributions of Public Health to Genetics Education for Health Care Professionals*, 32 HEALTH EDUC. & BEHAV. 668, 668 (2005).

In Part I, we discuss the rapidly expanding use of genetic testing and how Internet access has accelerated this process. The Internet has also had the effect, however, of allowing genetic testing to bypass the physician entirely, which brings another set of issues to the forefront, including the need for interpretation and counseling.

Part II discusses the dialectics of confidentiality and transparency of genetic information. There are important public health and legal issues involving responsibility to inform others when specific genetic information impinges on their well-being. The decision to take a genetic test and the decision to disclose its results may create asymmetries of information that eventually disrupt the equilibrium between insurers and policyholders. Furthermore, even when legal protections prohibit genetic discrimination in the workplace, few trust that all parties will fully comply with these laws.

Beyond the issues of transparency, Part III analyzes how the expansion of genetic tests to in vitro fertilization is offering parents the possibility of selecting embryos based on genetic traits. Pre-implantation genetic diagnosis (PGD) uses genetic tests to screen human embryos for genetic predispositions to rare disorders as well as prevalent and treatable diseases, including breast cancer. For medico-economic reasons, will couples with genetic predispositions one day be invited by health authorities to seek assisted reproduction to test their embryos before having children?

In the last Part, this Article examines the state of regulatory authority concerning test validity and reliability. The status of regulation for test quality differs widely between the United States and European countries. Meaningful and harmonized regulation on a global scale is difficult to implement because overregulation could limit innovation, while under-regulation may lead to commercial abuse, consumer confusion, and distrust of this promising health care revolution.

I. THE DIFFUSION OF GENETIC TESTING AND ITS IMPACT ON MEDICAL PRACTICES

According to a 2003 survey of eighteen OECD members,⁶ the expansion of genetic testing is staggering: between 2000 and 2002, the number of genetic tests

6. The Organisation for Economic Co-operation and Development (OECD) is composed of thirty democratic governments (including twenty-three European countries, Australia, Canada, Japan, Korea, Mexico, New Zealand, and the United States) who work together to compare policy experiences and address economic, social, and environmental challenges of globalization in order to identify good practices and coordinate domestic and international policies. The OECD promotes policies designed to achieve sustainable economic growth and employment and a rising standard of living in member and non-member countries. See ORG. FOR ECON. CO-OPERATION & DEV., ANNUAL REPORT 2009, at 9 (2009), *available at* <http://www.oecd.org/dataoecd/38/39/43125523.pdf>.

conducted in 827 hospitals nearly doubled.⁷ During 2001, 18,000 tissue samples crossed OECD country borders for laboratory testing in other countries.⁸ As of October 2009, genetic tests for predispositions to 1819 diseases, including type 2 diabetes, Alzheimer's disease, obesity, and breast cancer, were registered by GeneTests, an NIH sponsored think-tank.⁹ The number of laboratories performing those tests has remained stable since 2003 (Figure 1). On the other hand, the number of diseases for which a test is available has grown at an average annual rate of twelve percent since 2002.¹⁰ These two trends illustrate that laboratories are increasingly engaged in genetic testing and, as a result, are significantly shaping medical practices both nationally and globally.

A. Medical Practices and National Disparities

In 2003, only fifty-seven percent of laboratories in OECD countries required written informed consent prior to testing.¹¹ In the United States, no harmonized federal requirements for informed consent regarding genetic testing exist.¹² At a state level, Delaware, Nevada, New Jersey, New York, and Oregon laws require researchers to obtain individual informed consent before retaining genetic information.¹³ The absence of such an informed consent could conflict with the need to retain biological samples for quality assurance reasons. A New York State Civil Rights Law requires testing laboratories to obtain written informed consent prior to conducting certain genetic tests.¹⁴ Similarly, laboratories operating in Arkansas and Oklahoma must preserve patient privacy through the use of written informed consent forms prior to conducting genetic testing and research on biological tissue and blood.¹⁵ Other states require informed consent for genetic testing but do not require consent for research as long as patient

7. ORG. FOR ECON. CO-OPERATION & DEV., GENETIC TESTING: A SURVEY OF QUALITY ASSURANCE AND PROFICIENCY STANDARDS 10 (2007) [hereinafter OECD, GENETIC TESTING].

8. *Id.* at 13.

9. GeneTests, <http://www.genetests.org> (last visited Nov. 11, 2009).

10. This calculation is based on the 2002-2008 data presented in Figure 1.

11. OECD, GENETIC TESTING, *supra* note 7, at 46. Such a written informed consent would describe the genetic test and its limitations and risks and would be used to protect patient privacy and rights.

12. *See id.* at 125.

13. R. HAKIMIAN ET AL., NATIONAL CANCER INSTITUTE CANCER DIAGNOSIS PROGRAM: 50-STATE SURVEY OF LAWS REGULATING THE COLLECTION, STORAGE, AND USE OF HUMAN TISSUE SPECIMENS AND ASSOCIATED DATA FOR RESEARCH 6 (2007).

14. N.Y. CIV. RIGHTS LAW § 79-l(2) (Westlaw 2009); *see also* Memorandum from Columbia Univ. Med. Ctr. to Columbia Univ. Faculty Practitioners (Jan. 3, 2007), *available at* http://pathology.columbia.edu/diagnostic/requisitions/GeneticTestingPolicy_facultymemo_12607.pdf.

15. *See* HAKIMIAN ET AL., *supra* note 13, at 7.

identities are not disclosed. New Jersey is the strictest on the use of samples for research. The state's Genetic Privacy Act requires that samples used in genetic research be destroyed upon completion of the project.¹⁶ In most European countries, patients must provide written informed consent prior to genetic testing. However, according to the OECD survey, even in the absence of informed consent, only thirteen percent of laboratories declined to perform the test. Almost half of genetic testing laboratories in OECD member states are not accredited or certified.¹⁷ In the United States, all clinical laboratories must be certified under a common licensing law, whereas few European OECD countries impose licensing requirements.¹⁸ For instance, in Finland, Ireland, Sweden, Turkey, and the United Kingdom, laboratories are not required to obtain a government issued license for genetic testing.¹⁹

These data reflect significant regulatory disparity across countries, within countries and between hospital laboratories. Without adapted regulation and medical training programs, genetic tests and services have developed erratically, with poor clinical reliability, thus fostering the distrust of practitioners and patients. The difficulty of adopting harmonized medical training for the use and interpretation of genetic tests is partly due to the rapid growth in genetic testing availability. This difficulty is exacerbated by the pace of scientific breakthroughs in bioinformatics and sequencing technologies, which complicates designing updated training programs for laboratory technicians and medical practitioners. At a laboratory level, the OECD reported that "74% [of laboratory directors] were certified or registered to practice clinical laboratory medicine by an officially recognised body, and 67% had received formal training in molecular genetics."²⁰ Furthermore, the majority of laboratories employed technicians, ninety-one percent of whom had minimum education and training, to perform the genetic tests.²¹

The challenge of regulating genetic testing is to create an adequate framework that enables patients to access health care and targeted treatment without fear of misuse or discrimination based on their genetic profile.²² Many countries therefore recognize the need for tighter regulation regarding access to

16. *See id.*

17. *See* OECD, GENETIC TESTING, *supra* note 7, at 87-88.

18. Laurence M. Demers & Sharon S. Ehrmeyer, *Regulatory Issues Regarding Point-of-Care Testing*, in POINT-OF-CARE TESTING 163, 163 (Christopher Price, Andrew St John & Jocelyn M. Hicks eds., 2d ed. 2004).

19. *See* OECD, GENETIC TESTING, *supra* note 7, at 88-90.

20. *Id.* at 37.

21. *Id.* at 125.

22. Lizabeth A. Barclay & Karen S. Markel, *Discrimination and Stigmatization in Work Organizations: A Multiple Level Framework for Research on Genetic Testing*, 60 HUM. REL. 953, 953, 957-58, 969, 976 (2007).

genetic testing and subsequent health care. Standardized medical training and laboratory accreditation are also considered as possible ways to harmonize testing procedures and reliability of results.²³ In its guidelines on genetic testing, the OECD stresses that genetic tests should be delivered by a health care professional and within a quality assurance framework.²⁴

National and international organizations recognize the need to develop harmonized international best practice policies for quality assurance and accreditation of genetic tests.²⁵ Many OECD countries also identified the need for national gatekeepers, such as health authorities and organizations, to oversee testing availability, quality, and procedures.²⁶ Both the U.S. Food and Drug Administration (FDA) and the U.K. National Health Service (NHS) have issued guidance documents for industry, regulatory, and medical staff promoting best practice guidelines and procedures for the development and use of genetic diagnostic tests.²⁷ In the United Kingdom for instance, the government-supported U.K. Genetic Testing Network (UKGTN) aims to increase oversight awareness among laboratory directors.²⁸ Providing laboratories with incentives to comply with standards on genetic testing safety, effectiveness, and quality improvement would promote the harmonization of public policy.

23. See, e.g., Michael M. Hopkins et al., *Putting Pharmacogenetics into Practice*, 24 NATURE BIOTECH. 403, 403 (2006); GeneTests, Educational Materials, <http://www.ncbi.nlm.nih.gov/projects/GeneTests/static/concepts/conceptsindex.shtml> (last visited Nov. 11, 2009).

24. ORG. FOR ECON. CO-OPERATION & DEV., OECD GUIDELINES FOR QUALITY ASSURANCE IN MOLECULAR GENETIC TESTING 13 (2007) [hereinafter OECD GUIDELINES].

25. ORG. FOR ECON. CO-OPERATION & DEV., GENETIC TESTING: POLICY ISSUES FOR THE NEW MILLENNIUM 8-9 (2000).

26. See OECD GUIDELINES, *supra* note 24, at 19.

27. UK GENETIC TESTING NETWORK STEERING GROUP, PROCEDURES AND CRITERIA FOR THE EVALUATION OF GENETIC TESTS FOR NHS SERVICE 1 (2003), http://www.ukgtn.nhs.uk/gtn/digitalAssets/0/214_Background_Information_Gene_Dossier.pdf; U.S. Food and Drug Administration, OIVD Guidance, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm> (last visited Nov. 11, 2009).

28. See OECD, GENETIC TESTING, *supra* note 7, at 88.

Definitions

- *Clinical validity* is the ability of a test to detect or predict the associated disorder.²⁹ The clinical validity of a test measures the precision with which a test identifies a condition or a predisposition to a condition. Validity is defined in terms of specificity, sensitivity, and predictive value on a clinical basis.
- *Clinical utility* is determined by the risks and benefits associated with a test's introduction into routine practice.³⁰ Clinical utility expresses the value of test results in order to guide the tested individual in his/her choices regarding preventative strategies or treatment.

B. Online Distribution

Some medical laboratories take advantage of regulatory loopholes to circumvent health authorities, enabling the commercialization of genetic tests in a poorly controlled market. Commercial websites use the loose regulatory framework to increase their market share through various forms of retailing services. Retailers such as DNAdirect sell genetic tests manufactured by other companies. For example, the test for cystic fibrosis is sold for \$260.³¹ Another retailer, 23andMe, commercializes medical tests³² as well as tests for eye color transmission, manufactured by DNAPrint Genomics, Inc.,³³ and for muscular performance for sports professionals, manufactured by Genetic Technologies.³⁴ In 2007, Google invested \$3.9 million into 23andMe and, in parallel, decided to launch Google Health, a web-based medical record repository aimed at creating a personal, digital future for health-related data.³⁵ Google Health allows individuals to correlate their medical history and genetic test results with their treatments in order to minimize drug interactions and prevent adverse reactions.

29. Centers for Disease Control and Prevention, ACCE Model for Evaluating Genetic Tests, <http://www.cdc.gov/genomics/gtesting/ACCE/index.htm> (last visited Nov. 11, 2009).

30. *See id.*

31. DNAdirect, Who Should Consider Testing for Cystic Fibrosis?, <http://www.dnadirect.com/web/article/testing-for-genetic-disorders/cystic-fibrosis/30/who-should-consider-testing> (last visited Nov. 11, 2009).

32. 23andMe, <http://www.23andme.com> (last visited Nov. 11, 2009).

33. Richard A. Sturm & Tony N. Frudakis, *Eye Colour: Portals into Pigmentation Genes and Ancestry*, 20 TRENDS GENETICS 327, 330 (2004).

34. Grégory Katz-Bénichou, *L'éthique sportive est-elle un instrument de marketing?*, 30 REVUE FRANÇAISE DE GESTION 177, 187 (2004); Julian Savulescu & Bennett Foddy, *Comment: Genetic Test Available for Sports Performance*, 39 BRIT. J. SPORTS MED. 472, 472 (2005).

35. Google Inc.: Firm Tied to Co-Founder Receives an Investment, WALL ST. J., May 23, 2007, at B10.

Other retailers such as Clinical Data Online sell genetic tests to physicians to better predict response rates to a particular drug. Clinical Data Online is a direct-to-practitioner platform, whereas 23andMe is a direct-to-consumer website.³⁶

Other websites such as Navigenics or deCODEme analyze their customers' genetic profile and update results as soon as new tests are commercialized.³⁷ In other words, these firms do not offer single tests, but rather offer a continuing service as new tests become available. Registration fees are around \$2500 and the annual cost is \$250.³⁸ Similarly, companies such as Spain-based Labgenetics offer couples undergoing artificial reproductive technology the opportunity to use genetic tests to screen embryos through pre-implantation genetic diagnosis (PGD).³⁹ With the same genetic testing technology, Navigenics offers secondary prevention through early diagnosis, while Labgenetics offers primary prevention through embryo screening. In both cases, the revolution of consumer genomics has created a shift away from a physician-controlled approach towards a patient-empowered system.⁴⁰

C. Bypassing the Physician

Bolstered by the growing availability of commercialized tests on the Internet, genetic tests are thriving in an unregulated market. By turning to the Internet to purchase a genetic test, consumers bypass the doctor-patient relationship, together with its personalized genetic advice and counsel.⁴¹ Direct-to-consumer advertising of genetic tests does not encourage consumers to contact their health care provider.⁴² A recent study found that direct-to-consumer marketing of genetic tests increased consumers' awareness about diseases, but failed to accurately convey risk information.⁴³ Until recently, the physician decided whether to prescribe a genetic test and would subsequently adapt the patient's medical intervention according to the test results. Genetic test results are usually difficult for the layman to interpret because they are often imprecise and

36. See 23andMe, *supra* note 32.

37. deCODEme, <http://www.decodeme.com> (last visited Nov. 11, 2009).

38. Navigenics, <http://www.navigenics.com> (last visited Nov. 11, 2009).

39. Labgenetics, <http://www.labgenetics.com.es> (last visited Nov. 11, 2009).

40. See Morris W. Foster & Richard R. Sharp, *The Contractual Genome: How Direct-to-Consumer Genomic Services May Help Patients Take Ownership of Their DNA*, 5 PERSONALIZED MED. 399 (2008).

41. Adam J. Wolfberg, *Genes on the Web: Direct-to-Consumer Marketing of Genetic Testing*, 355 NEW ENG. J. MED. 543, 543 (2006).

42. Sarah E. Gollust, Sara Chandros Hull & Benjamin S. Wilfond, *Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing*, 288 JAMA 1762, 1762 (2002).

43. GENETICS & PUB. POLICY CTR., DIRECT-TO-CONSUMER GENETIC TESTING: EMPOWERING OR ENDANGERING THE PUBLIC? (2008), http://www.dnapolicy.org/images/issuebriefpdfs/2006_DTC_Issue_Brief.pdf.

indefinite.

Diseases commonly result from a combination of environmental factors and genetic factors. In weighing the genetic factors, it is important to know whether a disease is monogenic (caused by a single gene) or polygenic (caused by several genes).⁴⁴ In addition, mutations in some genes have a strong impact on the development of a disease. These mutations, such as those that cause cystic fibrosis, are known as highly penetrant, where a patient who has the mutation almost surely will develop the disease.⁴⁵ Mutations in other genes, such as those that are linked with hypercholesterolemia or autism, are not highly penetrant. In these cases, having the mutation may not mean that a patient will develop the disease.

For patients, attempting to interpret the complex results of genetic tests without any medical assistance could be a risky task. The results from a self-prescribed test can be all the more anxiety-provoking if the patient discovers that no treatment exists for the disorder, such as in the case of Huntington's chorea, which is fatal.⁴⁶ The announcement of the results of a positive genetic test could produce a violent emotional impact and disturb the patient's psychological balance.⁴⁷ A positive test for Huntington's could also impact family members who may discover themselves to be carriers of the disease and who may unknowingly have passed the genetic mutation to their offspring. Additionally, the reliability of tests is in most cases questionable, creating additional distress for patients. For instance, genetic testing for BRCA1 and BRCA2 misses an estimated fifteen percent of mutations.⁴⁸ Such false-negative test results may discourage patients from seeking further examination, leading to possible detrimental consequences. On the other hand, false-positive results for breast cancer testing could subject patients to further stressful and costly medical examinations, sometimes leading to unnecessary prophylactic mastectomies.⁴⁹ Prenatal diagnosis to determine chromosomal or genetic disorders in the fetus,

44. Thaddeus Judkins et al., *Single Nucleotide Polymorphisms in Clinical Genetic Testing: The Characterization of the Clinical Significance of Genetic Variants and Their Application in Clinical Research for BRCA1*, 573 *MUTATION RES.* 168, 172 (2005).

45. Béatrice Godard et al., *Population Genetic Screening Programmes: Principles, Techniques, Practices, and Policies*, 11 *EUR. J. HUM. GENETICS (SUPPLEMENT 2)* S49, S56 (2003).

46. Rory Johnson et al., *A MicroRNA-Based Gene Dysregulation Pathway in Huntington's Disease*, 29 *NEUROBIOLOGY DISEASE* 438, 438 (2008).

47. Andrea Farkas Patenaude, *Pediatric Psychology Training and Genetics: What Will Twenty-First-Century Pediatric Psychologists Need to Know?*, 28 *J. PEDIATRIC PSYCHOL.* 135, 136-37 (2003).

48. Donald A. Berry et al., *BRCA1/BRCA2, and Prevalence of Other Breast Cancer Susceptibility Genes*, 20 *J. CLINICAL ONCOLOGY* 2701, 2701 (2002).

49. Leslie R. Schover, *A Lesser Evil: Prophylactic Mastectomy for Women at High Risk for Breast Cancer*, 26 *J. CLINICAL ONCOLOGY* 3918, 3918 (2008).

known as Chorionic Villus Sampling, has a higher rate of false-positive results (1–1.5%) compared to amniocentesis (0.5%).⁵⁰ Although useful as medical devices, genetic tests alone could interfere both with patients' emotional stability and the quality of medical care they receive.

D. Duty to Inform?

In some cases, the duty to inform third parties about genetic test results has been interpreted as a duty to prevent foreseeable harm.⁵¹ When a patient refuses to disclose genetic information to relatives, it poses an ethical dilemma to health care professionals.⁵² When test results are kept confidential, which may be more likely when a patient orders the test directly, other persons at risk are not warned and lose the chance to receive preventative treatment.⁵³ The French case is illustrative: in 2003, the French national bioethics advisory committee considered whether informing a patient's relatives of a potential health risk should take precedence over protecting individual privacy.⁵⁴ The 2004 French bioethics law states that if tests reveal a serious genetic predisposition, "the physician should inform the patient about the potential consequences of his or her silence: putting vulnerable family members at risk, who could otherwise benefit from preventative medical attention."⁵⁵ In the United States, there have been legal cases in which patients' relatives have sued physicians for not warning them of their risk.⁵⁶ The *Safer v. Estate of Pack* case illustrates this: a daughter sued her father's physician for breaching his duty to warn her about a hereditary colon cancer risk.⁵⁷

In 2001, bioethicists Doukas and Berg proposed an original solution known as the "family covenant," to overcome some of the ethical dilemmas brought

50. Godard et al., *supra* note 45, at S70.

51. Graeme K. Suthers et al., *Letting the Family Know: Balancing Ethics and Effectiveness When Notifying Relatives about Genetic Testing for a Familial Disorder*, 43 J. MED. GENETICS 665, 665, 668-69 (2006).

52. R. Beth Dugan et al., *Duty to Warn At-Risk Relatives for Genetic Disease: Genetic Counselors' Clinical Experience*, 119C AM. J. MED. GENETICS 27, 27 (2003).

53. See generally Robert E. Gramling & Jennifer Irvin Vidrine, *Risk Communication During Screening for Genomic Breast Cancer Susceptibility*, 1 AM. J. LIFESTYLE MED. 54, 54 (2007) (discussing benefits of communicating risk).

54. NAT'L CONSULTATIVE ETHICS COMM. FOR HEALTH AND LIFE SCIENCES, OPINION NO. 76: REGARDING THE OBLIGATION TO DISCLOSE GENETIC INFORMATION OF CONCERN TO THE FAMILY IN THE EVENT OF MEDICAL NECESSITY 4 (2003), <http://www.ccne-ethique.fr/docs/en/avis076.pdf>.

55. CODE DE LA SANTÉ PUBLIQUE art. L1131-1 (Fr.).

56. Annette R. Patterson et al., *Custodianship of Genetic Information: Clinical Challenges and Professional Responsibility*, 23 J. CLINICAL ONCOLOGY 2100, 2103 (2005).

57. *Safer v. Estate of Pack*, 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996).

about by genetic testing.⁵⁸ An agreement is established prior to genetic testing between the patient, their family, and the physician regarding which genetic information should be shared and with whom. This contract seeks to strike a balance between the need to respect the privacy of patients undergoing genetic testing, the rights of family members to be informed of genetic disorders that could affect them, and the responsibility that both relatives and physicians have in communicating genetic test results. Genetic test results may disrupt the patient-physician relationship; this contract contributes to stabilize this relationship by anticipating what decisions should be made before and after the test results are known.⁵⁹

Nonetheless, the legal situation remains unclear regarding disclosure against a patient's will. In 2003, Falk and her colleagues surveyed medical geneticists, all members of the American Society of Human Genetics and the American College of Medical Genetics. Their findings indicated that over two thirds of the surveyed geneticists considered themselves to be responsible for warning the relatives of their patients when discovered to be at-risk for a genetic disease. Faced with a patient who refuses to notify at-risk family members, one quarter of the geneticists contemplated disclosing the information to the at-risk relatives without their patient's consent. Four respondents only took the liberty to warn at-risk relatives about their genetic profile.⁶⁰

However, is it the physician's or the individual's responsibility to disclose medical information?⁶¹ Advocating the idea that the patient should inform other family members, the French medical statistician Adolphe Bertillon proposed in 1876 that each family should update a record of their medical history that is then made accessible to descendants.⁶² In present times, this opinion is supported by the National Society of Genetic Counselors.⁶³ The American Society of Human Genetics, however, defends the position that information should be disclosed only if a high penetrance disease is preventable or treatable.⁶⁴ Although they diverge on this point, both are leading organizations promoting the role of

58. David J. Doukas & Jessica W. Berg, *The Family Covenant and Genetic Testing*, AM. J. BIOETHICS, Summer 2001, at 2, 5.

59. *See id.*

60. Marni J. Falk et al., *Medical Geneticists' Duty to Warn At-Risk Relatives for Genetic Disease*, 120A AM. J. MED. GENETICS 374, 374 (2003).

61. *See* Patterson et al., *supra* note 56, at 2102.

62. Alphonse Bertillon, *Mariage*, in DICTIONNAIRE ENCYCLOPÉDIQUE DES SCIENCES MÉDICALES 56 (Amédée Dechambre ed., Paris, Asselin 1876).

63. Wendy C. McKinnon et al., *Predisposition Genetic Testing for Late-Onset Disorders in Adults: A Position Paper of the National Society of Genetic Counselors*, 278 JAMA 1217, 1218 (1997).

64. Am. Soc'y of Human Genetics Soc. Issues Subcomm. on Familial Disclosure, *ASHG Statement: Professional Disclosure of Familial Genetic Information*, 62 AM. J. HUM. GENETICS 474, 474 (1998).

genetic counselors in health care to ensure the quality of genetic services and the best application of those services to society. Additionally, the National Society of Genetic Counselors and the American Society of Clinical Oncology have both published formal statements opposing the ethical duty to warn.⁶⁵ However, if genetic transparency provides a chance for prevention, does lack of disclosure from one family member hinder adequate treatment for another? Fundamentally, the underlying ethical dilemma consists in assessing whether the harm due to failure of disclosure outweighs the harm that may be caused by disclosure.⁶⁶

II. BALANCING CONFIDENTIALITY AND TRANSPARENCY

A. Confidentiality and Discrimination

In 2003, nearly half of the hospitals in OECD countries used genetic tests without prior patient consent, and thirty-seven percent did not have a written confidentiality policy regarding test results.⁶⁷ But what is really at stake when genetic data are disclosed to third parties such as health insurers⁶⁸ or employers?⁶⁹ A simple DNA sample represents an encrypted medical record containing statistical information, whose nature is radically different from that found in classic medical data.⁷⁰ Before consumers entrust their biological samples to companies performing genetic tests, they should enquire about the confidentiality clauses provided by the firms that collect DNA samples in hospitals or through the Internet.⁷¹ Some of the firms offering genetic tests sell the clinical data to other laboratories or other companies.⁷² The confidentiality agreements of companies such as deCODEme, Myriad, or 23andMe may include certain contractual clauses allowing them, in some cases, to transfer their clients' genetic data to third parties, much as credit card data is shared between commercial entities. However, an individual's genetic code presents far more exposure to one's personal state of well-being than a credit card number. While a

65. See Patterson et al., *supra* note 56, at 2103.

66. Regina E. Ensenaue, Virginia V. Michels & Shanda S. Reinke, *Genetic Testing: Practical, Ethical, and Counseling Considerations*, 80 MAYO CLINIC PROC. 63, 70 (2005).

67. OECD, GENETIC TESTING, *supra* note 7, at 46, 81.

68. Michael Hoy & Michael Ruse, *Regulating Genetic Information in Insurance Markets*, 8 RISK MGMT. INS. REV. 211, 211-12 (2005).

69. M. Aspinall et al., *US System of Oversight for Genetic Testing: A Report from the Secretary's Advisory Committee on Genetics, Health and Society*, 5 PERSONALIZED MED. 521, 521 (2008).

70. Patricia A. Roche & George J. Annas, *DNA Testing, Banking and Genetic Privacy*, 355 NEW ENG. J. MED. 545, 546 (2006).

71. John A. Robertson, *The \$1000 Genome: Ethical and Legal Issues in Whole Genome Sequencing of Individuals*, 3 AM. J. BIOETHICS W35, W38 (2003).

72. See Roche & Annas, *supra* note 70, at 546.

compromise of one's credit card number can be mitigated, in part, by cancelling and replacing the credit card, one cannot simply change one's set of chromosomes or genotype.⁷³ When a third party comes into possession of a genetic sample, it can discover information that we ignore, discover information that we would prefer to ignore, and discover information that we wish others to ignore.⁷⁴

What should we worry about? The view that we have nothing to fear from genetic transparency has been suggested by its proponents, including James Watson shortly after publishing the sequence of his genome.⁷⁵ We know, however, that Watson refused to allow one part of his genotype to be analyzed (the area implicated in the predisposition to Alzheimer's disease (Apoprotein E)).⁷⁶ His grandmother died of this serious neurological disorder, and for his own peace of mind, he does not wish to know of his predisposition to this disease.⁷⁷ Besides personal reasons, social arguments could also dissuade people from taking genetic tests. Indeed, the fear of genetic discrimination may discourage some patients from using genetic tests, thus depriving themselves of appropriate treatment. Some people may not want to know about late-onset and incurable diseases, particularly if the information might lead to discrimination.⁷⁸ Others attempt to persuade their physicians not to write their genetic test results in their medical records.⁷⁹ Individuals might also avoid disclosing test results to their physician for fear of discovery by insurance companies.⁸⁰ Upon discovery of genetic test results, some might give up purchasing more comprehensive health insurance, while others might decide to increase their coverage.

In the employment context, in order to avoid genetic information impinging on public freedom, the United States adopted several anti-discrimination laws. In 1990, Congress enacted the Americans with Disabilities Act (ADA),⁸¹ a civil

73. *See id.*

74. *See id.*

75. *See* Meredith Wadman, *James Watson's Genome Sequenced at High Speed*, 452 NATURE 788, 788 (2008).

76. Erika Check, *Celebrity Genomes Alarm Researchers*, 447 NATURE 358, 359 (2007).

77. Erika Check, *James Watson's Genome Sequenced: Discoverer of the Double Helix Blazes Trail for Personal Genomics*, NATURENEWS, June 1, 2007, <http://www.nature.com/news/2007/070528/full/news070528-10.html>.

78. *See* Nancy Kass & Amy Medley, *Genetic Screening and Disability Insurance: What Can We Learn from the Health Insurance Experience?*, 35 J.L. MED. & ETHICS (SPECIAL SUPPLEMENT) 66, 70 (2007) (discussing a risk that insurance companies might discriminate against individuals genetically disposed to disease).

79. Béatrice Godard et al., *Genetic Information and Testing in Insurance and Employment: Technical, Social and Ethical Issues*, 11 EUR. J. HUM. GENETICS (SUPPLEMENT 2) S123, S127 (2003).

80. *See id.* at 126.

81. Americans with Disabilities Act of 1990, 42 U.S.C. § 12112 (2006).

rights law prohibiting discrimination based on disability. The ADA Amendments Act was signed into law in 2008, giving broader protections for disabled workers.⁸² In 2000, an executive order was issued by President Bill Clinton, prohibiting discrimination in employment based on genetic information and imposing a duty of confidentiality regarding genetic data outside an employee's company.⁸³ However, this law does not prevent the employer from using the information internally as a decision or human resource management tool.⁸⁴ Once the employee is hired, medical exams can be performed, including genetic tests.⁸⁵ Refusing to comply with these genetic tests might lead to job loss or denial of a promotion.⁸⁶ Furthermore, in order to enforce the law, employees need to prove that their employers have discriminated against them on the basis of their genetic information. American case law has addressed various such instances: a medical laboratory that tested its own employees for genetic predispositions⁸⁷ or the 2001 case in which the Burlington Northern Santa Fe Railroad (BNSF) company used genetic tests on train drivers without their consent to detect their predispositions to Carpal Tunnel syndrome.⁸⁸ Under the ADA, however, employers are not permitted to run genetic tests on their employees without their consent once they have become disabled. Thus the actions of BNSF were widely criticized and led to demands for bans on genetic discrimination in the workplace.⁸⁹ A lawsuit arose in response to six employee complaints and the litigation was settled out of court: the railroad company agreed to pay \$2.2 million in damages to thirty-six of its employees and to terminate the collection of blood samples for genetic

82. ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553 (2008) (codified as amended in scattered sections of 42 U.S.C.).

83. To Prohibit Discrimination in Federal Employment Based on Genetic Information, Exec. Order No. 13,145, 65 Fed. Reg. 6875 (Feb. 10, 2000).

84. *See id.* at 6879.

85. ROBERT F. WEIR & ROBERT S. OLICK, *THE STORED TISSUE ISSUE* 187 (2004).

86. Ellen Wright Clayton, *Ethical, Legal and Social Implications of Genomic Medicine*, 349 *NEW ENG. J. MED.* 562, 562, 566-67 (2003).

87. Sally Lehrman, *Medical Tests Cost Lawrence Berkeley \$2.2 Million*, 405 *NATURE* 110, 110 (2000). In 1995, seven employees of the Lawrence Berkeley National Laboratory (LBNL) sued the company, claiming it had performed genetic tests, using stored blood samples, to test its workers for pregnancy, sexually transmitted diseases, and sickle-cell trait without their consent, and made decisions to lay off employees based on these results. Following this class action, LBNL agreed in 2000 to a provisional \$2.2 million settlement. *See WEIR & OLICK, supra* note 85, at 191-92.

88. Joanna Goven, *Assessing Genetic Testing: Who Are the "Lay Experts"?*, 85 *HEALTH POL'Y* 1, 5-6 (2008); Press Release, U.S. Equal Employment Opportunity Comm., *EEOC Settles ADA Suit Against BNSF for Genetic Bias* (Apr. 18, 2001), *available at* <http://www.eeoc.gov/press/4-18-01.html>.

89. *See Clayton, supra* note 86, at 564.

testing.⁹⁰

In the private insurance market, the Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996 in order to help individuals benefit from continuous health coverage, particularly following job moves.⁹¹ One objective was to improve access to long-term group health coverage by waiving pre-existing condition exclusions for individuals.⁹² It addresses the security and privacy of health data by regulating, but not altogether excluding, the use and disclosure of information concerning an individual's medical record or payment history held by health insurers and medical service providers.⁹³ Though its aim is to protect individuals, HIPAA has limitations: for instance, HIPAA cannot prevent an insurance company from raising the premiums for group health plans as a whole, based on the genetic information of one individual in that group.⁹⁴ Based on genetic information, the insurance provider can refuse to insure potential customers, potentially leaving them without health insurance coverage.

The private health insurance market is not as widespread in Europe as in the United States, but the possible use of genetic information in insurance and employment is increasingly generating debate and causing concern.⁹⁵ The European Convention on Human Rights and Biomedicine, also known as the Oviedo Convention, was approved by the Council of Europe in 1997 and was signed by thirty-four of its forty-seven member states,⁹⁶ with the principal objective of protecting individuals from genetic discrimination.⁹⁷ The Convention prohibits any form of discrimination based on a person's genetic heritage and limits the use of genetic tests for health and research purposes by mandating that appropriate genetic counseling be provided.

90. See WEIR & OLICK, *supra* note 85, at 188.

91. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 18, 26, 29, and 42 U.S.C.).

92. Len M. Nichols & Linda J. Blumberg, *A Different Kind of 'New Federalism'? The Health Insurance Portability and Accountability Act of 1996*, HEALTH AFF., May/June 1998, at 25, 32.

93. See George J. Annas, *HIPAA Regulations—A New Era of Medical-Record Privacy?*, 348 NEW ENG. J. MED. 1486, 1486-90 (2003).

94. *Genetic(al) Correctness*, 17 NATURE GENETICS 363, 364 (1997).

95. See Godard et al., *supra* note 79, at 124.

96. Pilar Nicolás, *Ethical and Juridical Issues of Genetic Testing: A Review of the International Regulation*, 69 CRITICAL REV. ONCOLOGY/HEMATOLOGY 98, 99 (2009); Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Chart of Signatures and Ratifications, <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=&DF=&CL=ENG> (last visited Nov. 11, 2009).

97. Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 4, 1997, Eur. T.S. No. 167, available at <http://conventions.coe.int/Treaty/EN/Treaties/html/164.htm>.

Among the member countries is Denmark, who signed the Convention in 1997 and ratified it by Parliamentary decision in 1999.⁹⁸ Genetic testing in Denmark is “regulated through the legal framework that applies to the Danish national health care system as a whole.”⁹⁹ However, because the Danish Constitution states no rules regarding genetic discrimination, the Oviedo Convention was incorporated into Danish national law in 1992 in order to address these issues.¹⁰⁰ The nondiscrimination rule in Article 14 of the Oviedo Convention prohibits the use of predictive genetic tests by insurance companies and employers. Although insurance companies and employers are not allowed to demand or make use of an individual’s genetic information, they are authorized to inquire about disorders or diseases which have already manifested in the individual or a family member. Individuals with a family history of breast cancer, for instance, could therefore be considered at-risk even in the absence of genetic test information. Another example is Spain, in which the Constitution of 1978 and the General Health Care Act of 1986 guarantee the right to health care.¹⁰¹ Spain’s national legislation does not prohibit the use of predictive genetic tests. Nevertheless, in accordance with the Spanish Constitution, the Oviedo Convention supersedes national legislation and can be applied in Spain, thus protecting individuals from genetic discrimination, as outlined in Article 11 of the Convention. Over a dozen European countries have published Ethical-Legal Papers describing patients’ rights in Europe. Their aim is to contribute to a vaster five-year EU funded program, the EuroGentest, to build adequate frameworks and guidelines in order to achieve harmonization of genetic testing services across Europe.¹⁰²

The Convention has not, however, been signed by some of Europe’s leading countries, such as the United Kingdom and Germany.¹⁰³ In Germany, the government issued a draft legislation in 2004 that would enable employers to perform genetic tests on job candidates in order to identify existing or potential

98. See Nicolás, *supra* note 96, at 106; HERMAN NYS ET AL., PATIENT RIGHTS IN THE EU: DENMARK, EUROPEAN ETHICAL-LEGAL PAPERS NO. 2, at 7 (2007), available at http://www.eurogentest.org/web/files/public/unit4/full_text_Denmark.pdf.

99. Organisation for Economic Co-operation & Development, Regulatory Developments in Genetic Testing in Denmark, http://www.oecd.org/document/19/0,3343,en_2649_34537_2403475_1_1_1_1,00.html (last visited Nov. 11, 2009).

100. See Nys et al., *supra* note 98, at 40.

101. SARAH DEFLOOR ET AL., PATIENT RIGHT IN THE EU: SPAIN, EUROPEAN ETHICAL-LEGAL PAPERS NO. 15, at 6, (2008), available at <http://www.eurogentest.org/web/files/public/unit4/spain.pdf>; Antonio Durán, Juan L. Lara & Michelle van Waveren, *Spain: Health System Review*, HEALTH SYSTEMS TRANSITION, Issue 4, 2006, at 150.

102. Jean-Jacques Cassiman, *Research Network: EuroGentest – A European Network of Excellence Aimed at Harmonizing Genetic Testing Services*, 13 EUR. J. HUM. GENETICS 1103, 1103 (2005).

103. See Council of Europe, *supra* note 97.

genetic disorders.¹⁰⁴ In the United Kingdom, a Discrimination Law Review was proposed in February 2005 to create a clearer framework on the protection against genetic discrimination, but has not been adopted.¹⁰⁵ Although most European countries do protect individuals from genetic discrimination, the European Group of Science, Ethics and New Technologies released a study in 2003 conducted on behalf of the Institute of Directors revealing that, out of 353 interviewed corporate managers and directors, thirty-four percent were in favor of genetic screening for heart diseases if the employee consented.¹⁰⁶ This figure suggests that many European health systems, traditionally based on universal coverage, might shift their model from a mutualistic paradigm to a more individualized approach, based on genetic risk assessment. With the availability of genetic tools, employers—rather than policymakers—could provoke a shift in health care coverage systems.

Employers' fear is met by the companies' pragmatism: can they take the risk of signing a work contract with an employee whose health is questionable? An employee's health insurance represents a significant expense, and the group's premium can increase if an employee becomes seriously ill. In addition to the costs of higher health insurance premiums, employers are also responsible for indirect costs of illness such as the cost of replacing a sick employee. Employers might contemplate using genetic tests to prevent workplace accidents and their associated liabilities through the application of tests to detect altered sleep patterns, allowing them to match an individual's sleep profile to the nature of his work.¹⁰⁷ Another issue could arise from identification of a rare but debilitating disease. Could an applicant for auto insurance be turned down on the basis of his genetic profile, despite the fact that the applicant has never had the slightest accident or suffered from any of the disease symptoms?¹⁰⁸ All these examples illustrate the potential of using genetic testing to assess risk factors for conditions that have not yet (and may never) appear. Under what circumstances, if any, should increased risk factors be used to affect current employment?

International organizations have also expressed concerns about the misuse of genetic testing data. For example, the United Nations Educational, Scientific and

104. See Barclay & Markel, *supra* note 22, at 958.

105. DEP'T. FOR CMTYS. & LOCAL GOV'T., DISCRIMINATION LAW REVIEW: A FRAMEWORK FOR FAIRNESS: PROPOSALS FOR A SINGLE EQUALITY BILL FOR GREAT BRITAIN 3 (2007), available at <http://www.communities.gov.uk/documents/corporate/pdf/325332.pdf>.

106. EUR. GROUP ON ETHICS IN SCI. & NEW TECHS., ETHICAL ASPECTS OF GENETIC TESTING IN THE WORKPLACE 9 (2003), http://ec.europa.eu/european_group_ethics/docs/avis18_en.pdf.

107. Sarah-Jane Paine, Philippa H. Gander & Noemie Travier, *The Epidemiology of Morningness/Eveningness: Influence of Age, Gender, Ethnicity, and Socioeconomic Factors in Adults (30-49 Years)*, 21 J. BIOLOGICAL RHYTHMS 68, 69-76 (2006).

108. Paul R. Billings et al., *Discrimination as a Consequence of Genetic Testing*, 50 AM. J. HUM. GENETICS 476, 478 (1992).

Cultural Organization (UNESCO) enacted a declaration on the protection of genetic data to protect employees from discrimination on the basis of genetic tests.¹⁰⁹ The aim of this declaration is “to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data.”¹¹⁰ However, this declaration is not a convention and, as such, the United Nations cannot sanction member states that infringe the declaration’s ethical principles.

In order to strengthen existing state laws on genetic discrimination, the U.S. Congress enacted the Genetic Information Nondiscrimination Act (GINA) in May 2008.¹¹¹ Following thirteen years of deliberations and revisions, this act was put forward by then-Senator Barack Obama and subsequently unanimously adopted by both houses of Congress. GINA prohibits the use of genetic tests by recruiters and insurers.¹¹² Companies using genetic tests to recruit, fire, or re-grade employees face fines of up to \$500,000.¹¹³ Despite the law’s intended goal of protecting employees, there is concern regarding the bill’s effectiveness. Enforcement will remain difficult because a dismissed worker cannot easily prove that he or she is a victim of genetic discrimination because of loopholes in the law. For instance, a company can request a medical history of the employee’s family and incidentally discover family genetic disorders.¹¹⁴ A company can also include genetic tests in health programs it offers its employees and access the results.¹¹⁵ How then can one prove that a company has used this genetic information to re-grade or lay someone off?

B. Implications for Health Insurers

Personalized medicine is becoming the central argument to convince people to disclose their genetic information for medico-economic reasons.¹¹⁶ The GINA regulations prohibit discrimination on the basis of genetic information by insurance companies.¹¹⁷ However, refusing to take a genetic test could be

109. International Declaration on Human Genetic Data, G.A. Res 32/15, art. 14(a), U.N. ESCO, 20th Sess. (Oct. 16, 2003).

110. *Id.* at art. 1(a).

111. Kathy L. Hudson, M.K. Holohan & Francis S. Collins, *Keeping Pace with the Times—The Genetic Information Nondiscrimination Act of 2008*, 358 NEW ENG. J. MED. 2661, 2661 (2008).

112. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, §§ 101(a), 202(a), 122 Stat. 881, 883, 907 (to be codified at 29 U.S.C. § 1182(b) and 42 U.S.C. § 2000ff-1).

113. *Id.* § 101(e), 122 Stat. 881, 886 (to be codified at 29 U.S.C. § 1132).

114. *Id.* § 202(b)(1), 122 Stat. 881, 907 (to be codified at 42 U.S.C. § 2000ff-1).

115. *Id.* § 202(b)(2)(A), 122 Stat. 881, 907 (to be codified at 42 U.S.C. § 2000ff-1).

116. P.A. Deverka, T. Doksum & R.J. Carlson, *Integrating Molecular Medicine into the US Health-Care System: Opportunities, Barriers, and Policy Challenges*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 427, 427 (2007).

117. Genetic Information Nondiscrimination Act of 2008.

interpreted by the insurer as a refusal of transparency, one that exposes the patient to medical risks and the insurer to excess health costs.¹¹⁸ Although preserved, the right to refuse disclosure of genetic information is facing growing economic pressure.¹¹⁹ For instance, in 2000, genetic testing manufacturer Myriad entered into a multi-year agreement with Kaiser Permanente, a managed care organization, to provide its breast and ovarian cancer genetic tests to Kaiser Permanente's customers.¹²⁰ With this agreement, Kaiser joined well-known insurers, health maintenance organizations (HMOs), and managed care organizations (MCOs) such as Aetna, US Healthcare, and Empire Blue Cross and Blue Shield, all of which cover genetic diagnostic services for their members.¹²¹ Some patients might regard this information disclosure as an opportunity to benefit from preventive treatment earlier and at a lower cost than they would without the test.¹²² Others, however, might refrain from taking the test for fear of losing health coverage. Two costs are at stake: the cost of the additional premium the policyholder would have to pay in case of a genetic disorder, and the cost of the treatment of this disorder if not covered by the insurance policy. Although difficult to assess, this economic dilemma could induce an asymmetry of information between policyholders and insurance companies.¹²³ In such cases, a policyholder could be denied health coverage altogether if the withheld information eventually becomes uncovered, despite having paid regular premiums.

A second form of asymmetry concerns moral hazard. An individual who is protected by an insurance policy may behave in a less prudent way than an individual who is not covered for certain risks. Hypothetically, insured individuals predisposed to type 2 diabetes might unconsciously neglect an appropriate diet if they pay for comprehensive health care coverage and receive adequate treatment. In such a case, insured and insurer have the same level of information; however, the policyholder's insurance coverage may reduce his incentive to avoid risky behavior. Hence, the level of genetic information the

118. Bartha Maria Knoppers, Béatrice Godard & Yann Joly, *A Comparative International Overview*, in *GENETICS AND LIFE INSURANCE: MEDICAL UNDERWRITING AND SOCIAL POLICY* 173, 183 (Mark A. Rothstein ed., 2004).

119. William Nowlan, *A Rational View of Insurance and Genetic Discrimination*, 297 *SCIENCE* 195, 195 (2002).

120. Judy Mouchawar et al., *Impact of Direct-to-Consumer Advertising for Hereditary Breast Cancer Testing on Genetic Services at a Managed Care Organization: A Naturally-Occurring Experiment*, 7 *GENETICS MED.* 191, 191 (2005).

121. *Myriad Genetics Signs Agreement with Kaiser Permanente*, 5 *ONCOLOGIST* 175, 175 (2000).

122. See Godard et al., *supra* note 79, at 123; Caryn Lerman & Alexandra E. Shields, *Genetic Testing for Cancer Susceptibility: The Promise and the Pitfalls*, 4 *NATURE REV. CANCER* 235, 237 (2004).

123. See Godard et al., *supra* note 79, at 126; see also Hoy & Ruse, *supra* note 68, at 224.

policyholder possesses could have a direct correlation with his insurance status as well as his behavior and lifestyle.

In 2000, the recommendations of the U.K. Genetics and Insurance Committee (GAIC) stated that the genetic test for Huntington's disease was sufficiently reliable and accurate for insurance companies to use the results when assessing applications for life insurance.¹²⁴ Insurers could therefore continue to impose a genetic test for this highly penetrant monogenic disease. However in 2001, the Association of British Insurers (ABI) signed a five-year moratorium with the British government suspending all requests for DNA tests by potential insurers.¹²⁵ This moratorium, which allows customers with adverse genetic test results to obtain significant levels of coverage (up to \$800,000), has been extended to 2014.¹²⁶ Its purpose, prompted by a concern regarding test accuracy, is to preserve consumer access to insurance as well as insurer access to information on the health risks of potential customers.

British insurers cannot require their clients to undergo genetic tests before offering an insurance policy, but they can require that prior genetic test results be disclosed before agreeing to cover an individual.¹²⁷ The objective is to reduce the asymmetry of information between the client and the insurer, a situation that can lead to a phenomenon known as "adverse selection."¹²⁸ Again, insurers encourage customer transparency through premium incentives and test reimbursement.

Patients can also take advantage of asymmetric knowledge regarding genetic risk. It has been observed that individuals who know that they are carriers of Alzheimer's disease genetic predispositions are six times more likely to modify their insurance.¹²⁹ The insured knows of a health risk that the insurer does not, therefore the premium does not reflect true genetic information. Hence, asymmetric information regarding genetic risk affects both parties to a contract.

124. Press Release, U.K. Dep't of Health, Genetics and Insurance Committee, Huntington's Disease (Oct. 2000), available at http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_087703.pdf.

125. Susan Mayor, *UK Insurers Agree Five Year Ban on Using Genetic Tests*, 323 BRIT. MED. J. 1021, 1021 (2001).

126. See generally U.K. DEP'T OF HEALTH, CONCORDAT AND MORATORIUM ON GENETICS AND INSURANCE 6 (2005) (discussing the extension of the moratorium until November 1, 2011); Sowmiya Moorthie & Carol George, *Moratorium on the Use of Genetic Test Results Extended*, PHG FOUND., June 18, 2008, <http://www.phgfoundation.org/news/4249> (discussing the decision by the ABI to further extend the moratorium to 2014).

127. See U.K. DEP'T OF HEALTH, *supra* note 126, at 3.

128. Katrina Armstrong et al., *Life Insurance and Breast Cancer Risk Assessment: Adverse Selection, Genetic Testing Decisions, and Discrimination*, 120A AM. J. MED. GENETICS 359, 359 (2003).

129. Cathleen D. Zick et al., *Genetic Testing for Alzheimer's Disease and Its Impact on Insurance Purchasing Behavior*, 24 HEALTH AFF. 483, 487 (2005).

Access to genetic tests may enable insurance companies to substantially reduce the asymmetries of information that threaten their financial viability,¹³⁰ but they are aware that individuals who know they are at high risk are more likely to purchase health insurance.¹³¹

In France, the Belorgey regulation was signed in 2001 between patient associations, insurance companies, banks, and the ministries of health and finance. This convention was designed to guarantee patients the ability to take out a bank loan despite serious health risks.¹³² In practice, however, this convention was not uniformly adhered to by banks and insurers, and in 2004, out of 35,000 cancer survivors using this procedure, 9000 did not obtain the loan for which they had applied.¹³³ Failing, therefore, to fulfill its objectives, the regulation was replaced in 2007 by the *s'Assurer et Emprunter avec un Risque Aggravé de Santé* or AERAS convention.¹³⁴ The strengthened regulation increases the chances for a person presenting a health risk to obtain a bank loan. For instance, the cut-off age for eligibility is increased to 70 years, the maximum housing loan is increased to €300,000 (\$450,000), and tighter deadlines are imposed to process loan applications.¹³⁵ Additionally, a mediator can be designated to verify whether the AERAS procedure is adequately implemented to prevent any form of discrimination against the applicant. The need to strengthen the Belorgey convention just six years following its enactment is illustrative. Such revisions, additional regulations, and moratoria underline the difficulties lawmakers face in using genetic tests in the actuarial sector. In practice, the mandate of UNESCO's International Committee for Bioethics—that “no person should be the object of discrimination based on their genetic characteristics”¹³⁶—proves to be fragile.

Discrimination dilemmas arise in two ways. On the one hand, an individual has the ability to go to court to defend his rights if he feels he is a victim of discrimination. On the other hand, an unborn fetus does not have the legal or

130. See Godard et al., *supra* note 79, at 126.

131. Knoppers et al., *supra* note 118, at 174.

132. Convention Belorgey, Visant à améliorer l'accès à l'emprunt et à l'assurance des personnes présentant un risque de santé aggrave [Aiming to Improve Access to Loans and Insurance for Individuals with High Health Risks], Sept. 19, 2001, <http://www.convention-belorgey-informations.fr/texte-officiel.php?page=2>.

133. Nicolas Tilmant Tatischeff, *La nouvelle convention AERAS*, INSTITUT DES ASSURANCES DE BORDEAUX, Dec. 3, 2007, <http://www.iab-abtesa.com/index.php?page=article&id=42>.

134. Law No. 2007-131 of Jan. 31, 2007, Journal Officiel de la République Française [J.O.] [Official Gazette of France], Feb. 1, 2007, p. 1945.

135. AERAS CONVENTION Tit. IV, at 12, (July 6, 2006), available at http://www.aeras-infos.fr/sections/les_documents_offici/la_convention/texte_de_la_conventi/downloadFile/file/convention_aeras.pdf?nocache=1167154356.09.

136. The Universal Declaration on the Human Genome and Human Rights, U.N. ESCO Res. 16, at 43, U.N. Doc. C/RES/29/16 (Nov. 11, 1997).

physical capacity to do the same. The market for genetic tests, applied to birth screening for the purpose of primary prevention, could soon attract the interest of health care providers, manufacturers, and insurers looking to minimize prospects of litigation.

III. THE EXPANSION OF GENETIC TESTING TO EMBRYO SELECTION

A. Preimplantation Genetic Diagnosis

During the next decade, health care professionals will increasingly become involved in discussing reproductive options when providing genetic testing to patients and their families affected by hereditary cancer syndromes. This trend will be driven by several factors, including the expanding clinical availability of genetic tests that predict risks for many conditions, including those for pediatric and adult cancers. In vitro Fertilization (IVF), the process of combining egg and sperm to create an embryo outside of the body, and genetic testing are converging technologies. Already, substantial literature exists regarding the use of Preimplantation Genetic Diagnosis (PGD) for prenatal diagnosis.¹³⁷ Following IVF, this technology consists of extracting a single cell from the embryo and testing it for pathogenic genetic mutations. Only embryos not carrying these mutations are implanted into the womb.¹³⁸

By 2005, about 5,000 PGD applied to IVF cycles were reported worldwide.¹³⁹ Depending on which of the models is chosen, the cumulative cost of PGD and IVF for single-gene disorders can be as high as \$12,000 to \$15,000 per cycle.¹⁴⁰ The availability of PGD is increasing as hundreds of IVF centers in the United States and worldwide acquire expertise in the micromanipulation of embryos and gain access to laboratories to which specimens can be sent for single-cell genotyping.¹⁴¹ Because of the growing number of IVF cycles associated with PGD, extensive genetic data collection might soon help define a large-enough distribution of cases to permit statistically significant stratification

137. Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL'Y L. & ETHICS 283, 290 (2008).

138. Caroline Mackie Ogilvie, Peter R. Braude & Paul N. Scriven, *Preimplantation Genetic Diagnosis—An Overview*, 53 J. HISTOCHEMISTRY & CYTOCHEMISTRY 255, 255 (2005).

139. Yury Verlinsky & Anver Kuliev, *Preimplantation Genetic Diagnosis and Its Role in Assisted Reproduction Technology*, in TEXTBOOK OF IN VITRO FERTILIZATION AND ASSISTED REPRODUCTION: THE BOURN HALL GUIDE TO CLINICAL AND LABORATORY PRACTICE 453, 458 (Peter R. Brinsden ed., 3d ed. 2005).

140. Joe Leigh Simpson, Sandra A. Carson & Pauline Cisneros, *Preimplantation Genetic Diagnosis (PGD) for Heritable Neoplasia*, 34 J. NAT'L CANCER INST. MONOGRAPHS 87, 89 (2005).

141. Debora Spar, *Where Babies Come From: Supply and Demand in an Infant Marketplace*, HARV. BUS. REV., Feb. 2006, at 133, 133-40, 142-43, 166.

of genetic profiles in the population.¹⁴²

This genetic stratification might have important policy implications for health care systems.¹⁴³ Will health authorities cover health care expenditures for deleterious genotypes depending on the extent of genetic screening that was undertaken before birth? Will couples seeking assisted reproduction be advised to test their embryos before having children? As for couples with genotypes carrying few deleterious mutations, will parents be encouraged to reproduce in order to spread healthy chromosomes throughout the population?

B. The U.K. Experience

In 2006, a British couple hesitated to procreate because the husband carried a genetic predisposition to a rare and incurable disease: neurofibromatosis type 1. In 2007, the couple resorted to IVF and PGD to select their future child's genotype.¹⁴⁴ To avoid covering a lifetime of expensive treatment, the National Health Service agreed to compensate the parents £7,000 (\$12,000) for having taken the precaution of birth screening.¹⁴⁵ Government coverage of PGD is not limited to incurable genetic disorders. In the spring of 2006, the United Kingdom's regulatory authority, the Human Fertilisation and Embryology Authority (HFEA),¹⁴⁶ approved PGD for breast cancer mutation carriers. The HFEA periodically updates the list of genetic diseases for which preimplantation diagnosis is licensed by the HFEA, without indicating whether the full cost is covered by the National Health Service (NHS).¹⁴⁷ The six public and private centers that offer PGD in the UK are licensed by the HFEA.¹⁴⁸ Twenty-nine diseases were listed by the HFEA as being approved for PGD in 2004. In 2009,

142. Lon R. Cardon & Lyle J. Palmer, *Population Stratification and Spurious Allelic Association*, 361 LANCET 598, 598 (2003).

143. Grégory Katz-Bénichou, *The Advent of the Genetic Quotient*, 49 DIOGENES 20, 25 (2002).

144. C. Spits et al., *Preimplantation Genetic Diagnosis for Neurofibromatosis Type 1*, 11 MOLECULAR HUM. REPROD. 381, 386 (2005).

145. Rupert Neate, *Boy Born Free of Potentially Deadly Gene Thanks to IVF Screening*, TELEGRAPH (London), June 4, 2008, <http://www.telegraph.co.uk/new/2074753/Boy-born-free-of-potentially-deadly-gene-thanks-to-IVF-screening.html>.

146. The Human Fertilization and Embryology Authority (HFEA) was created by an Act of Parliament in 1990 to regulate the clinical practice of assisted conception and the use of human embryos. See HUMAN FERTILISATION & EMBRYOLOGY AUTH., ANNUAL REPORT AND ACCOUNTS—2008/09, at 8 (2009), available at http://www.hfea.gov.uk/docs/19th_HFEA_Annual_report.pdf.

147. HUMAN FERTILISATION & EMBRYOLOGY AUTH., PREIMPLANTATION GENETIC DIAGNOSIS (PGD): CONDITIONS LICENSED BY THE HFEA 2-3 (2009), http://www.hfea.gov.uk/docs/List_of_PGD_conditions.pdf.

148. U.K. DEP'T OF HEALTH, PREIMPLANTATION GENETIC DIAGNOSIS (PGD)—GUIDING PRINCIPLES FOR COMMISSIONERS OF NHS SERVICES 4 (2002), <http://www.cadasiltrust.org/assets/pdf/PGDNHSGuidelines.pdf>.

this number quadrupled to 116 genetic disorders, including breast, colon, and ovarian cancers, many of which are treatable, poorly penetrant, and late onset diseases (Figure 2).¹⁴⁹ The HFEA table illustrates that, even for treatable disorders, embryo selection with PGD is indicated by the U.K. health authorities. In the case of breast cancer screening, “the first license application to perform PGD for *BRCA1*-linked hereditary breast and ovarian cancer was made in 2007.”¹⁵⁰ In January 2009, the first baby selected through PGD to eliminate embryos carrying an inherited *BRCA* gene mutation was born.¹⁵¹ For some rare diseases, embryo selection seems to be significantly more cost effective than long term expensive therapy. Over the next decades, medico-economic arguments could influence health authorities to adopt an elective, rather than curative, approach to control health care expenditures.¹⁵²

A new phenomenon is occurring with regards to PGD. There has been a small number of cases in which deaf couples have used IVF and PGD to select embryos with the same genetic traits that they themselves have in order to share a common lifestyle with their offspring.¹⁵³ Since 2007, the Human Fertilization and Embryology Act 1990 has been under revision by the U.K. House of Parliament to update the regulation of embryo research and assisted reproduction. The revisions state that it should become illegal to perform PGD and choose to keep an embryo that has a “serious medical condition” when there is the choice of other embryos without such conditions.¹⁵⁴ In addition to this, it may become illegal for an adult with genes for a “serious medical condition” to donate eggs or sperm for use in IVF when there are other available donors without genetic defects. The description that accompanies the bill includes genetically-induced deafness as one example of a “serious medical condition.” If passed, the legislation would make it illegal for parents using PGD to implant embryos with “deafness” genes if “non-deaf” embryos are available. The bill would also make it illegal for a deaf adult to donate gametes for IVF, even to close relatives.¹⁵⁵

This pending regulation revives the debate over normative reproduction and

149. Human Fertilisation & Embryology Authority, PGD Conditions Licensed by the HFEA, <http://www.hfea.gov.uk/pgd-screening.html> (last visited Nov. 11, 2009).

150. Philippa Brice, *First UK Birth Following PGD for Hereditary Breast Cancer*, PHG FOUND., Jan. 9, 2009, <http://www.phgfoundation.org/news/4445>.

151. *See id.*

152. *See, e.g.*, TROY DUSTER, BACKDOOR TO EUGENICS 53-54 (2d ed. 2003); Ralph Snyderman & Jason Langheier, *Prospective Health Care: The Second Transformation of Medicine*, 7 GENOME BIOLOGY 104 (2006).

153. Matti Häyry, *There Is a Difference Between Selecting a Deaf Embryo and Deafening a Hearing Child*, 30 J. MED. ETHICS 510, 512 (2004).

154. Human Fertilisation and Embryology Act, 2008, c. 22, § 14 (Eng.).

155. David King, *The Human Fertilisation and Embryology Bill 2008: A Commentary*, CTR. FOR GENETICS & SOC’Y, Apr. 15, 2009, <http://www.geneticsandsociety.org/article.php?id=4632>.

the dissemination of genetic traits to future generations. With powerful tools such as genetic tests, should public health authorities continue to invest in treating individuals after birth rather than selecting them before birth?

C. Wrongful Births and Health Economics

Gaucher's disease illustrates the economic implications of using genetic testing in order to minimize health care expenditure through reducing the incidence of catastrophic diseases. This rare genetic disorder is characterized by a lysosomal deficit, which causes a dysfunction of the spleen, liver, lungs, and skeleton.¹⁵⁶ The treatment for Gaucher's disease, which has been commercialized by Genzyme Diagnostics, is an intravenous enzyme replacement therapy that costs on average \$200,000 per year per patient.¹⁵⁷ Genzyme has also commercialized a genetic test that costs around \$800 to detect the embryo's predisposition to this disease. From a utilitarian approach, the cost disparity between prevention and treatment is considerable for health insurers and public health authorities. For families affected by the disease, the cost of treatment alone could justify the systematic diffusion and reimbursement of the genetic test to couples with predispositions.¹⁵⁸ In order to maintain the principle of guaranteeing equal access to health care, treatment reimbursement could be given to those rare cases that the test did not detect (false negatives).

In other cases, false negative tests could lead to wrongful birth litigations. This was illustrated in 2000 with the Perruche case in France. During her pregnancy in 1982, Mrs. Perruche showed symptoms of rubella and was therefore prescribed a diagnostic test. Test results were falsely negative, she did not therefore voluntarily interrupt her pregnancy and she gave birth to a child who developed Gregg's syndrome, or congenital rubella syndrome, which caused the child to have mental and neurological disabilities. She sued her obstetrician for not having been given the possibility to abort and won the trial. She received damages from the obstetrician's insurance company (*Le Sou Médical - Mutuelle d'Assurances du Corps de Santé Français*, MACSF), and subsequently filed a new claim for damages for her disabled son. Although the obstetrician did not cause the disability, he was simply unable to diagnose the rubella that caused it. The French final court of appeal condemned him and the medical laboratory which had performed the test to pay damages of €120,000 (\$180,000) to the Perruche family. This judgment sparked a legal controversy and a national

156. Gregory A. Grabowski, *Gaucher Disease: Lessons from a Decade of Therapy*, 144 J. PEDIATRICS (SUPPLEMENT 1) 15, 15-16 (2004).

157. Shachar Zuckerman et al., *Carrier Screening for Gaucher Disease: Lessons for Low-Penetrance, Treatable Diseases*, 298 JAMA 1281, 1282 (2007).

158. Grégory Katz-Bénichou, *L'inepte et l'inapte*, in CORPS NORMALISÉ, CORPS STIGMATISÉ, CORPS RACIALISÉ 313, 328 (Gilles Boëtsch, Christian Hervé & Jacques J. Rozenberg eds., 2007).

debate: can handicapped persons file suit against and obtain damages from their parents and obstetricians for letting them be born with a disability?¹⁵⁹ The Perruche jurisprudence was an affirmative answer to this question.¹⁶⁰

In 2002, the French parliament passed a law, known as the “*Loi Kouchner*,” overruling this jurisprudence highlighting that the prejudice caused to a child born handicapped cannot be repaired, unless the liability for the handicap is attributable to the physician.¹⁶¹ The law states that in case of non-detection of a fetal disorder, only the parents can claim damages. Within a year following the Perruche case verdict, MACSF monthly premiums for obstetricians increased five-fold (€457 to €2000; \$684 to \$3000).¹⁶² After the law was enforced in 2002, these premiums dropped significantly but nevertheless remained three times higher than prior to the case. In 2005, annual premiums were €10,000 (\$15,000) for gynecologists and €15,000 (\$22,750) for obstetricians.¹⁶³

The risk of wrongful birth damages is setting new standards for obstetricians and their insurance companies, paving the way for widespread adoption of genetic testing for embryo selection.¹⁶⁴ Referring to the Perruche case, one obstetrician confessed that “when in doubt, it is more prudent to discard any suspicious embryo in order to avoid litigation.”¹⁶⁵ In this context, precautionary eugenics would appear to find legal and economic justification, thus reframing the scope and scale of the “baby business.”¹⁶⁶

D. Stakeholders’ Converging Interests

Typically limited to *sterile* couples, IVF is now offered to *fertile* couples.¹⁶⁷ Egg freezing techniques by companies such as Extend Fertility¹⁶⁸ are offering fertile women a chance to take control of their biological clock and, thereby, take

159. DANIELLE MOYSE & NICOLE DIEDERICH, L’IMPACT DE L’ “ARRÊT PERRUCHE” SUR LES ÉCHOGRAPHISTES ET LES GYNÉCOLOGUES OBSTÉTRICIENS 7 (2005), http://www.snude.org/public/2_la_vie_syndicale/7_les_dossiers/pdf/Impact_Perruche2.pdf

160. *See id.* at 8.

161. Law No. 2002-303 of Mar. 4, 2002, Journal Officiel de la République Française [J.O.] [Official Gazette of France], Mar. 5, 2002, p. 4118.

162. GRÉGORY KATZ-BÉNICHOU, LE CHIFFRE DE LA VIE 239 (2002).

163. *See* MOYSE & DIEDERICH, *supra* note 159, at 34.

164. *Cf.* Roger D. Klein & Maurice J. Mahoney, *Medical Legal Issues in Prenatal Diagnosis*, 34 CLINICS PERINATOLOGY 287, 290-95 (2007) (discussing the wrongful birth lawsuits and prenatal testing).

165. Israël Nisand, *La naissance sous condition*, 3 LA LETTRE DE L’ESPACE ÉTHIQUE DE L’AP-HP 18 (2001) (quotation in text translated by author).

166. DEBORA L. SPAR, THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION 99 (2006).

167. *See* Grégory Katz-Bénichou, *Le tamisage des naissances*, CITÉS, Issue 4, 2006, at 83, 92.

168. Extend Fertility, <http://www.extendfertility.com> (last visited Nov. 11, 2009).

advantage of IVF cycles to perform embryo genotyping and birth screening.¹⁶⁹ The spreading use of preimplantation genetic selection results widely from converging interests among different stakeholders:

- 1) IVF clinics are willing to offer a wider range of services to couples, including birth screening;
- 2) Healthcare providers and malpractice insurers are attempting to reduce medico-legal risks and minimize compensation claims in cases of a wrongful birth;
- 3) Genetic test manufacturers and retailers are seeking to increase their sales;
- 4) Parents are keen to pay for new diagnostic technologies in order to optimize their child's genetic heritage; and
- 5) Health authorities are willing to invest in primary prevention to control health expenditures.

The converging interests of these stakeholders may accelerate the adoption of genetic testing for birth screening. Preventative medicine is entering a new era in which the concept of prevention is itself being redefined. Until the end of the twentieth century, primary prevention focused on avoiding the appearance of a disease through control of environmental factors or patient behavior. In the twenty-first century, genetic tests may transform primary prevention to include avoiding the birth of a diseased person altogether.

E. Genetic Testing Applied to Semen Donors

Overarching these ethical concerns are pragmatic considerations applied to artificial reproductive technologies and the genetic selection of sperm donors. For example, a technique known as Intra Cytoplasmic Sperm Injection (ICSI) is used to circumvent male infertility. In most cases of male infertility, the sperm cell is fertile per se, however, it cannot break the female egg membrane due to a genetic mutation inactivating the sperm tail. The ICSI process consists in collecting such a genetically deficient sperm cell, and injecting it mechanically with a micropipette into the female egg. On the one hand, this technique allows infertile males to procreate; on the other hand, it transmits the infertility mutations to the next male generation.¹⁷⁰ Medical scientists have since

169. LIZA MUNDY, EVERYTHING CONCEIVABLE: HOW ASSISTED REPRODUCTION IS CHANGING MEN, WOMEN, AND THE WORLD 6, 319-20 (2007).

170. See, e.g., Jan A.M. Kremer et al., *Does Intracytoplasmic Sperm Injection Lead to a Rise in the Frequency of Microdeletions in the AZFc Region of the Y Chromosome in Future Generations?*, 13 HUM. REPROD. 2808, 2808 (1998); Sherman J. Silber & Sjoerd Repping, *Transmission of Male Infertility to Future Generations: Lessons from the Y Chromosome*, 8 HUM.

recognized that this attempt to eliminate a genetic defect could, in fact, contribute to its dissemination.¹⁷¹

Hence, why not test upstream the genetic profile of the sperm donor, rather than use downstream complex and expensive techniques such as ICSI at each generation?¹⁷² Is it not more cost effective to clear the entire germ line of this genetic mutation once and for all? In other words, why not adopt *germinal decontamination* through genetic donor screening?¹⁷³

The business model of sperm banks today echoes, to some extent, the Nobel Prize sperm bank created in 1980 by Robert Graham in collaboration with and in memory of the biologist Hermann Muller.¹⁷⁴ Set up in California, this bank, known as “The Repository for Germinal Choice,” accepted sperm donations only from Nobel laureates and high IQ individuals.¹⁷⁵ The bank was closed in 1999.¹⁷⁶ Since then, sperm banks, such as the California Sperm Bank, Cryobiology, Xytex and California Cryobank, have developed a thriving and competitive market.¹⁷⁷ Fairfax Cryobank, a subsidiary of the American firm Genetics and IVF Institute, commercializes sperm and eggs with a genetic profile presented as being from “high quality donors.”¹⁷⁸ Pricing for IVF vials varies according to donor profiles: the standard offer, or “family solution,” costs \$175; the “Fairfax” label costs \$235; and the “Fairfax doctorate” costs \$305.¹⁷⁹ The “doctorate” label indicates that the sperm donor holds a Ph.D., a degree considered to be a sign of high intellectual ability. Assuming that intelligence is genetically inherited,¹⁸⁰ the message to parents is evident: for an additional \$130, parents can offer their offspring a superior IQ. Why not pay the high price then, if a Ph.D. is encoded in the sperm’s DNA?

REPROD. UPDATE 217, 217, 223-225 (2002).

171. See David C. Page, Sherman Silber & Laura G. Brown, *Men with Infertility Caused by AZFc Deletion Can Produce Sons by Intracytoplasmic Sperm Injection, But Are Likely To Transmit the Deletion and Infertility*, 14 HUM. REPROD. 1722, 1725 (1999).

172. Grégory Bénichou, *Comment transformer l'humain en sable*, in VERS LA FIN DE L'HOMME, 127, 135 (Christian Hervé & Jacques J. Rozenberg eds., 2006).

173. Cf. Silber & Repping, *supra* note 170, at 225 (discussing how couples must decide for themselves if the likely transmission of infertility is worth the benefit of ICSI treatment).

174. DAVID PLOTZ, *THE GENIUS FACTORY: THE CURIOUS HISTORY OF THE NOBEL PRIZE SPERM BANK* 4, 31-32, 38 (2005).

175. See *id.* at 4.

176. See *id.* at xviii.

177. See *id.* at 173.

178. Fairfax Cryobank, *Why Choose Fairfax Cryobank for Donor Sperm*, <http://www.fairfaxcryobank.com/whychoose.shtml> (last visited Nov. 11, 2009).

179. Fairfax Cryobank, *Fees 2009*, <http://www.fairfaxcryobank.com/fees09.shtml> (last visited Nov. 11, 2009).

180. RICHARD J. HERRNSTEIN & CHARLES MURRAY, *THE BELL CURVE: INTELLIGENCE AND CLASS STRUCTURE IN AMERICAN LIFE* 1, 11-13 (1994).

In its 2009 brochure, Fairfax Cryobank claims that “fewer than 3% actually are accepted as semen donors for Fairfax Cryobank.”¹⁸¹ Donors are selected following screening processes involving a health questionnaire; physical examination; medical, genetic, and infectious disease testing; a semen quality evaluation; and several interviews with staff.¹⁸² Presented as a biological elite, these genetically screened donors are asked to provide their medical history as well as pictures of themselves as children in order to give prospective parents an idea of their future child’s physical appearance.¹⁸³ Customers may also browse among donor physical traits to select height, weight, skin, eye and hair colors, as well as personality traits.¹⁸⁴ The sperm bank business is creating a shift in the way genetic tests are utilized. Originally applied to embryo selection in order to prevent the transmission of medical conditions, genetic tests are now also used to elect and transmit genetic traits to future generations.

For \$2995, parents undergoing IVF can also select their child’s gender through MicroSort, a sperm sorting tool commercialized by the IVF Institute.¹⁸⁵ The technique consists of separating sperm cells carrying the Y and X chromosomes based on their molecular weight.¹⁸⁶ The MicroSort technique appears to be a commercial success in Asia, especially in China where parents must comply with the one child policy. Boys are favored over girls because they can obtain higher earning jobs. Already, demographic studies anticipate that by the end of the twenty-first century, a fifth of the Chinese male population will not be able to find a wife.¹⁸⁷ What will be the result of the widespread use of genetic testing for gender selection?

In India, Dr. Anoop Gupta, medical director of the IVF and Fertility Clinic in New Delhi, reported that hundreds of couples undergoing IVF cycles would be prepared to use the MicroSort test.¹⁸⁸ In India, girls are considered to be an economic burden to their family as they need a dowry to get married. Rather than resorting to euthanasia of newborn girls, parents are willing to invest in the MicroSort technique to maximize their chances of having boys. Although the semen sorting process might reduce euthanasia practices in some countries, it

181. FAIRFAX CRYOBANK, FAIRFAX CRYOBANK: A GIVF CRYOBANK 2 (2009), available at <http://www.fairfaxcryobank.com/pdf/cryobankFolder.pdf>.

182. *See id.* at 2-5.

183. *See id.* at 6-7.

184. Fairfax Cryobank, *supra* note 179.

185. MicroSort, <http://www.microsort.net> (last visited Nov. 11, 2009).

186. Harvey Stern et al., Abstract, *MicroSort® Babies 1994-2003: Preliminary Postnatal Follow-up Results*, 80 FERTILITY & STERILITY (SUPPLEMENT 3) 248, 249 (2003).

187. Gautam N. Allahbadia, *The 50 Million Missing Women*, 19 J. ASSISTED REPROD. & GENETICS 411, 411 (2002).

188. R. Ramachandran, *Inde: la science facilite la sélection sexuelle*, LE COURRIER DE L’UNESCO, Sept. 1999, http://www.unesco.org/courier/1999_09/fr/dossier/intro06.htm.

will probably not prevent sex discrimination at birth but, on the contrary, may contribute to IVF popularity among fertile couples because of the opportunity to select gender.

The principles behind semen sorting are not limited to screening sperm for gender selection; ongoing research attempts to apply similar techniques to women's gametes to screen for competent oocytes.¹⁸⁹ Genetic testing appears to be a useful tool for the discovery of new genes and to provide information on oocyte quality.¹⁹⁰ This technology is helping to improve the selection of healthy eggs and embryos that will result in good pregnancy rates.¹⁹¹ Applied to sperm or oocytes, semen selection might, in the future, improve or even replace embryo selection. On the one hand, germinal screening may sidestep ethical controversies related to the moral status of human embryos and their destruction;¹⁹² on the other hand, it might fuel the debate over normative reproduction and private eugenics.¹⁹³

F. Regulation of Gender Selection and Prenatal Screening

Present throughout the history of mankind, gender selection is met with renewed enthusiasm thanks to the development of powerful genetic tests.¹⁹⁴ Traditional methods, such as sweet or salty diets before and during pregnancy have often been used by parents in the hope that it will influence the outcome of the child's gender. These techniques were successful, but only in fifty percent of cases! Nowadays, genetic technologies such as MicroSort offer parents a ninety-three percent chance of having a girl.¹⁹⁵ However, the current debate over these tests is less about their reliability, but more about the social and ethical implications of sex discrimination.¹⁹⁶ Although many countries have established guidelines for gender selection based on medical reasons, this practice seems more difficult to regulate for non-medical reasons. Indeed, on what basis should

189. Said Assou et al., *The Human Cumulus-Oocyte Complex Gene-Expression Profile*, 21 HUM. REPROD. 1705, 1717 (2006).

190. Melanie Hamel et al., *Identification of Differentially Expressed Markers in Human Follicular Cells Associated with Competent Oocytes*, 23 HUM. REPROD. 1118, 1126 (2008).

191. D. De Neubourg et al., *Single Top Quality Embryo Transfer as a Model for Prediction of Early Pregnancy Outcome*, 19 HUM. REPROD. 1476, 1476 (2004).

192. LEON R. KASS, *LIFE, LIBERTY AND THE DEFENSE OF DIGNITY: THE CHALLENGE OF BIOETHICS* 86-91, 114 (2002).

193. JÜRGEN HABERMAS, *THE FUTURE OF HUMAN NATURE* 96 (2003).

194. Paul Robinson, *Prenatal Screening, Sex Selection and Cloning*, in A COMPANION TO BIOETHICS, 173, 182 (Helga Kuhse & Peter Singer eds., 2001).

195. MicroSort, *Current Results as of January 1, 2008*, <http://www.microsort.net/results.php> (last visited Nov. 11, 2009).

196. HUMAN FERTILISATION & EMBRYOLOGY AUTH., *SEX SELECTION: CHOICE AND RESPONSIBILITY IN HUMAN REPRODUCTION* 3, 22 (2003).

regulators interfere with parents' choices, as long as gender selection is often proposed to sterile and fertile couples in the IVF package in addition to PGD?

In the Oviedo Convention on Human Rights and Biomedicine, the Council of Europe states that "[t]he use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided."¹⁹⁷ Despite the Convention, private companies nevertheless operate in European countries, such as Belgium, to offer parents sperm sorting technologies for gender selection.¹⁹⁸ In the United Kingdom, clinics offering PGD can only operate under a HFEA license.¹⁹⁹ Furthermore, PGD can only be performed for gender selection in order to select embryos that do not carry a serious, inherited, sex-linked disorder.²⁰⁰ However, because sperm sorting does not systematically involve storage of sperm, it does not come under the HFEA jurisdiction. This legal loophole allows private, non-licensed clinics to perform sex selection for non-medical purposes.²⁰¹

In the United States, sperm sorting is proposed in almost every state, and is often associated with prenatal genetic testing procedures. Signature Genomic Laboratories is a private firm in Washington that charges parents \$1850 to use its "Signature PrenatalChip" to test for various genetic disorders.²⁰² By 2008, physicians had sent the company DNA samples of fetuses from 380 women in order to have them analyzed for the presence of over seventy genetic disorders, including mental retardation, physical malformation, and health and behavioral problems.²⁰³ A federally funded study to evaluate prenatal genetic screening has been conducted in 4000 pregnancies.²⁰⁴ Until now distinctive approaches, prenatal testing and neonatal screening are bound to converge in a fully integrated preventative approach. Why then should parents and obstetricians wait until birth to diagnose genetic disorders that could have been detected at an embryonic stage through genomic profiling?²⁰⁵

197. See Council of Europe, *supra* note 97, at 5.

198. MicroSort, Physician Collaborators, <http://microsort.net/searchcollab.php#BELG> (last visited Nov. 11, 2009).

199. Nadja Kanellopoulou, *Sex Selection: Options for Regulations*, 1 SCRIPT-ED 218, 218 (2004).

200. See *id.* at 219; HUMAN FERTILISATION & EMBRYOLOGY AUTH., *supra* note 196, at 7.

201. See Kanellopoulou, *supra* note 199, at 219.

202. PRESIDENT'S COUNCIL ON BIOETHICS, *THE CHANGING MORAL FOCUS OF NEWBORN SCREENING* 80 (2008).

203. See *id.* at 80-81.

204. Bridget M. Kuehn, *Prenatal Genome Testing Sparks Debate*, 300 JAMA 1637, 1637 (2008); Rob Stein, *Fresh Hopes and Concerns as Fetal DNA Tests Advance*, WASH. POST, Oct. 26, 2008, at A1.

205. See PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 202, at 80.

The President's Council on Bioethics 2008 report on newborn screening²⁰⁶ reaffirms the essential validity and relevance of the Wilson-Jungner screening criteria adopted by the World Health Organization in 1968.²⁰⁷ Among these criteria, "[t]he condition sought should be an important health problem" and "[t]here should be an accepted treatment for patients with recognized disease."²⁰⁸ The President's Council on Bioethics also rejects "any simple application of the technological imperative, i.e., the view that screening for a disorder is justified by the mere fact that it is detectable . . . even if the disorder is poorly understood and has no established treatment."²⁰⁹

In the midst of this complex and evolving regulatory framework, genomic tools could lead health systems from a curative approach to a predictive and preventative model. Health care practitioners – particularly obstetricians and oncologists – may soon find themselves at the leading edge of the application of assisted reproductive technologies for families affected by genetic disorders such as cancer.²¹⁰ Indeed, physicians might be increasingly mindful of informing the patient and/or family members regarding hereditary cancer risks. They might also more frequently be subject to liability for wrongful birth, resulting from their perceived failure to inform their patients of the possible application of reproductive technologies.²¹¹ These trends raise central challenges for policymakers, particularly due to the difference of pace between the fast online commercialization of genetic tests and the lengthy adoption of regulatory procedures meant to frame their distribution.

IV. EVOLUTION OF REGULATORY PROCEDURES FOR THE COMMERCIALIZATION OF GENETIC TESTS

A. U.S. National Regulation

Reports on the regulatory framework for genetic tests highlight a pressing need for tougher regulation and clearer guidelines²¹² to assess test sensitivity,

206. *See id.*

207. *Id.*; see J.M.G. WILSON & G. JUNGNER, PRINCIPLES AND PRACTICE OF SCREENING FOR DISEASE (1968).

208. PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 202, at 22.

209. *See id.* at 106.

210. *See* Susan L. Crockin, *Legal Issues Related to Parenthood After Cancer*, 34 J. NAT'L CANCER INST. MONOGRAPHS 111 (2005).

211. GENETIC & PUB. POLICY CTR., REPRODUCTIVE GENETIC TESTING: ISSUES AND OPTIONS FOR POLICYMAKERS 38-39 (2004), *available at* <http://www.dnapolicy.org/images/reportpdfs/ReproGenTestIssuesOptions.pdf>.

212. *See* GAIL H. JAVITT & KATHY HUDSON, PUBLIC HEALTH AT RISK: FAILURES IN OVERSIGHT OF GENETIC TESTING LABORATORIES 19 (2006), *available at* <http://www.dnapolicy.org/images/reportpdfs/PublicHealthAtRiskFinalWithCover.pdf>.

specificity, and reliability.²¹³ Within the U.S. Department of Health and Human Services, agencies that oversee genetic testing are diffuse. They include the Centers for Medicare and Medicaid Services, the Food and Drug Administration (FDA), the Centers for Disease Control, and the Office of Human Research Protections. These different regulatory bodies are working towards defining and setting quality standards for genetic testing, including implementing the Clinical Laboratory Improvement Amendments (CLIA) of 1988, which aim to “strengthen federal oversight of clinical laboratories to assure that the test results are accurate and reliable.”²¹⁴

Early in their history in the United States, the speed with which diagnostic genetics tests developed resulted in limited oversight. Regulation depended largely on whether a laboratory used its own reagents or a manufacturer’s test kit to perform genetic tests. The first regulations came about in 1998 with the analyte-specific reagent rule that allowed only physicians and certified laboratories access to reagents to ensure their quality and safety.²¹⁵ In order to circumvent regulatory constraints and access the market more rapidly, some test manufacturers began to produce “home-brew” tests to evade accreditation procedures.²¹⁶ “Home-brews” are genetic tests developed in-house by certified laboratories with approved reagents, rather than by non-accredited corporations, and they are marketed to consumers or other companies. The FDA, according to the analyte-specific reagent rule, regulates only the reagents that compose the home-brew test, but does not regulate how reagents are assembled to produce the test.²¹⁷ Additionally, CLIA does not require laboratories to demonstrate the clinical validity of their home-brews. Furthermore, CLIA prohibits the Centers for Medicare and Medicaid Services from giving either prospective review or pre- or post-market approval of new tests.²¹⁸ Test kits, on the other hand, are regulated by the FDA as in vitro diagnostic devices. Out of the 1100 genetic tests commercially available on the market in 2006, less than a dozen were subject to FDA oversight.²¹⁹

213. “Genetic tests have varying degrees of *sensitivity* (does the test find the allele(s) it was designed to find or does it produce ‘false negatives’?), *specificity* (does the test register only the allele(s) it was designed to find, or does it produce ‘false positives’?), and *reliability* (will the same test produce the same results at different times and in different laboratories?).” Goven, *supra* note 88, at 5.

214. JAVITT & HUDSON, *supra* note 212, at 7 (citing H.R. REP. NO. 100-899 (1988)).

215. WILLIAM B. COLEMAN & GREGORY J. TSONGALIS, *MOLECULAR DIAGNOSTICS: FOR THE CLINICAL LABORATORIAN* 248 (2006).

216. Gail H. Javitt & Kathy Hudson, *Federal Regulation of Genetic Testing Neglect*, 22 *ISSUES SCI. & TECH.* 59, 61 (2006).

217. Steven Gutman, *The Role of Food and Drug Administration Regulation of In vitro Diagnostic Devices—Applications to Genetics Testing*, 45 *CLINICAL CHEMISTRY* 746, 748 (1999).

218. JAVITT & HUDSON, *supra* note 212, at 10.

219. AUDREY HUANG, *GENETICS & PUB. POL’Y CTR., WHO REGULATES GENETIC TESTS?*

Companies also attempt to evade CLIA and FDA regulations through a variety of other means. Some testing laboratories present test results to their customers as “data” and not “diagnoses” in order to prevent any litigation on test reliability.²²⁰ Others sell their tests on the Internet in order to bypass physicians’ prescriptions, reach customers directly, and widen their market.²²¹

Definitions

- A *market approved genetic test* is validated in the United States by the FDA’s Pre-Market Notification (PMN or 510k).²²² In the EU, a market approved genetic test must comply with the directive on In Vitro Diagnostic Medical Devices (Directive 98/79/EC or IVD Directive). Introduced in 2003, this directive is implemented by health authorities in each EU member state. Approved medical devices must bear the CE mark.²²³
- *Test kits* are ready-to-use genetic tests assembled by a laboratory and sold to another laboratory, distributor, or customer.²²⁴
- A *home-brew test* is developed in-house by laboratories and marketed as a clinical laboratory service.²²⁵ Neither the FDA nor the European Union oversees home brew tests. However, home brew test ingredients - or analyte specific reagents (ASRs) - are regulated in the United States by the FDA, under the Clinical Laboratory Improvement Amendments (CLIA),²²⁶ and by the IVD Directive in the EU.²²⁷

(2008), http://www.dnapolicy.org/images/issuebriefpdfs/Who_Regulates_Genetic_Tests_Issue_Brief.pdf.

220. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF: CLASS II SPECIAL CONTROLS GUIDANCE DOCUMENT: DRUG METABOLIZING ENZYME GENOTYPING SYSTEM (2005), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071085.pdf>; *FDA to Regulate New Types of ‘Home Brew’ DNA Tests*, 27 NAT’L INTELLIGENCE REP. 4 (2006).

221. See Sarah E. Gollust, Benjamin S. Wilfond & Sara Chandros Hull, *Direct-to-Consumer Sales of Genetic Services on the Internet*, 5 GENETICS MED. 332, 336 (2003); Gollust et al., *supra* note 42, at 1762.

222. U.S. Food and Drug Administration, Medical Devices 510(k) Clearances Overview, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm> (last visited Nov. 11, 2009).

223. Council Directive, 98/79, 1998 O.J. (L 331) 4 (EC).

224. AUDREY HUANG, GENETICS & PUB. POL’Y CTR., FDA REGULATION OF GENETIC TESTS 1 (2007), http://www.dnapolicy.org/images/issuebriefpdfs/FDA_Regulation_of_Genetic_Test_Issue_Brief.pdf.

225. National Human Genome Research Institute, FDA Issues Guidance On “Home Brew” and In Vitro Tests, <http://www.genome.gov/19518345> (last visited Nov. 11, 2009).

226. U.S. Food and Drug Administration, Clinical Laboratory Improvement Amendments (CLIA), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>

In 2000, the Secretary's advisory committee on genetic testing recommended that the FDA oversee all genetic tests, but the FDA decided not to exercise its authority.²²⁸ Industry involved in the field of genetic testing feared that regulation would stifle innovation and lead to high costs.²²⁹ In this patchy regulatory framework, could the FDA risk being held accountable for not protecting the population from potentially inaccurate medical tools?²³⁰

However in 2007, the FDA took a stance on overseeing genetic tests by issuing a draft guidance for industry, clinical laboratories, and FDA staff on the use of In Vitro Diagnostic Multivariate Index Assays (IVDMIAs),²³¹ a type of laboratory-developed test, based on gene expression analysis of a large number of genes,²³² produced by companies such as Clinical Data, CombiMatrix, Dako and Monogram. Nevertheless, these recommendations are not legally binding for test manufacturers and users as stated by the FDA itself: "FDA's guidance documents . . . do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations . . . The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required."²³³

In response to the FDA's minimal oversight, biotech firm Genentech filed a petition with the FDA in December 2008. The firm requested that the FDA oversee and regulate all in vitro diagnostic tests according to the same standards, regardless of their end use.²³⁴ In line with this position, the Dutch firm Agendia

IVDRegulatoryAssistance/ucm124105.htm (last visited Nov. 11, 2009).

227. Commission Communication, 2009 O.J. (C 95) 8 (EC).

228. Ronald A. Salerno & Lawrence J. Lesko, *Pharmacogenomic Data: FDA Voluntary and Required Submission Guidance*, 5 PHARMACOGENOMICS 503, 503-504 (2004).

229. Lawrence J. Lesko et al., *Pharmacogenetics and Pharmacogenomics in Drug Development and Regulatory Decision-Making: Report of the First FDA-PWG-PhRMA-DruSafe Workshop*, 43 J. CLINICAL PHARMACOLOGY 342, 355-56 (2003).

230. See Kathryn A. Phillips & Stephanie L. Van Bebber, *A Systematic Review of Cost-Effectiveness Analysis of Pharmacogenomic Interventions*, 5 PHARMACOGENOMICS 1139, 1141 (2004) (criticizing the FDA approval process for not requiring cost-effectiveness analysis of pharmacogenomic interventions).

231. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, CLINICAL LABORATORIES, AND FDA STAFF: IN VITRO DIAGNOSTIC MULTIVARIATE INDEX ASSAYS 2-3 (2007), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071455.pdf>.

232. Kikuya Kato, *Algorithm for In vitro Diagnostic Multivariate Index Assay*, 16 BREAST CANCER 248, 248 (2009).

233. FOOD & DRUG ADMIN., *supra* note 231, at 3.

234. Shawna Williams, *Genentech Petitions FDA for Level Regulatory Playing Field*, GENETICS & PUB. POLICY CTR. ENEWS, Dec. 2008, http://www.dnapolicy.org/news.english.action=detail&newsletter_id=39&article_id=183.

was the first genetic test manufacturer to have voluntarily submitted a test to the FDA for distribution in the United States.²³⁵ On the other hand, the test manufacturer Clinical Data firmly opposed the suggested regulatory enforcement. The company argued that its tests, such as the PgxPredict used in treatment response, demonstrated clinical value and any additional regulation would only impede innovation.²³⁶ Such a position could, however, imply that any manufacturer of non FDA-cleared genetic tests would be free to make claims of superiority regardless of scientific and clinical evidence. This lack of oversight might also be a concern for physicians who would not have access to clinical data to evaluate the medical implications of new molecular diagnostic tools.

In 2007, the FDA's IVDMA guidelines highlighted the importance of adopting formal regulation. Following Genentech's petition, the FDA announced in December 2008 that it would "explore ways" to collaborate with the Centers for Medicare and Medicaid Services in order to coordinate their roles regarding genetic diagnostic products.²³⁷ This decision is all the more pressing as the lack of an adapted legal framework could eventually become detrimental to patient safety and create an uneven marketplace for test manufacturers.

B. State Regulation

Although U.S. national regulation apparently remains stagnant, some states have taken action in response to consumer complaints about the cost and accuracy of genetic tests. In June 2008, the California Department of Public Health issued letters to thirteen laboratories, including 23andMe, Navigenics, and deCode Genetics, to cease and desist performing genetic testing for California residents until the laboratories meet the requirements specified in state law. A few months before, the New York Department of Public Health sent letters to thirty-one genetic testing companies requiring them to obtain licenses in order to solicit DNA specimens from the state's residents. Similarly, the California letters stated that "genetic test companies must obtain state licenses as clinical laboratories."²³⁸

235. The 'Mammaprint' genetic test is used as a decision tool for breast cancer treatment. See Agendia BV, Food & Drug Admin., 510(k) Submission for Mammaprint Service in the U.S. (filed June 22, 2007), available at http://www.accessdata.fda.gov/cdrh_docs/pdf7/K070675.pdf (displaying the FDA submission by Agendia); see generally Marc J. van de Vijver et al., *A Gene-Expression Signature as a Predictor of Survival in Breast Cancer*, 347 NEW ENG. J. MED. 1999 (2002) (describing the microarray analysis later patented as 'Mammaprint').

236. P. Deroin, *Genentech veut réglementer des tests pharmacogénomiques*, 28 BIOFUTUR 5 (2009).

237. PRICEWATERHOUSECOOPERS, DIAGNOSTIC 2009: MOVING TOWARDS PERSONALISED MEDICINE 42 (2009), available at <http://www.pwc.com/en-GX/pharma-life-sciences/pdf/diagnostics-2009-final.pdf>.

238. Andrew Pollack, *Gene Testing Questioned by Regulators*, N.Y. TIMES, June 26, 2008, at

In order to be granted a California clinical laboratory license, these firms must provide satisfactory validation documentation to verify the test performance specifications of all genetic tests.²³⁹ These companies are under the jurisdiction of the California Business & Professions Code which prohibits offering a clinical laboratory test directly to the consumer without a physician's order.²⁴⁰

Despite regulations by certain states, the strategic location of genomic scanning facilities and online marketing services has allowed manufacturers to cross borders and bypass local laws.²⁴¹ For instance, companies such as Navigenics and 23andMe claim they do not need a local state license since their testing platforms are located outside California and operate under a different state license. Moreover, these companies would be able to sell their tests online to residents in over a dozen states such as Alaska, Kansas, or Texas where no law prohibits individuals from ordering a genetic test.²⁴² On top of this, online customers are recruited globally and ship their tissue samples from abroad, further weakening state regulation.

C. European Regulation

There are disparities among European countries concerning the classification of and access to genetic tests.²⁴³ Some European country regulatory bodies consider analytic validity, how accurately the test identifies the gene or marker, as sufficient to commercialize a test.²⁴⁴ Others believe that the test's clinical validity, the accuracy with which the test predicts or diagnoses a disease, is a more pressing concern.²⁴⁵ The U.K. Genetic Testing Network has developed a "Gene Dossier" in order to evaluate genetic tests and assess which tests should be used by the National Health System.²⁴⁶ In France, the health product authority (AFSSAPS) requires genetic test manufacturers to conform to essential

C1.

239. CAL. BUS. & PROF. CODE § 1265 (West 2003).

240. *See id.* § 1288.

241. *See* Hogarth et al., *supra* note 3, at 171.

242. GENETICS & PUB. POLICY CTR., SURVEY OF DIRECT-TO-CONSUMER TESTING STATUTES AND REGULATIONS 1-14 (2007), *available at* <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf>.

243. OECD, GENETIC TESTING, *supra* note 7, at 12.

244. THE REGULATORY FRAMEWORK FOR GENOMIC TESTS: EVIDENCE TO THE HOUSE OF LORDS SCIENCE AND TECHNOLOGY SUB-COMMITTEE ON GENOMIC MEDICINE 5 (2008), *available at* <http://www.parliament.uk/documents/upload/stGMHogarthandMelzer.pdf>.

245. STUART HOGARTH & DAVID MELZER, THE IVD DIRECTIVE AND GENETIC TESTING: PROBLEMS AND PROPOSALS 16 (2007).

246. Jörg Schmidtke, Hanover Med. Sch., A Comparison of Criteria for Clinical Validity and Utility in Various National and International Frameworks (May 2008).

requirements concerning technical quality.²⁴⁷ Clinical validity and utility of a genetic test are considered to be only marginal criteria for access to the market. A market approval procedure, similar to that applied to drugs, is expected to be implemented for genetic tests in France.²⁴⁸ In an attempt to harmonize regulation in the European Union, Germany's genetic tests indication criteria are regarded as the basis of future guidelines to be endorsed by the European Society of Human Genetics and to be adopted throughout Europe.²⁴⁹

The European Union's In Vitro Diagnostic (IVD) Directive, adopted in 2000, seeks to harmonize national legislation among EU member states in order to improve an individual's level of health protection.²⁵⁰ Although the directive provides a framework for the regulation of IVD product approval, it does not regulate the methods used by manufacturers to achieve the CE-mark²⁵¹ required to commercialize a test developed in-house by laboratories, known as laboratory developed tests (LDTs).

Moreover, in the EU, most genetic tests are classified as "low risk," which means that they are not independently evaluated before reaching the market.²⁵² For example, in the U.K., if a company sells its tests as kits to a laboratory, then these tests are subject to the IVD Directive.²⁵³ On the other hand, if a test is developed by a company and performed in its own laboratory, it is classified as a LDT. The regulatory status of such tests is ambiguous, because some European countries consider them to be medical devices, while others do not. Therefore, not all European countries are obliged to regulate LDTs under the IVD Directive.²⁵⁴ Companies such as 23andMe commercialize LDTs in the European Union but perform the tests in laboratories outside the European Union. These tests do not come under the IVD Directive. Nevertheless, in an attempt to tighten regulation on the use of genetic tests, the U.K. government's advisory body, the

247. CODE DE LA SANTÉ PUBLIQUE art. L.5221 (Daloz 2008).

248. CONSEIL D'ETAT, LA RÉVISION DES LOIS DE BIOÉTHIQUE 70 (2009).

249. See EuroGenTest, Harmonizing Genetic Testing Across Europe, Clinical Utility Gene Cards, <http://www.eurogentest.org/web/info/public/unit3/geneCards.xhtml> (last visited Nov. 11, 2009) (displaying indication criteria for genetic testing for a variety of diseases as originally written by the German Society of Human Genetics).

250. Commission Communication, 2009 O.J. (C 95) (EC).

251. The CE mark is mandatory for products placed in the European Economic Area. This marking certifies that a product has met European Union consumer safety, health and environmental requirements.

252. HUMAN GENETICS COMM'N, MORE GENES DIRECT: A REPORT ON DEVELOPMENTS IN THE AVAILABILITY, MARKETING AND REGULATION OF GENETIC TESTS SUPPLIED DIRECTLY TO THE PUBLIC (2007), available at <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/More%20Genes%20Direct.pdf>.

253. NAT'L INST. STANDARDS & TECH., THE IN VITRO DIAGNOSTICS DIRECTIVE (1998), available at <http://ts.nist.gov/Standards/Global/upload/ivdmd-guide-817.pdf>.

254. See THE REGULATORY FRAMEWORK FOR GENOMIC TESTS, *supra* note 244.

Human Genetics Commission, has called for a new system of regulation, particularly for non-medical “lifestyle” genetic tests. Lifestyle genetic tests are typically over-the-counter diagnostic kits that claim to identify a person’s chances of developing conditions such as obesity, heart disease or even osteoporosis. Depending on test results, health-conscious consumers will adapt their lifestyle to reduce the risk of onset of an illness.²⁵⁵ In Germany, a new law was passed in 2009 to significantly limit the use of direct-to-consumer genetic tests, such as paternity tests.²⁵⁶

These persistent disparities in European regulation of genetic tests are cause for concern. This situation offers the public little confidence that regulatory bodies are capable of adequately controlling this developing market.²⁵⁷ In response, the Global Harmonization Task Force, which includes the European Union, the United States, Canada, Australia, and Japan, is actively following the developments in IVD regulation in order to achieve greater uniformity between national medical device regulatory systems.²⁵⁸ In the EU, the enforcement of the Directive 2007/47/EC, which will become mandatory in March 2010, will contribute to harmonizing the classification and use of medical devices.²⁵⁹

On an international scale, in response to this lack of clear premarket approval for genetic tests, both the FDA and the European Medicines Agency (EMA) issued guidance on Voluntary Genomic Data Submissions in 2006. This initiative is a concerted effort to regulate the outcome of genetic testing and to bridge technologies in an attempt to fill the regulatory gaps associated with genetic tests.²⁶⁰ However, because submissions are voluntary, data are not consistently collected and regulatory agencies are still a long way from overseeing the entire genetic testing value chain.

CONCLUSION

The growing availability of genetic tests has a number of implications for public health. In this paper, we have analyzed four interconnected issues: (i) patient access to online genetic services and its impact on medical practices; (ii) the disclosure of genetic information to health insurers and the risk of

255. Human Genetics Commission, HGC Calls for Regulation of Direct-to-Public Tests (Dec. 4, 2007), http://www.hgc.gov.uk/Client/news_item.asp?NewsId=83.

256. Caroline Wright, *Ban on Direct-to-Consumer Genetic Tests in Germany*, PHG FOUND., Apr. 28, 2009, <http://www.phgfoundation.org/news/4562>.

257. Jane Kaye, *The Regulation of Direct-to-Consumer Genetic Tests*, 17(R2) HUM. MOLECULAR GENETICS R180, R180 (2008).

258. Global Harmonization Task Force, <http://www.ghtf.org> (last visited Nov. 11, 2009).

259. Council Directive 2007/47, 2007 O.J. (L 247) 21-22 (EC).

260. Michael S. Orr et al., *The Experience with Voluntary Genomic Data Submissions at the FDA and a Vision for the Future of the Voluntary Data Submission Program*, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 294, 294 (2007).

discrimination; (iii) the expansion of genetic testing for embryo selection and the risk of liberal eugenics; and (iv) the adoption of adequate regulation to ensure quality standards for test commercialization.

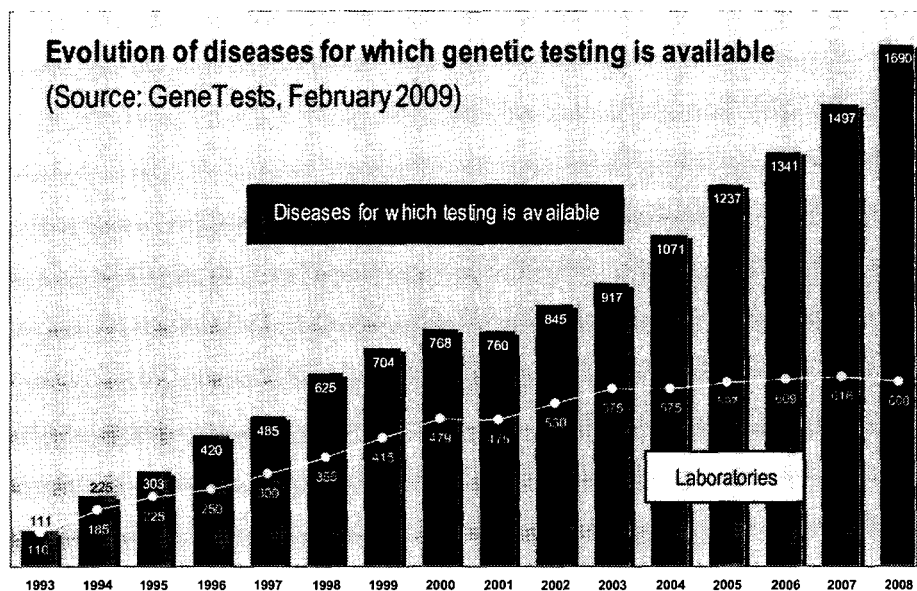
Access to online genetic services has, on the one hand, empowered patients to become more proactive in the management of their health. On the other hand, these services often bypass physicians' prescriptions and expertise to interpret genetic information. Dilemmas arise from this shift in the patient-physician relationship. If genetic transparency provides a chance for prevention, does lack of disclosure from one family member hinder adequate treatment for another? Although there is no consensus on this debate, fundamentally, the underlying ethical dilemma that policymakers face is assessing whether the harm due to failure of disclosure outweighs the harm that may be caused by disclosure.

The tension between confidentiality and transparency is also related to health insurance. Indeed, the fear of genetic discrimination dissuades some patients from using genetic tests, thus depriving themselves of appropriate treatment. In order to avoid genetic information impinging on public freedom, most European countries adopted the Oviedo Convention in 1997 and, more recently, the U.S. Congress passed the Genetic Information Nondiscrimination Act in 2008. Both statutes seek to protect individuals from genetic discrimination by insurance companies. However, in some cases outlined in these laws, insurers and employers might still find roundabout ways of discriminating on the basis of genetic information. Furthermore, refusing to take a genetic test could be interpreted by the insurer as a refusal of transparency, exposing the patient to medical risks and the insurer to excess health costs. Although preserved, the right to *not* disclose genetic information is facing growing economic pressure.

Risks of genetic discrimination do not affect adults alone, they also concern human embryos. The convergence of reproductive technologies (IVF) and predictive technologies (PGD) revives the debate over normative reproduction and the dissemination of genetic traits to future generations. The risk of wrongful birth damages is setting new standards for obstetricians and their insurance companies, paving the way for the widespread adoption of genetic testing for embryo selection. With powerful tools such as genetic tests, should public health continue to invest in treating individuals after birth rather than selecting them before birth? The converging interests of parents, IVF clinics, test manufacturers, health care professionals, and health authorities may further accelerate the adoption of genetic testing for birth screening, with medico-economic justifications.

Beyond ethical challenges related to liberal eugenics, policymakers are confronted with other regulatory issues, in particular the adoption of quality standards for test commercialization. National and international regulation of test approvals and services has developed erratically, creating gaps on a local scale. Both the United States and the EU are striving to harmonize their procedures for

test commercialization in order to guarantee the quality, validity, and utility of diagnostic tools. This issue is becoming all the more pressing due to the growing frequency of genetic services operating beyond borders, at the crossroads of different legal and health care systems. Furthermore, the digitization of genetic information and the dematerialization of medical data reinforce the need for international harmonization. However, regulation alone cannot cope with all the present challenges. The education of health care professionals as gatekeepers is undoubtedly central in order for patients and society to reap the medical benefits of this promising genetic era.

FIGURE 1²⁶¹

261. National Center for Biotechnology Information, GeneTests: Growth of Laboratory Directory (Feb. 2009), <http://www.ncbi.nlm.nih.gov/projects/GeneTests/static/whatsnew/labdirgrowth.shtml>.

FIGURE 2²⁶²

Conditions Licensed by the United Kingdom HFEA for PGD (2009)	
<ul style="list-style-type: none"> • Adrenoleukodystrophy (Adrenomyeloneuropathy) • Agammaglobulinaemia • Alpers Syndrome • α thalassaemia/mental retardation syndrome • Alport's Syndrome • Alzheimers Disease - early onset • Anderson Fabry Disease • Androgen Insensitivity Syndrome • Aplastic anaemia - severe** • Barth Syndrome • Battens Disease (infantile) • Beta Hydroxyisobutyryl CoA Hydrolase Deficiency (Methacrylic Aciduria) • Beta Thalassaemia** • Bilateral Frontoparietal Polymicrogyria • BRCA 1 (increased susceptibility to breast cancer)* • Bruton Agammaglobulinemia Tyrosine Kinase • Cardiac Valvular Dysplasia • Carney Complex* • Charcot Marie Tooth Disease • Chondrodysplasia Punctata • Choroideraemia • Chromosomal rearrangements (various) • Chronic Granulomatous Disease • Coffin-Lowry Syndrome • Congenital Adrenal Hyperplasia • Congenital Fibrosis of the Extraocular Muscles • Congenital Stationary Night Blindness • Crouzon Syndrome • Cystic Fibrosis • Cystinosis* • Diamond Blackfan Anaemia** • Dystonia 1 Torsion Autosomal Dominant (DYT1) • Ectodermal dysplasia (Hypohidrotic) 	<ul style="list-style-type: none"> • Epidermolysis Bullosa (Hallopeau-Siemens & Herlitz junctional) • Facioscapulohumeral Dystrophy • Familial Adenomatous polyposis coli • Fanconi's Anaemia A** • Fanconi's Anaemia C** • Fragile X Syndrome • Gaucher's Disease (Type II) • Gonadal mosaicism • Greig's Cephalopolysyndactyly • Haemophilia A • Haemophilia B • Hereditary diffuse gastric cancer* • Hereditary motor and sensory neuropathies • Homozygous Familial Hypercholesterolaemia • Hunters Syndrome • Huntington's Disease • Hydrocephalus • Hydroxyisobutyryl CoA Hydrolase Deficiency • Hyper IgM Syndrome - Hypogammaglobulinaemia** • Hypospadias (severe) • Ichthyosis • Incontinentia Pigmenti • Juvenile Retinoschisis • Krabbe Disease • Leber's hereditary optic neuropathy / Lebers Optic atrophy • Leigh's (subacute necrotising encephalopathy of childhood) • Lenz syndrome • Lesch Nyhan Syndrome • Leukocyte Adhesion Deficiency (Type I)** • Li-Fraumeni Syndrome • Lymphoproliferative Syndrome • Lynch Syndrome (MLH 2)* • Lynch syndrome (MLH 1)*

262. See Human Fertilisation & Embryology Authority, *supra* note 149.

<ul style="list-style-type: none"> • Macular Dystrophy (childhood onset - variant of Retinitis pigmentosa) • Marfan Syndrome • Medium-chain acyl-Co A dehydrogenase • MELAS (Mitochondrial encephalomyopathy, lactic acidosis and stroke-like episodes) • Menkes Syndrome • Myoclonic epilepsy and ragged red fibres (MERFF) • Metachromatic Leukodystrophy • Multiple Endocrine Neoplasia (Type I) • Multiple Exostoses • Muscular Dystrophy (Beckers) • Muscular Dystrophy (Duchenne) • Muscular Dystrophy (Oculopharyngeal) • Myotonic Dystrophy • Myotubular myopathy • Neurogenic muscle weakness, ataxia, retinitis pigmentosa (NARP) • Neurofibromatosis type I • Neurofibromatosis type II • Niemann Pick Disease Type C • Ornithine carbamoyl transferase Deficiency (OTC) • Ornithine transcarbamylase deficiency (OTD) • Osteogenesis Imperfecta (Type II) • Osteopathia Striata with Cranial Sclerosis • Otopalatodigital syndrome (Type 2) 	<ul style="list-style-type: none"> • Partial Lipodystrophy, Familial (Type 2) • Pelizaeus Merzbacher Disease • Phenylketonuria (PKU) • Plakophilin 1 (PKP1) associated ectodermal dysplasia syndrome • Polycystic kidney disease • Pompe Disease (early onset) • Prader Willi Syndrome • Pyrodoxine-dependent seizures • Recurrent Digynic Triploidy • Recurrent hydatidiform mole • Retinitis Pigmentosa • Retinoblastoma • Retinoschisis (Juvenile) • Sandhoff Disease • Sensorineural deafness - autosomal recessive non-syndromic • Severe Combined Immune Deficiency (x-linked) • Sickle Cell Anaemia** • Spastic paraplegia • Spinal Muscular Atrophy (SMA1) • Tay Sachs Disease (infantile onset) • Torsion Dystonia • Treacher Collins Syndrome • Tuberous Sclerosis (TSC2)* • Turner's syndrome (Mosaic) • Von Hippel Lindau Syndrome • Wiscott-Aldrich Syndrome** • Wolman's Disease (Acid Lipase Deficiency)
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*These conditions are licensed by the HFEA on a case-by-case basis, for specific patients.

**These conditions have also been licensed for use in cases involving HLA tissue typing. HLA tissue typing tests are licensed on a case-by-case basis, for specific patients.

From a Constitutional Right to a Policy of Exceptions: *Abigail Alliance* and the Future of Access to Experimental Therapy

Seema Shah* and Patricia Zettler†

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INTRODUCTION

In 1999, nineteen-year-old Abigail Burroughs was diagnosed with head and neck cancer.¹ Abigail underwent the conventional treatments—chemotherapy and radiation therapy—with no success.² Her physician recommended that Abigail attempt to enroll in clinical trials for two unapproved drugs that her physician hoped might have an effect on her tumor.³ Abigail, however, was unable to enroll in the trials because she did not meet the scientific criteria for inclusion.⁴ In June 2001, shortly after enrolling in a clinical trial of a third unapproved drug, Abigail passed away.⁵ Following her death, her father founded the Abigail Alliance for Better Access to Developmental Drugs (Abigail Alliance) to advocate for increased access to unapproved drugs for terminally ill patients.⁶

In January 2003, the Abigail Alliance submitted to the Food and Drug Administration (FDA) a proposal for new regulations to increase access to unapproved therapy. They proposed creating a tiered approval system that would allow terminally ill patients to purchase unapproved drugs that had completed Phase 1⁷ clinical trials.⁸ In April 2003, the FDA rejected this proposal because it

1. See Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v Von Eschenbach*, 297 JAMA 205, 205 (2007); Sue Kovach, *The Abigail Alliance: Motivated by Tragic Circumstances, Families Battle an Uncanny Bureaucracy*, LIFE EXTENSION MAG., Sept. 2007, http://www.lef.org/magazine/mag2007/sep2007_report_abigail_01.htm.

2. See Jacobson & Parmet, *supra* note 1, at 205.

3. See *id.*; Kovach, *supra* note 1.

4. See Jacobson & Parmet, *supra* note 1, at 205. The cetuximab trial only enrolled patients with colon cancer, while the gefitinib trial was restricted to patients with lung cancer. See *id.*; Rabiya S. Tuma, *Expanded-Access Programs: Little-Heard Views from Industry*, ONCOLOGY TIMES, Aug. 10, 2008, at 19. The Abigail Alliance website also states that the drug companies that sponsored the trials “couldn’t provide [Abigail] with [the drug] for compassionate use.” See Kovach, *supra* note 1. Other sources suggest that the companies refused to seek FDA approval to supply Abigail the drug outside of clinical trials. See, e.g., Beryl Lieff Benderly, *Experimental Drugs on Trial*, SCI. AM., Oct. 2007, at 92, 96. The programs that provide patients access to unapproved drugs outside of clinical trials are discussed in more detail in Part III, *infra*.

5. See Jacobson & Parmet, *supra* note 1, at 205.

6. See *id.*; see also Abigail Alliance for Better Access to Developmental Drugs, <http://abigail-alliance.org> (last visited Nov. 20, 2009) [hereinafter Abigail Alliance Website].

7. Clinical trials are split up into four phases, each designed to answer a different research question. Phase 1 trials “test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.” See ClinicalTrials.gov, Frequently Asked Questions, <http://www.nlm.nih.gov/services/ctphases.html> (last visited Nov. 20, 2009). In Phase 2, trials involve larger numbers of subjects and collect further safety data, but this

“would upset the appropriate balance that [the FDA is] seeking to maintain, by giving almost total weight to the goal of early availability and giving little recognition to the importance of marketing drugs with reasonable knowledge for patients and physicians of their likely clinical benefit and their toxicity.”⁹ The Abigail Alliance then filed a formal citizen petition with the FDA (a required step before one can file a lawsuit against the agency), again calling for a tiered approval system.¹⁰ Before the FDA responded to the citizen petition, Abigail Alliance filed suit, alleging that FDA regulations that restrict terminally ill patients’ access to unapproved drugs violate a fundamental constitutional right protected by the Due Process Clause of the Fifth Amendment.¹¹

A D.C. district court judge dismissed Abigail Alliance’s case, finding that a constitutional right to access unapproved drugs did not exist and that the government’s policy restricting access to unapproved drugs survived rational basis review.¹² The Alliance appealed to the D.C. Circuit.¹³ In a decision that surprised many commentators,¹⁴ Judges Rogers and Ginsburg reversed the

phase also examines the efficacy of the investigational product. Phase 3 trials involve large groups of subjects in order to establish the efficacy and monitor side effects. Phase 4 trials are sometimes conducted after a drug goes onto the market to determine if the drug has side effects in particular subgroups and whether it has long-term complications. *Id.*

8. See *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. 03-1601, 2004 U.S. Dist. LEXIS 29594, at *3-*4 (D.D.C. Aug. 30, 2004); see also Citizen Petition of the Abigail Alliance & Wash. Legal Found. to the Food & Drug Admin., *In re Tier 1 Initial Approval Program To Expedite the Availability of Lifesaving Drugs* (June 11, 2003), available at http://www.abigail-alliance.org/WLF_FDA.pdf. In addition to petitioning the FDA, the Abigail Alliance also lobbied Congress to advocate for their proposed legislation.

9. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 700 (D.C. Cir. 2007) (internal quotations and citation omitted). One of the more significant concerns that the Abigail Alliance raised is that in many clinical trials, research subjects are randomized to receive either the unapproved therapy or placebo. Many trials therefore offer patients only a fifty-fifty chance at getting the unapproved therapy. The Abigail Alliance was seeking to expand access outside of clinical trials for individuals who were not eligible or who did not want to risk receiving placebo instead of the unapproved therapy.

10. See *Abigail Alliance*, 2004 U.S. Dist. LEXIS 29594, at *4.

11. See *id.* at *4-*5, *25-*26. The FDA officially responded to the citizen petition in December 2003, after Abigail Alliance filed suit against the agency. See U.S. Food and Drug Administration, Chronological List of Petitions and Advisory Opinions: From January 1, 2003 through December 30, 2003, <http://www.fda.gov/ohrms/dockets/CITPETS/03citpetlist.htm> (last visited Oct. 12, 2009).

12. See *Abigail Alliance*, 2004 U.S. Dist. LEXIS 29594, at *2.

13. See *Abigail Alliance*, 495 F.3d at 700-01.

14. See, e.g., Susan Okie, *Access Before Approval — A Right To Take Experimental Drugs?*, 355 NEW ENG. J. MED. 437, 437 (2006) (discussing the “surprising court decision”).

district court's decision and held that terminally ill patients did, in fact, have a constitutional right to access unapproved drugs.¹⁵ The FDA then filed a petition for rehearing en banc. That petition was granted, and the en banc court vacated the panel's decision.¹⁶ Subsequently, the Supreme Court denied Abigail Alliance's petition for certiorari.¹⁷ The D.C. Circuit is widely recognized as having special expertise on matters of administrative law, and the *Abigail Alliance* opinion is now considered an authoritative judgment on the topic of a constitutional right to access experimental therapies.¹⁸

The *Abigail Alliance* case demonstrates the highly sympathetic nature of claims for access to unapproved therapy outside of clinical trials when such access is the last hope of a terminally ill patient. In the wake of this case, legal claims for access have been made through contractual or quasi-contractual mechanisms.¹⁹ These cases raise many complex policy questions, some of which may be difficult or inappropriate for courts to take into account.²⁰ In this Article, we argue that a constitutional right to access unapproved therapy should not be recognized by the courts. Further, claims for expanded access are too uncertain and costly to merit substantial regulatory changes. Rather than expanding access to unapproved therapy outside of clinical trials, we contend that more efforts should be made to expand access to the clinical trials themselves.

In Part I, we analyze the reasoning behind the *Abigail Alliance* decision, examine why the en banc D.C. Circuit did not grant a right of access to unapproved therapy, and consider objections that have been raised in favor of a right to medical self-defense. In Part II, we first consider the contractual and quasi-contractual litigation in this area and then demonstrate that courts lack the

15. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 472 (D.C. Cir. 2006). Judge Griffith dissented. *See id.* at 486.

16. *Abigail Alliance*, 495 F.3d at 701.

17. *Abigail Alliance*, 495 F.3d at 695, *cert. denied*, 128 S. Ct. 1069 (2008).

18. The only subsequent opinion to cite *Abigail Alliance* on the question of a constitutional right to access unapproved treatment followed the majority's reasoning. *See CareToLive v. von Eschenbach*, 525 F. Supp. 2d 952 (S.D. Ohio 2007), *aff'd*, No. 07-4465, 2008 U.S. App. LEXIS 18780 (6th Cir. Aug. 28, 2008). In *CareToLive v. von Eschenbach*, a judge in the Southern District of Ohio relied on *Abigail Alliance* to reject prostate cancer patients' constitutional claim for access to Provenge, an unapproved "biological product intended to treat a particular type of metastatic prostate cancer." *See CareToLive*, 525 F. Supp. 2d at 958, 965-66.

19. *See, e.g., Gunvalson v. PTC Therapeutics, Inc.*, 303 Fed. Appx. 128, 129-30 (3d Cir. 2008) (discussing a claim for access based on a theory of promissory estoppel).

20. *Cf. O. Carter Snead, Unenumerated Rights and the Limits of Analogy: A Critique of the Right to Medical Self-Defense*, 121 HARV. L. REV. F. 1, 12 (2007) (arguing that the existence of a right to medical self-defense "must be resolved in the public square through the democratic process").

requisite institutional competence necessary to adjudicate these claims. We explain and evaluate existing FDA regulations in this area in Part III. In Part IV, we argue that, as a matter of policy, claims for access to unapproved therapy outside of clinical trials should rarely be granted. We conclude in Part V that the current approach to providing access to unapproved therapy outside of clinical trials runs the risk of creating a costly policy of exceptions. Instead, we propose reforming clinical trial requirements to involve more participants, including more terminally ill patients, in clinical trials, while providing access outside of clinical trials only in limited circumstances.

I. THE *ABIGAIL ALLIANCE* CASE: SHOULD WE GRANT ACCESS TO UNAPPROVED THERAPY OUTSIDE OF CLINICAL TRIALS?

In the *Abigail Alliance* case, the en banc D.C. Circuit faced the following question:

Whether the liberty protected by the Due Process Clause embraces the right of a terminally ill patient with no remaining approved treatment options to decide, in consultation with his or her own doctor, whether to seek access to investigational medications that the [FDA] concedes are safe and promising enough for substantial human testing.²¹

An eight-judge majority ruled that the constitutional right to liberty does not extend to a right to access unapproved drugs.²² In reaching this conclusion, the majority relied on the two-part analysis for substantive due process cases that the Supreme Court articulated in *Washington v. Glucksberg*.²³ According to that analysis, a court first must consider whether the plaintiffs have provided “a careful description of the asserted fundamental liberty interest.”²⁴ The majority assumed, for the sake of argument, that *Abigail Alliance* had satisfied this first requirement.²⁵

The dissent, written by Judge Rogers and joined by then-Chief Judge Ginsburg, disagreed with the majority’s description of the liberty interest at

21. *Abigail Alliance v. von Eschenbach*, 495 F.3d 695, 701 (D.C. Cir. 2007).

22. See *Abigail Alliance*, 495 F.3d at 697, 701-02. Judge Griffith wrote the majority opinion for the en banc court. See *id.* at 697. Judges Ginsburg and Rogers, who formed the majority for the panel court’s decision, dissented from the en banc court’s decision. See *id.* at 714 (Rogers, J., dissenting).

23. *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997).

24. *Abigail Alliance*, 495 F.3d at 701-02 (quoting *Glucksberg*, 521 U.S. at 720-21) (internal quotation marks omitted).

25. See *id.* at 702.

stake.²⁶ While the majority defined the interest asserted by Abigail Alliance as a right to take on “enormous risks” to obtain “*potentially* life-saving drugs,”²⁷ the dissent defined the asserted interest as a “specific right to act to save one’s own life.”²⁸ The dissent faulted the majority’s description as overly broad and inappropriately focused on personal autonomy, a concept that the Supreme Court has held cannot be the sole basis for a protected liberty interest.²⁹ The dissent argued that Abigail Alliance asserted a specific right grounded in self-preservation, not an abstract interest based in personal autonomy.³⁰ In order to make this argument, however, the dissent departed from how the Abigail Alliance itself had described the right at stake. Moreover, the majority rightly noted that redescribing the liberty interest as a broad right to save one’s life was not the kind of careful description required by *Glucksberg*.³¹

The second step under the *Glucksberg* analysis required the court to consider whether a liberty interest in access to unapproved drugs was “deeply rooted in this Nation’s history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed.”³² Abigail Alliance argued that a protected liberty interest in access was deeply rooted in our nation’s history for two reasons: 1) there is a long history of the government not interfering with access to drugs; and 2) based on existing common law doctrines, prohibiting access to unapproved drugs was “inconsistent with the way that our legal tradition treats persons in all other life-threatening situations.”³³ Although the court ultimately ruled against Abigail Alliance, it focused a great deal of analysis on these issues. Examining the court’s analysis illuminates the complex policy issues involved in providing access to experimental therapy.

A. The History and Tradition of Drug Regulation

Abigail Alliance argued that a protected liberty interest in access was deeply rooted in our nation’s history because of a lack of governmental interference with access to drugs for much of our nation’s history. Government regulations did not address the efficacy of drugs before the 1962 Amendments to the Food, Drug,

26. *See id.* at 714, 716 (Rogers, J. dissenting) (“[T]he description of the right is of crucial importance—too broad and a right becomes all-encompassing and impossible to evaluate; too narrow and a right appears trivial.”).

27. *Id.* at 710.

28. *Id.*

29. *Id.* at 716 (citing *Glucksberg*, 521 U.S. at 725).

30. *See id.*

31. *Id.* at 701 n.5.

32. *Id.* at 701-02 (quoting *Glucksberg*, 521 U.S. at 720-21) (internal quotations omitted).

33. *See id.* at 703, 707.

and Cosmetic Act (FDCA).³⁴ The majority opinion noted, however, that access to unapproved drugs of unproven safety has long been restricted.³⁵ States and colonies began regulating drugs for safety as early as 1736, when Virginia passed a law that regulated the sale of drugs in an attempt to prevent deceptive sales practices by pharmacies.³⁶ Federal drug safety regulation began in 1848, when the government banned the importation of adulterated drugs.³⁷

The court further concluded that whether a historical right to access unapproved drugs existed did not depend on the fact that the first major efficacy regulation occurred in 1962. Focusing on the discretion granted to Congress and administrative agencies to regulate in light of new information, the court determined that “a lack of government interference throughout history might be some evidence that a right is deeply rooted. But standing alone, it cannot be enough.”³⁸ In sum, the court found evidence that the states and the federal government historically have regulated access to unapproved drugs, but it also concluded that a history of such regulation was not necessary to reject the argument that a constitutional right to access exists.

B. Common Law Doctrines Supporting a Right of Access

After determining that the absence of efficacy regulation for much of our nation’s history was not enough to support a fundamental right of access, the court considered whether the common law doctrines of necessity, intentional interference, and self-defense supported a fundamental right of self-preservation. Much of this discussion focused on whether an unapproved drug of uncertain safety and efficacy could be considered necessary for prolonging the life of a terminally ill patient.

1. The Doctrine of Necessity

Necessity, or choice of evils, provides an individual with a defense when “physical forces beyond the actor’s control rendered illegal conduct the lesser of

34. *See id.* at 703, 706.

35. *Id.* at 703.

36. *See id.* at 703-04. Specifically, the law sought to prevent “dangerous and intolerable” drug selling practices by prohibiting surgeons and apothecaries from selling patients greater quantities of drugs than the patients needed and from concealing the composition and treatment value of drugs. EDWARD KREMERS, GLENN SONNEDECKER & GEORGE URDANG, *KREMERS AND URDANG’S HISTORY OF PHARMACY* 158 (1986).

37. *See Abigail Alliance*, 495 F.3d at 704.

38. *Id.* at 706.

two evils.”³⁹ Relying on *United States v. Oakland Cannabis Buyers’ Cooperative*,⁴⁰ the majority dismissed the necessity argument because Congress had previously expressly eliminated a necessity defense in the context of access to unapproved drugs.⁴¹ Through the FDCA, Congress explicitly restricted patients’ access to only those drugs that were approved as safe and effective, thereby eliminating a necessity defense for terminally ill patients.⁴² Because Congress had clearly eliminated the necessity defense by passing the FDCA, the court did not reach the question of whether the necessity doctrine could ever provide support for a constitutional right.⁴³ In rejecting the necessity defense, the majority also relied on the fact that there is significant uncertainty regarding whether unapproved drugs can save patients’ lives.⁴⁴

By contrast, the dissent argued that the necessity defense is evidence of a tradition of protection for the right to self-preservation. The dissent drew an analogy to *Cruzan v. Director, Missouri Department of Health*. In *Cruzan*, the Supreme Court acknowledged a fundamental right to refuse medical treatment grounded in the tort of battery.⁴⁵ Recognition of this right did not constitutionalize the tort of battery, nor did it take away Congressional power to override the common law protection of battery.⁴⁶ It simply took the existence of battery law protections as evidence of an underlying constitutional right to refuse medical treatment, just as, according to the dissent, the necessity defense is evidence of an underlying constitutional right to self-preservation.⁴⁷

Although the majority relied on Congress’s elimination of the necessity defense and did not explicitly address these arguments by the dissent, there is reason to doubt that necessity could ground a constitutional right to medical self-defense. Professor Carter Snead has convincingly argued that necessity cannot

39. *Id.* at 707 (quoting *United States v. Oakland Cannabis Buyers’ Cooperative*, 532 U.S. 483, 490 (2001)).

40. 532 U.S. 483 (2001).

41. *See Abigail Alliance*, 495 F.3d at 707-08 (“Under any conception of legal necessity, one principle is clear: The defense cannot succeed when the legislature itself has made a determination of values Congress may limit or even eliminate a necessity defense that might otherwise be available. That is precisely what the FDCA has done.”).

42. *See id.*

43. *See id.*

44. *Abigail Alliance*, 495 F.3d at 709 n.15 (“[T]he safety and efficacy records of experimental drugs are not fully known. We thus cannot know until after the clinical testing process has been completed that these drugs are in fact necessary.”).

45. *Id.* at 718 (Rogers, J., dissenting) (citing *Cruzan v. Director, Mo. Dep’t of Health*, 497 U.S. 261 (1990)).

46. *See id.* at 718.

47. *See id.*

support the right to access unapproved drugs because of the uncertainty inherent in using such drugs.⁴⁸ One of the legal elements of the necessity defense is that “the individual must believe in good faith that the unlawful act will remedy the greater evil.”⁴⁹ Given the uncertainty surrounding the safety and efficacy of drugs in clinical trials, Snead argued that terminally ill patients cannot assert in good faith that such drugs are necessary to save their lives.⁵⁰ Without some degree of confidence that the means used will save the patient’s life, there cannot be a viable claim to exercise the right.

In the majority’s and dissent’s disagreement about the necessity defense, there are two factors at play. The first is the amount of certainty needed to trust that a particular means of self-defense will be useful, and the second factor is the desperation that may drive one to use a means of self-defense even if it is unlikely to be effective. A terminally ill patient who has no other treatment options could “believe in good faith” that an unapproved drug is the only thing that could possibly save her life and is therefore necessary for prolonging her life, despite evidence that the drug is unlikely to be effective.⁵¹ Other contexts in which the necessity defense is used do not help resolve which of these factors should receive greater weight. It is not clear how to take into account uncertainties regarding whether an actor’s conduct will successfully protect him.⁵² There is likely to be some degree of uncertainty about any extreme

48. See Snead, *supra* note 20, at 10.

49. *Id.*

50. *Id.* (“It seems more accurate to say . . . terminally ill patients strongly hope (with some evidence derived from animal models) that the experimental unapproved therapy will yield some benefit.”).

51. Cf. *Abigail Alliance*, 495 F.3d at 715 (Rogers, J., dissenting) (“The court commits a logical error of dramatic consequence by concluding that the investigational drugs are somehow not ‘necessary.’ While the potential cures may not prove *sufficient* to save the life of a terminally ill patient, they are surely *necessary* if there is to be any possibility of preserving her life.”) (internal citation omitted); Geetaa Anand, *Saying No to Penelope*, WALL ST. J., May 1, 2007, at A1 (quoting the father of a terminally ill four-year-old girl as saying: “If anything has a prayer of saving her, how can you argue it’s not the right thing to do?”).

52. The legal literature does not discuss this question in depth, although cursory references to the interaction between the necessity doctrine and uncertainty can be found. See, e.g., Steven M. Bauer & Peter J. Eckerstrom, *The State Made Me Do It: The Applicability for the Necessity Defense to Civil Disobedience*, 39 STAN. L. REV. 1173, 1180 n.40 (1987) (discussing the fact that “[c]ausation is seldom an issue because necessity cases only reach trial after the defendant has performed an act averting some harm, so the court can look at the act retrospectively”); Shaun P. Martin, *The Radical Necessity Defense*, 75 U. CIN. L. REV. 1527, 1586 (2005) (observing that when assessing the efficacy of lawful and nonlawful alternatives, “[b]ecause there is inherent uncertainty regarding the consequences of any future act, any assessment of efficacy is both nonbinary and probabilistic”).

measure taken to protect one's life; an abortion may not succeed in saving the life of the mother and a handgun aimed at an intruder may not fire. It may be that the law only allows for the necessity defense when the likelihood that the measure will succeed is above some threshold of certainty, and medical procedures like abortions or weapons like handguns are assumed to function above this threshold of certainty. Alternatively, unapproved drugs may fall into a category of their own, because complicated scientific judgments are a prerequisite to establishing their safety and efficacy.

Resolving when drugs should be made available requires complex analysis of many factors, including the existing data about safety and efficacy, the severity of the diseases they would be used to treat, and the available alternatives. The policy solution to this problem has been to allow the FDA to regulate the testing and approval of drugs and to determine what evidence is needed before a particular drug can be made available for use. Therefore, the existence of a necessity defense does not directly pertain to the question of access to experimental therapy and cannot support a right of access to therapy before it has been approved.

2. The Tort of Intentional Interference

Abigail Alliance also argued that the tort of intentional interference provides support for a right to access unapproved drugs. This tort consists of a tortfeasor preventing an individual from providing aid that is *necessary* to another's bodily security.⁵³ However, the majority concluded that withholding unapproved drugs is not intentional interference because drugs that have not been proven safe and effective cannot be considered necessary to bodily security.⁵⁴ Thus, FDA regulations that restrict access to unapproved drugs do not prevent patients from receiving necessary aid, and intentional interference does not help establish a constitutional right to access.⁵⁵

The dissent countered that the tort of intentional interference does provide grounding for the self-preservation interest in accessing unapproved drugs. In some cases, investigational treatments are the only means terminally ill patients have for prolonging their lives.⁵⁶ The majority “confuse[d] what is necessary with what is sufficient” when it concluded that unapproved drugs cannot be considered “reasonably necessary” because they have not been proven safe and

53. *Abigail Alliance*, 495 F.3d at 708 (citing RESTATEMENT (FIRST) OF TORTS § 326).

54. *See id.* at 708-09.

55. *See id.*

56. *See id.* at 719 (Rogers, J., dissenting).

effective.⁵⁷

Again, the crux of the disagreement between the majority and the dissent is how to evaluate the uncertain effects of untested drugs on terminally ill patients. At the time the patients want the drugs, neither doctors nor lawyers nor policymakers can know what effects, if any, those drugs may have. The dissent disregards this inherent uncertainty because of the lack of other options for saving the patient's life. The majority, on the other hand, relies on this uncertainty to dismiss the claim that unapproved drugs could ever be necessary, without acknowledging the lack of alternative treatments for patients. Balancing the many considerations involved is difficult when the choice before the court is binary—the court can either recognize a constitutional right of access or not. Agencies like the FDA may be able to make more nuanced judgments about access policy in general, and about particular drugs, based upon the available data. The FDA can create limited programs of access for individuals in great need when there are data to support that the drug will be safe and effective enough, weigh the risks and benefits to determine which particular conditions or patients should be eligible for these programs, or choose not to allow access in particular cases.

C. Right to Self-Defense

Another argument asserted in favor of a constitutional right to access unapproved drugs was that both self-defense and abortion jurisprudence ground the right to self-preservation or medical self-defense.⁵⁸

1. Traditional Self-Defense as a Basis for the Right

Self-defense and a right to self-preservation are clearly related concepts. A claim of self-defense can be made “when a victim is being attacked by an aggressor and uses reasonable force to overcome immediate danger.”⁵⁹ Abigail Alliance argued that the Supreme Court’s abortion jurisprudence has demonstrated that traditional self-defense applies to the medical context.⁶⁰ According to Abigail Alliance, the analogy between medical self-defense and traditional self-defense is not disturbed by the fact that drugs pose risks of side

57. *Id.*

58. *See id.* at 717-22.

59. *Id.* at 709 (majority opinion).

60. *See id.* They argued that in addition to recognizing the right to privacy, *Roe v. Wade* “recognized another, entirely separate right to abortion: a woman's right to abort a fetus at any stage of a pregnancy if doing so is necessary to preserve her life or health.” *Id.*

effects because an act of traditional self-defense may also pose risks.⁶¹ For example, a victim's attempt to defend herself may anger her attacker, leading her attacker to harm her more egregiously than he otherwise would have.⁶² Under this reasoning, terminally ill patients should be permitted to access unapproved drugs even if those drugs pose serious risks.

The majority found the self-defense analogy inapt,⁶³ concluding that "terminally ill patients cannot fairly be characterized as using reasonable force to defend themselves when they take unproven and possibly unsafe drugs."⁶⁴ Abigail Alliance sought the right to assume "enormous risks in pursuit of *potentially* life-saving drugs," not the right to defend one's own life through the use of reasonable force.⁶⁵ Furthermore, the majority distinguished the interest in access to unapproved drugs from a woman's right to protect her health by terminating a pregnancy because terminating a pregnancy has known or estimable therapeutic value, while unapproved drugs do not.⁶⁶ Again, the court relied on the uncertain safety and efficacy of unapproved drugs to reject medical self-defense as a basis for a constitutional right.⁶⁷

In opposition to the majority's reasoning, constitutional law scholar Eugene Volokh has argued forcefully for the right to medical self-defense. Volokh's first justification for a constitutional right to medical self-defense, its similarity to lethal self-defense, is based on the premise that a constitutional right to lethal self-defense exists.⁶⁸ Volokh argues that there are two important limitations on medical self-defense, both of which also apply to lethal self-defense.⁶⁹ These similarities between the limitations on lethal self-defense and medical self-defense appear to be the only basis Volokh provides to demonstrate that the two

61. *See id.*

62. *See id.*

63. *See id.* at 709-10.

64. *Id.* at 710.

65. *Id.* at 709-10.

66. *See id.* at 710.

67. *See id.*

68. For a full description of Volokh's arguments in favor of finding a constitutional right to lethal self-defense, see Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Treatments, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007). Volokh's claim that lethal self-defense has constitutional roots has not been directly challenged by those who have responded to his assertion of a right to medical self-defense; however, there may be some debate about the constitutional roots of the lethal self-defense doctrine. *See, e.g.,* Kimberly Kessler Ferzan, *Self-Defense and State*, 5 OHIO ST. J. CRIM. L. 449, 473 (2008) ("First, it seems unimaginable that there is not a constitutional right to act in self-defense. Second, there does not seem to be any clear answer as to where one might find it.").

69. Volokh, *supra* note 68, at 1821.

rights are analogous.⁷⁰

First, he argues that both rights are limited to situations in which the defense is both necessary to prevent death or “radically debilitating” harm and exercised against the source of the threatened harm.⁷¹ For example, a victim may not injure a person who is not her attacker, and a terminally ill patient may not steal a drug from a drug company.⁷² A terminally ill patient may, however, attack her disease with a “voluntarily provided” drug.⁷³

The second limitation that Volokh elaborates is that both rights only exist in the face of an imminent threat.⁷⁴ A victim has a right to use lethal self-defense against an attacker only when a lethal response is necessary and the victim has no alternatives.⁷⁵ According to Volokh, a terminally ill patient similarly may use medical self-defense only when she is diagnosed with a “medical threat” and there is no “permitted satisfactory therapy.”⁷⁶ Volokh does not define what would constitute permitted satisfactory treatments, so it is difficult to determine when a patient could make a valid claim for access to unapproved therapy on his view.

Volokh’s relatively thin analogy between medical self-defense and traditional self-defense does not withstand critical examination.⁷⁷ Lethal self-defense “is conceived as a justification for the *use of force* to repel the application of *force* by another.”⁷⁸ Terminally ill patients seeking access to unapproved drugs cannot be understood to be using force against others.⁷⁹ Perhaps one could argue that terminally ill patients use force against their diseases when they seek medical treatment, and in that way they are like victims of crime who fight their attackers with lethal self-defense.⁸⁰ However, equating

70. *See id.* at 1821.

71. *See* Volokh, *supra* note 68, at 1821-22. In Volokh’s view, radically debilitating or serious threats include the threat of dementia or paralysis but not the common cold or minor bruises.

72. *See id.*

73. *Id.* at 1822.

74. *See id.* at 1823-24.

75. *See id.* at 1823.

76. *Id.* at 1824.

77. *See* Richard M. Cooper, Response, 121 HARV. L. REV. F. 31, 32 (2007) (“In arguing by analogy for a ‘right of medical self-defense,’ Professor Volokh disregards the ways in which the proposed analogy does not hold.”); Snead, *supra* note 20, at 6 (“Granting for the sake of argument that there is a fundamental unenumerated right to lethal self-defense, it seems that this is materially different from the kind of entitlement Professor Volokh argues for in the medical domain.”).

78. Snead, *supra* note 20, at 7.

79. *See id.*; *see also* Abigail Alliance v. von Eschenbach, 495 F.3d 695, 710 (D.C. Cir. 2007) (“[T]erminally ill patients cannot fairly be characterized as using reasonable force to defend themselves when they take unproven and possibly unsafe drugs.”).

80. *See* Snead, *supra* note 20, at 7.

disease to human attackers is problematic.⁸¹ Disease and death are fundamentally a part of human existence.⁸² Life-threatening human attacks are relatively rare.⁸³ If self-defense is expanded to encompass disease threats, we will be left “in a state of perpetual emergency; permanently in the sphere of exceptions rather than rules. Taken to an extreme, this attitude might be corrosive of ethical safeguards crucial to the respect for persons in the realm of biomedical research.”⁸⁴ For example, if terminal illness is viewed as an emergency equivalent to a lethal attack perpetrated by another person, important protections, like informed consent, may be disregarded in favor of doing anything and everything possible to save a patient, regardless of the risks and that patient’s preferences.⁸⁵ Such an approach could also justify overriding individual patient rights in favor of important research that can address diseases that pose large risks for many others in society. For these reasons, Volokh’s analogy is unpersuasive.

2. Medical Self-Defense and Abortion

Volokh also argues that the Supreme Court’s abortion jurisprudence supports the right to medical self-defense by affirming a woman’s right to abort a postviability fetus to protect her own health.⁸⁶ The political controversy around abortion generally, and postviability abortion specifically, suggests that abortion jurisprudence may not be a promising basis for a right to medical self-defense.⁸⁷ Furthermore, within abortion jurisprudence itself, legislative deference is recommended in instances of scientific uncertainty.⁸⁸ *Gonzales v. Carhart*,⁸⁹

81. See *id.* at 8-9.

82. See *id.* at 8.

83. See Melonie Heron et al., *Deaths: Final Data for 2006*, NAT’L VITAL STATISTICS REP., Apr. 17, 2009, at 1, 5 tbl.B, available at http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_14.pdf (finding that assault was the fifteenth leading cause of death in the United States in 2006, accounting for only 0.8% of deaths).

84. Snead, *supra* note 20, at 8. Scholars have also offered other, less persuasive arguments that dispute the analogy between lethal and medical self-defense. For example, the law prescribes the relationships between persons, but not between persons and bacteria, viruses, genes, or other agents of disease. See Cooper, *supra* note 77, at 32-33. Also, a victim carries out lethal self-defense with whatever means are handy, while a terminally ill patient must engage in a transaction in interstate commerce to carry out medical self-defense. See *id.* at 33-34. These arguments may take an overly literal approach to the concept of self-defense.

85. See Snead, *supra* note 20, at 9.

86. See Volokh, *supra* note 68, at 1824 (“The Supreme Court has already recognized medical self-defense in one context: abortion needed to protect the woman’s life or health.”).

87. See Snead, *supra* note 20, at 3.

88. *Gonzales v. Carhart*, 550 U.S. 124, 166-67 (2007).

decided a month before Volokh published his article but likely after Volokh wrote the piece, suggests that courts should defer to “legislative judgment about the medical necessity of certain interventions” when there is ambiguity regarding the safety and efficacy of the intervention.⁹⁰ Issues about legislative deference are discussed later,⁹¹ but it is important to note that a right to medical self-defense would require deference to an individual’s judgment (and not the legislature’s judgment) about medical necessity in the face of scientific uncertainty. If courts were to take this approach, they would come into conflict with the *Carhart* holding.⁹²

D. Judicial Reluctance to Recognize New Fundamental Rights

Because the majority opinion in *Abigail Alliance* found no constitutional right to access unapproved drugs, the court determined that the FDA’s policy restricting access to unapproved drugs was subject to rational basis review.⁹³ The court then concluded that the FDA’s policy was rationally related to the legitimate government purpose of protecting patients from “unreasonable risks from investigational drugs that may be neither safe nor effective” and affirmed the district court’s decision.⁹⁴

There are additional reasons that the court might have reached this verdict that were not explicitly addressed in the case. One other such reason is that extending substantive due process protection to previously unrecognized fundamental rights is an extraordinary exercise of power. The Supreme Court has

89. 550 U.S. 124.

90. Snead, *supra* note 20, at 4; see also Cooper, *supra* note 77, at 37 (“In [*Gonzales v. Carhart*], the Supreme Court observed that it ‘has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty.’”) (quoting *Gonzales v. Carhart*, 127 S. Ct. 1610, 1636 (2007)).

91. See Section II.B, *infra*.

92. *Carhart*, 550 U.S. 124.

93. *Abigail Alliance v. von Eschenbach*, 495 F.3d 695, 712 (D.C. Cir. 2007); see also *Washington v. Glucksberg*, 521 U.S. 702, 721, 728 (1997) (holding that if the interest at issue is not a protected liberty interest, the government may burden that interest as long as the infringing policy is “rationally related to legitimate government interests”).

94. *Abigail Alliance*, 495 F.3d at 712-14. By contrast, the dissent considered whether the liberty interest to save one’s life was deeply rooted in our traditions and implicit in the concept of ordered liberty. The dissent concluded that this interest was entrenched in our nation’s history, dating back to Samuel Adams’s 1772 reference to “the duty of self-preservation.” *Id.* at 717 (Rogers, J., dissenting). Having determined that a protected liberty interest existed, the dissent would have remanded the case to the district court to determine whether “there exist[ed] a compelling governmental interest, narrowly tailored, to overcome the Alliance’s interest.” *Id.* at 728.

explained that:

[W]e “have always been reluctant to expand the concept of substantive due process because guideposts for responsible decisionmaking in this uncharted area are scarce and open-ended.” By extending constitutional protection to an asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action. We must therefore “exercise the utmost care whenever we are asked to break new ground in this field,” lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court.⁹⁵

Moreover, as argued below,⁹⁶ this area is one in which “there is no defect in the system of democratic deliberation and . . . reasonable people might decide the underlying questions of value and fact either way.”⁹⁷ Thus, courts may rightly be more reluctant to intervene here.

Furthermore, the consequences of recognizing a right to medical self-defense may be dangerous. A right to medical self-defense might create “an exemption for a large class of transactions from a central provision of the drug regulatory system that has been instrumental in creating the conditions in which medical products, including drugs to treat life-threatening and otherwise serious medical conditions, are developed.”⁹⁸ Such an exemption might necessitate radical changes to FDA policies and the Controlled Substances Act.⁹⁹ Courts might be reluctant to recognize a right to medical defense that is destructive of trusted and important regulatory programs. For these reasons, and for the reasons examined above, it is easy to understand the decision reached in *Abigail Alliance*. Recognizing a fundamental right to access unapproved drugs is a tenuous proposition that is unlikely to be revisited by the courts.

95. *Glucksberg*, 521 U.S. at 720 (quoting *Collins v. Harker Heights*, 503 U.S. 115, 125 (1992)) (citations omitted).

96. Section II.B, *infra*.

97. Cass R. Sunstein, *The Right to Die*, 106 YALE L.J. 1123, 1162 (1997).

98. Cooper, *supra* note 77, at 35.

99. *See id.* A decision that was destructive of these regulatory schemes might be viewed as analogous to *Lochner v. New York*, 198 U.S. 45 (1905). *See* Cooper, *supra* note 77, at 39. *Lochner* was an early twentieth century decision in which the Supreme Court invalidated a law that aimed to protect the health of bakers by limiting the number of hours they could work, on the ground that it violated a constitutional right to freely contract. *See* 198 U.S. at 53. *Lochner* ushered in an era in which the Court overturned more laws and regulations than it historically had invalidated, and it has been widely criticized as an example of judicial overreaching by defining constitutional rights too broadly. *See, e.g.,* Keith E. Whittington, *Congress Before the Lochner Court*, 85 B.U. L. REV. 821, 821 (2005).

II. CONTRACTUAL AND QUASI-CONTRACTUAL CLAIMS TO OBTAIN ACCESS TO EXPERIMENTAL THERAPY THROUGH LITIGATION

Abigail Alliance's attempt to establish a constitutional right of access to experimental therapy may have been unsuccessful, but others have brought cases with the aim of expanding access to experimental therapies under contractual and quasi-contractual legal theories. However, these claims are unlikely to be successful, in part because courts properly recognize that the judicial system is not the appropriate forum for review of this issue.

A. Efforts to Obtain Access Through Litigation

Although there has been a great deal of discussion about litigation as an effective tool to compel access to experimental therapy,¹⁰⁰ patients' hopes and commentators' concerns seem largely unfounded. The majority of individual claims seeking access to unapproved drugs have involved allegations that a research sponsor had a contractual duty to provide access to the experimental therapy.¹⁰¹ Whether the amount of litigation increases may turn on whether courts determine that by providing informed consent documents to research participants, research sponsors incur contractual obligations. If courts find contractual claims can flow from consent documents, a variety of novel legal theories may be applied against research sponsors, which could lead to a flurry of litigation. In this section, we examine whether contractual claims for access are legally

100. John D. Winter, *Is it Time to Abandon FDA's No Release from Liability Regulation for Clinical Studies?*, 63 FOOD & DRUG L.J. 525, 526 (2008) ("At the same time that manufacturers are being required to accept the additional risks associated with pediatric and geriatric patients in clinical studies, there has been a growing number of theories of clinical trial liability and a trend of patients advocating for early or continued access to investigational medicines when a sponsor did not wish to proceed with a study, principally because of an uncertain risk/benefit ratio. To the extent courts or FDA prospectively require greater access to investigational medicines because of patient demand, sponsor liability risks are increased."). See generally Michelle M. Mello, David M. Studdert & Troyen A. Brennan, *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40, 40 (2003) (arguing that the rise in litigation will lead to a "more legalistic, mechanistic approach to ethical review that does not further the interests of human subjects or scientific progress").

101. See *Gunvalson v. PTC Therapeutics, Inc.*, 303 Fed. Appx. 128 (3d Cir. 2008) (discussing a claim for access based on a theory of promissory estoppel); *Vinion v. Amgen Inc.*, 272 Fed. Appx. 582 (9th Cir. 2008); *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006); *Dahl v. HEM Pharmaceuticals Corp.*, 7 F.3d 1399 (9th Cir. 1993); *Suthers v. Amgen, Inc.*, 441 F. Supp. 2d 478 (S.D.N.Y. 2006). In addition to these cases, there has been at least one claim alleging a right of access based on unfair business practices. See Bernadette Tansey, *The Dilemma of a Dying Man*, S.F. CHRON., Feb. 16, 2003, at 11.

viable.¹⁰²

Courts have split on the question of whether informed consent documents for clinical trials constitute contracts.¹⁰³ One court has found that informed consent documents are unilateral contracts.¹⁰⁴ Other courts have distinguished informed consent documents from contracts either because of the absence of consideration and a meeting of the minds or because researchers have discretionary power to end the study at any time.¹⁰⁵ A subset of the courts that have distinguished informed consent documents from contracts have found that while the documents are not themselves contracts, elements of the consent documents or consent processes may support contractual claims.¹⁰⁶ As a result of these diverse decisions, the legal effect of informed consent documents remains unclear.¹⁰⁷

102. We do not attempt to predict the very complicated issue of what consequences might flow from increased litigation. It is possible that if courts are more inclined to recognize consent forms as contracts, research sponsors will simply include disclaimers of any obligation to provide access to experimental therapy. Courts may respond, however, by finding some clauses unconscionable. Furthermore, consent forms are subject to review by institutional review boards that may not permit sponsors to make such broad disclaimers. Therefore, it is hard to know what the effects of increased litigation might be.

103. See *Vinion v. Amgen Inc.*, 272 Fed. Appx. 582 (9th Cir. 2008); *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006); *Dahl v. HEM Pharmaceuticals Corp.*, 7 F.3d 1399 (9th Cir. 1993); *Suthers v. Amgen, Inc.*, 441 F. Supp. 2d 478 (S.D.N.Y. 2006). Courts have also split on the question of whether informed consent documents for medical treatment constitute contracts. See, e.g., 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 164 (2008).

104. *Dahl*, 7 F.3d at 1404-05.

105. See *Abney*, 443 F.3d at 547; *Suthers*, 441 F. Supp. 2d at 482-84.

106. See *Vinion*, 272 Fed. Appx. 582; *Abney*, 443 F.3d at 547; *Suthers*, 441 F. Supp. 2d at 482-84.

107. Compare Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941, 972 (2006) ("Notwithstanding the fact that most subjects sign written consent documents to enroll in a study, courts have displayed reluctance to find binding contractual obligations in the research setting."), and E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1, 33 (2003) (arguing that there is no discernible trend suggesting that consent documents constitute contracts), with Michelle M. Mello & Steven Joffe, *Compact Versus Contract – Industry Sponsors' Obligations to Their Research Subjects*, 356 NEW ENG. J. MED. 2737, 2738 (2007) ("Only a few courts have ruled on whether a research consent form can constitute a legal contract that binds the investigators and institution, but their answer has nearly always been yes.").

1. Decisions Holding that Informed Consent Documents Constitute Contracts

Plaintiffs have succeeded in only one case regarding access to unapproved therapy; there, the court provided access by holding that the informed consent document constituted a contract.¹⁰⁸ In *Dahl v. HEM Pharmaceuticals Corp.*, the Ninth Circuit found that an informed consent document constituted a unilateral contract.¹⁰⁹ A unilateral contract exists when an offer does not invite a return promise and the offer is accepted through performance, such as when a reward is offered for a lost pet.¹¹⁰ The petitioners in *Dahl* participated in a double-blind, placebo-controlled clinical trial¹¹¹ of Ampligen, an unapproved drug.¹¹² They had signed consent forms in which HEM Pharmaceuticals promised to offer them Ampligen for twelve months through an open-label study¹¹³ at the conclusion of the placebo-controlled trial, provided that Ampligen proved more effective than the placebo.¹¹⁴ At the conclusion of the trial, HEM refused to provide the participants with Ampligen, and the petitioners sought a preliminary injunction that would compel HEM to provide them Ampligen.¹¹⁵

The court held that a binding unilateral contract was formed once the participants completed the double-blind, placebo-controlled trial.¹¹⁶ In *Dahl*,

108. *Dahl*, 7 F.3d 1399. In *Grimes v. Kennedy Krieger Institute, Inc.*, the Maryland Supreme Court found that an informed consent document for research constituted a bilateral contract. 782 A.2d 807, 843, 858 (Md. 2001). However, *Grimes* is outside the scope of this Article because it did not concern claims for access to unapproved therapy.

109. *Dahl*, 7 F.3d at 1404; see also Mello & Joffe, *supra* note 107, at 2740 (noting that *Dahl* “supports the general proposition that a consent form can create a binding obligation on an industry sponsor to provide the investigational medication after the trial is over”); Saver, *supra* note 107, at 973 n.135 (noting that the *Dahl* court held that the informed consent form and other study documents constituted a unilateral contract).

110. See RESTATEMENT (SECOND) OF CONTRACTS § 50 (1981); see also *Dahl*, 7 F.3d at 1404-05 (explaining unilateral contracts).

111. In a double-blind, placebo-controlled trial, some participants receive the experimental drug and some receive the placebo; neither the participants nor the researchers know who is receiving the experimental drug or the placebo. See *Dahl*, 7 F.3d at 1401.

112. See *id.*

113. In an open-label study both the researchers and the participants know that the participants are receiving the experimental drug and not a placebo or control drug. See *id.* at 1402.

114. See *id.* at 1401-02.

115. See *id.* at 1401. FDA rejected HEM’s application for a treatment Investigational New Drug (IND) for Ampligen due to safety concerns about liver toxicity, severe abdominal pain, and irregular heartbeat. But FDA did permit HEM to continue with clinical trials of Ampligen. See *id.* at 1402.

116. See *id.* at 1405.

“[t]he deal was, ‘if you submit to our experiment, we will give you a year’s supply of Ampligen at no charge.’”¹¹⁷ The Ninth Circuit concluded that a unilateral contract was formed because the participants “performed by submitting to the double-blind tests. They incurred the detriment of being tested upon for HEM’s studies in exchange for the promise of a year’s treatment of Ampligen.”¹¹⁸ While this holding was a success for the terminally ill plaintiffs, the situation in *Dahl* is unlikely to recur. Pharmaceutical companies and sponsors have likely learned from this case that explicit promises to provide future access should not be made in consent forms.

2. Decisions that Distinguish Informed Consent Documents from Contracts

In two very similar cases brought by research participants against Amgen, courts concluded that consent documents may provide evidence for some contractual obligations but did not hold that the consent documents themselves constituted contracts.¹¹⁹ Both *Abney v. Amgen* and *Suthers v. Amgen* involved Parkinson’s patients who had participated in Phase 2 clinical trials of a synthetic protein delivered to the brain.¹²⁰ In *Abney*, the protocol and the informed consent document stated that participants could elect to continue the protein treatment for twenty-four months following the end of the trial, but they also stated that Amgen could choose to discontinue the trial for various reasons, including safety concerns.¹²¹ In *Suthers*, subjects were told they might be invited to participate in a study after the initial trial was over in which they would be guaranteed to receive the protein, but the informed consent document did not indicate the length of time that they would receive treatment nor did it guarantee they would

117. *Dahl*, 7 F.3d at 1405.

118. *Id.*

119. See *Abney v. Amgen, Inc.*, 443 F.3d 540, 547 n.5 (6th Cir. 2006); *Suthers v. Amgen, Inc.*, 441 F. Supp. 2d 478, 483 (S.D.N.Y. 2006). But see Mello & Joffe, *supra* note 107, at 2738 (arguing that the *Abney* court held that the informed consent document created a contract between the university and the participants).

120. See *Abney*, 443 F.3d at 543-44; *Suthers*, 441 F. Supp. 2d at 481; Mello & Joffe, *supra* note 107, at 2737. Parkinson’s disease is a progressive neurodegenerative disorder that involves the loss of nerve cells in the brain that produce the neurotransmitter dopamine. Symptoms include motor problems (e.g., tremors) as well as cognitive deficits. The protein at issue in *Abney* and *Suthers*, glial cell line-derived neurotrophic factor (GDNF), was considered a promising treatment for Parkinson’s disease for various reasons, including its positive effect on dopaminergic neuron survival in vitro. See Erika Check, *Second Chance*, 13 NATURE MED. 770, 770 (2007); Carrie B. Hurelbrink & Roger A. Barker, *The Potential of GDNF as a Treatment for Parkinson’s Disease*, 185 EXPERIMENTAL NEUROLOGY 1, 1 (2004).

121. See *Abney*, 443 F.3d at 544; *Suthers*, 441 F. Supp. 2d at 481.

be chosen for the follow-up study.¹²² Nevertheless, the plaintiffs in *Suthers* claimed that they were promised they would “receive [the protein] indefinitely.”¹²³

After new findings raised safety and efficacy concerns about the protein used in these two trials, Amgen exercised its discretion to halt the trials and all use of the protein.¹²⁴ Following Amgen’s decision to stop the trial, the research participants filed suit against Amgen and moved for a preliminary injunction to compel the company to provide them with the treatment.¹²⁵ The participants based part of their motion on breach of contract.¹²⁶ The plaintiffs in both *Abney* and *Suthers* alleged that the informed consent document created a binding contract through which Amgen was obligated to supply them with the protein.¹²⁷

The *Abney* and *Suthers* decisions addressed the participants’ contract claims differently. In *Abney*, the Sixth Circuit held that even if the informed consent documents constituted contracts, they did not bind the sponsor, Amgen.¹²⁸ The documents memorialized an agreement between the participants and the researchers, and the researchers were independent contractors hired by the sponsor.¹²⁹ The court found that, under Kentucky law, independent contractors could not be considered Amgen’s agents or employees.¹³⁰ Therefore, any agreement between the researchers and subjects could not bind Amgen.¹³¹ Because the court concluded that any agreement memorialized in the consent document did not bind Amgen, it did not reach the question of whether the

122. *Suthers*, 441 F. Supp. 2d at 483-84.

123. *Id.* at 484.

124. *See Abney*, 443 F.3d at 544-45. The new findings were: 1) several of the participants had developed neutralizing antibodies that Amgen worried would clear the synthetic GDNF from the patients’ systems or attack naturally-occurring GDNF, which would result in permanent damage to vital organs; 2) results from a long-term study of GDNF in primates indicated that some of the primates had developed cerebral toxicity; and 3) results of the clinical trial indicated that GDNF was not significantly more effective than placebo. Amgen consulted the FDA before ending the clinical trial. The FDA allowed but did not compel Amgen to supply GDNF to these patients for compassionate use. After consulting three bioethicists and five Parkinson’s disease experts, Amgen concluded it should halt use of GDNF. *See Abney*, 443 F.3d at 545.

125. *See id.* at 545; *Suthers*, 441 F. Supp. 2d at 482.

126. *See Abney*, 443 F.3d at 546; *Suthers*, 441 F. Supp. 2d at 480.

127. *See Abney*, 443 F.3d at 545, 547; *Suthers*, 441 F. Supp. 2d at 482.

128. *Abney*, 443 F.3d at 548.

129. *Id.*

130. *See Abney*, 443 F.3d at 547; *Abney v. Amgen, Inc.*, 2005 U.S. Dist. LEXIS 14258, at *17 (E.D. Ky. July 8, 2005).

131. *Abney*, 443 F.3d at 549.

consent document constituted a contract.¹³²

In *Suthers*, the court concluded that the participants may be able to prove a set of facts to support the claim that the informed consent document imposed some contractual obligations on Amgen.¹³³ However, the court only referred to the possibility that consent forms could provide evidence for certain contractual obligations and never referred to the consent forms as contracts.¹³⁴ Moreover, the court concluded that Amgen did not have the specific contractual obligation asserted by the participants—the obligation to supply the treatment to participants indefinitely—because the consent document informed participants that Amgen could halt the clinical trial at any time.¹³⁵ By deciding the issues on these grounds, the court did not reach the question of whether the researchers were Amgen’s agents.¹³⁶ The *Suthers* decision therefore suggests that a consent form may provide evidence for some contractual obligations, but it also indirectly distinguishes consent documents from contracts.¹³⁷

In a third case brought against Amgen, the Ninth Circuit addressed an oral rather than a written contract claim and concluded that the informed consent document did not support the plaintiffs’ claim that Amgen breached an oral contract.¹³⁸ The plaintiffs in *Vinion v. Amgen* were two individuals suffering from asbestosis, an incurable lung condition,¹³⁹ who entered a clinical trial of Amgen’s drug Enbrel.¹⁴⁰ The plaintiffs alleged that during the initial consent process for

132. See *Abney*, 443 F.3d at 547.

133. See *Suthers*, 441 F. Supp. 2d at 486. The *Suthers* court did not reach the question of whether the investigators were Amgen’s agents because it determined that no “clear and unambiguous” promise of access to GDNF was made. See *id.*

134. See *id.* at 482-84.

135. See *id.* at 484.

136. See *id.* at 486.

137. See *Suthers*, 441 F. Supp. 2d at 483 (“That the Informed Consent contains language consistent with the existence of *some* contractual obligation on the part of Amgen does not answer the question of whether the contractual promise that plaintiffs seek to impose can be fairly read into the Informed Consent.”).

138. See *Vinion v. Amgen*, 52 Fed. Appx. 582 (9th Cir. 2008).

139. Asbestosis is caused by the inhalation of asbestosis fibers. Asbestosis patients suffer from scarred lung tissue and progressively decreasing breathing capacity. Asbestosis can cause death or other serious diseases, including lung cancer. See Thomas A. Sporn & Victor L. Roggli, *Asbestosis*, in *PATHOLOGY OF ASBESTOS-ASSOCIATED DISEASES* 71 (Victor L. Roggli, Tim D. Oury & Thomas A. Sporn, eds., 2004); MayoClinic.com, *Asbestosis*, <http://www.mayoclinic.com/health/asbestosis/DS00482> (last visited Nov. 18, 2009).

140. Appellants’ Opening Brief at 7-9, *Vinion v. Amgen*, 252 Fed. Appx. 582 (9th Cir. 2008) (No. 05-36121). Enbrel was approved for the treatment of arthritis but was not approved for the treatment of asbestosis. See *id.* at 9.

the trial, the investigator (who was also their personal physician) made an oral promise that Amgen would provide them with Enbrel free of charge at the conclusion of the trial.¹⁴¹ According to the plaintiffs, this oral promise constituted a contract that Amgen breached when it did not provide them with Enbrel after the trial concluded.¹⁴²

Both the Montana district court and the Ninth Circuit rejected the plaintiffs' oral contract claim.¹⁴³ The courts examined the consent document, as well as the contract between Amgen and the principal investigator, to assess the oral contract claim, concluding that "the written agreements did not contain a promise that the Companies would provide the study drug for free indefinitely once the study ended."¹⁴⁴ Neither court directly addressed the question of whether an informed consent document constitutes a contract. However, the courts' decisions to look to the consent documents for evidence of an oral contract suggest a willingness to use consent documents as evidence of some contractual obligations¹⁴⁵ but not necessarily as contracts in themselves.

As in *Abney*, the *Vinion* court found that the investigators were not acting as Amgen's agents and therefore could not make oral promises to bind the company.¹⁴⁶ In her dissent, Judge Betty Fletcher suggested that this finding did not take adequate account of Montana state law, which allows for agency to be established in a variety of ways.¹⁴⁷ More specifically, under Montana law, the mere silence of the principal can create ostensible agency in another party.¹⁴⁸ She

141. *See id.* at 8.

142. *See id.* at 22-29. The plaintiffs could have obtained Enbrel legally through an off-label prescription; however, the plaintiffs' insurance would not pay for Enbrel, and the plaintiffs could not afford to purchase Enbrel themselves. *See id.* at 8.

143. *See Vinion*, 52 Fed. Appx. at 584; *Vinion v. Amgen*, CV 03-202-M-DWM, slip op. at 2 (D. Mont. Nov. 9, 2005), available at <http://www.websupp.org/data/DMT/9:03-cv-00202-166-DMT.pdf>. In the Ninth Circuit appeal, Judge Betty Fletcher dissented; however, she agreed with the majority that the plaintiffs' contract claims were properly dismissed by the district court. *See Vinion*, 52 Fed. Appx. at 585 (Fletcher, J., dissenting).

144. *Vinion*, 272 Fed. Appx. 582; *see also Vinion*, CV 03-202-M-DWM, slip op. at 8 ("Neither the original Consent Form nor the amended form contained any indication that study subjects would be entitled to receive Enbrel after the study was terminated or after they were withdrawn from the study, even if they had shown a positive response to the drug.").

145. *See Vinion*, 272 Fed. Appx. 582; *Suthers v. Amgen, Inc.*, 441 F. Supp. 2d 478, 483 (S.D.N.Y. 2006); *Vinion*, CV 03-202-M-DWM, slip op. at 8.

146. *Vinion*, 272 Fed. Appx. at 584 (affirming that the investigator was not the "Companies' actual or apparent agent" because "there was no action or inaction by the Companies that would have led the Appellants to a reasonable belief that [the investigator] was the Companies' agent").

147. *Id.* at 585 (Fletcher, J., dissenting).

148. *Id.* (citing *C.A.R. Transp. Brokerage Co., Inc. v. Darden Rests., Inc.*, 213 F.3d 474 (9th

argued that the informed consent document failed to indicate that the investigator was not Amgen's agent and that provisions of the document could be read to imply that the investigator was, in fact, Amgen's agent.¹⁴⁹ Judge Fletcher contended that, "In the present context, while it is true that the nature of clinical studies requires pharmaceutical companies to let the doctors deal with patients, it is incumbent upon the companies to make its role and the physician's role clear at the outset."¹⁵⁰

The question of whether investigators may be acting as agents of the research sponsor when obtaining informed consent may vary by state and also by how the informed consent document describes the relationship between investigator and sponsor. This agency issue is important because to the extent that research sponsors employ independent contractors to conduct the research, informed consent discussions and documents are less likely to support a contractual claim against the sponsor. Judge Fletcher's opinion suggests that there may be some legal interpretations that would hold sponsors liable for the statements made by independent contractors they hire, but only in certain cases. Of course, the more lucrative contractual claims are those made against research sponsors, so the increasing use of independent contractors or organizations to conduct research may decrease incentives to bring suit.

3. Recovery Under Promissory Estoppel

A recent case tested the viability of using a promissory estoppel theory in claims for access to experimental therapy. In *Gunvalson v. PTC Therapeutics, Inc.*, a teenager seeking access to an unapproved drug for muscular dystrophy succeeded in obtaining a preliminary injunction under the theory of promissory estoppel (or quasi-contract).¹⁵¹ The district court found that the company was obligated to provide access and issued the injunction.¹⁵² However, the defendants filed for interlocutory appeal, and the Third Circuit overturned the decision, concluding that the district court had abused its discretion because Gunvalson's promissory estoppel claim was not reasonably likely to succeed on the merits.¹⁵³

Cir. 2000)).

149. *Id.* at 586.

150. *Id.* at 585.

151. *Gunvalson v. PTC Therapeutics, Inc.*, Civ. No. 08-cv-3559, 2008 U.S. Dist. LEXIS 64012, at *4 (D.N.J. Aug. 21, 2008). The plaintiff also moved for the preliminary injunction on fraudulent misrepresentation and negligent misrepresentation grounds; however, because the court granted the injunction on the promissory estoppel ground, the discussion focuses on that theory. *See id.*

152. *See id.* at *7.

153. *See Gunvalson v. PTC Therapeutics, Inc.*, 303 Fed. Appx. 128, 129 (3d Cir. 2008).

This result is in line with the general trend of courts looking unfavorably on claims for access to experimental therapy. What is interesting about the *Gunvalson* case, however, is that the fact pattern and analysis in the case illuminate how strong the barriers are to obtaining access to experimental therapy through litigation.

First, even when plaintiffs craft creative arguments that lower the evidentiary burdens, it may still be difficult to obtain access to unapproved treatments. The plaintiff in *Gunvalson* was Jacob Gunvalson, a sixteen-year-old boy diagnosed with Duchenne Muscular Dystrophy (DMD).¹⁵⁴ Jacob's mother became an advocate of DMD research, and through her advocacy work, she developed a relationship with officers and employees of PTC Therapeutics (PTC). In 2006, PTC began a Phase 2a clinical trial of PTC124, an unapproved drug being studied for the treatment of DMD,¹⁵⁵ in which participants were selected to receive PTC124 after eligibility was determined using a muscle biopsy.¹⁵⁶ At the time, Jacob was enrolled in a different clinical trial, and the Gunvalsons claimed that PTC's vice president, a friend of the family, advised them to keep Jacob in that trial, assuring them Jacob could receive PTC124 at a later date.¹⁵⁷ This alleged promise became the basis for the Jacob's promissory estoppel claim.¹⁵⁸ Promissory estoppel claims require less documentary and testimonial evidence than written or even oral contract claims. In order to obtain a preliminary injunction, Jacob merely had to demonstrate that his claim had a reasonable likelihood of success.¹⁵⁹ However, even with this relatively low evidentiary burden, Jacob's claim ultimately did not succeed.

Second, although some courts may be swayed by the very sympathetic

154. See *Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *2; Malorye Allison, *Gunvalson Decision Sends Shockwaves Through Industry*, 11 NATURE BIOTECH. 1201, 1201 (2008).

155. See *Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *11; see also Reed Abelson, *Advocating a Treatment, but Denied Access to It*, N.Y. TIMES, July 17, 2008, at C3; PTC Therapeutics, About Us, http://www.ptcbio.com/1.0_about_us.aspx (last visited Nov. 18, 2009).

156. *Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *2. PTC conducted the phase 2a trial for four weeks using thirty-eight participants. See Defendant PTC Therapeutics, Inc.'s Memorandum of Law in Opposition to Plaintiff's Motion for a Preliminary Injunction at 6, *Gunvalson v. PTC Therapeutics, Inc.*, Civ. No. 08-cv-3559, 2008 U.S. Dist. LEXIS 64012 (D.N.J. Aug. 21, 2008) [hereinafter Defendant PTC Therapeutics' Memorandum].

157. See *Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *3; Brief of Plaintiffs Jacob, John and Cheri Gunvalson in Support of Their Motion for a Preliminary Injunction, *Gunvalson v. PTC Therapeutics, Inc.*, Civ. No. 08-cv-3559, 2008 U.S. Dist. LEXIS 64012 (D.N.J. Aug. 21, 2008).

158. See *Gunvalson v. PTC Therapeutics, Inc.*, 303 Fed. Appx. at 129-30; *Gunvalson*, 2008 U.S. Dist. LEXIS 64012 at *3-*4.

159. See *Gunvalson v. PTC Therapeutics, Inc.*, 303 Fed. Appx. at 129-30; *Gunvalson*, 2008 U.S. Dist. LEXIS 64012 at *4.

nature of claims for access, as the district court may have been in this case,¹⁶⁰ many others will not, as the Third Circuit demonstrated.¹⁶¹ DMD, the disease with which Jacob was diagnosed, is a genetic disease without any approved treatments that causes degenerative deterioration of skeletal and cardiac muscle tissue, usually leading to death by age twenty-five.¹⁶² The grave nature of Jacob's condition and his youth may have made his promissory estoppel claim particularly sympathetic.¹⁶³ Indeed, the district court concluded that the Gunvalsons were reasonably likely to be able to show that PTC had a legal obligation to provide Jacob PTC124 based on their promissory estoppel claim, despite the fact that there was a serious question about whether Jacob could show that he detrimentally relied on the vice president's alleged promise.¹⁶⁴ However, the Third Circuit overturned the district court's holding based on their conclusion that Jacob could not demonstrate he had detrimentally relied on the statements that he need not enroll in the earlier trial in order to be eligible for later trials.¹⁶⁵ The court noted in particular that Mrs. Gunvalson had sent emails expressing her disappointment that Jacob had been found ineligible for the trial, indicating that Jacob's reason for not enrolling in the initial trial was his ineligibility, not any statement that the vice president might have made.¹⁶⁶ The highly sympathetic

160. *See Gunvalson*, 2008 U.S. Dist. LEXIS 64012.

161. While the judges of the Third Circuit were not swayed by their sympathies, the opinion indicates the court was sensitive to the family's circumstances. *Gunvalson*, 303 Fed. Appx. at 130 ("[W]e are sympathetic to the plight of Jacob and his family. . . . Nevertheless, we are constrained by the law . . .").

162. *See Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *2; Lisa Phillips, *Contract Law and Ethical Issues Underscore the Latest Lawsuit About Access to Experimental Drugs for Duchenne Muscular Dystrophy*, NEUROLOGY TODAY, Sept. 2008, at 20, 20.

163. *See Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *14-*16 (noting that the harm to Jacob without access to the medication is much greater than the harm to PTC in distributing the medication and describing the Gunvalson's unique relationship with PTC's vice president); *see also Gunvalson*, 303 Fed. Appx. at 130 (noting the court's sympathy for the Gunvalson family).

164. *See Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *7. Specifically, there was some question about whether Jacob had the correct diagnosis to be eligible for PTC's Phase 2a trial. PTC Therapeutics argued that when it was enrolling participants in the Phase 2a trial, Jacob was diagnosed with Becker Muscular Dystrophy (BMD), not DMD. Only patients diagnosed with DMD were eligible to participate in clinical trials of PTC124. Thus, according to PTC, Jacob did not enroll in the trial because he was ineligible, not because he relied on a promise made by the vice president. But the district court found that "the evidence suggests that Jacob actually does have DMD, not BMD." *See Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *13.

165. *See Gunvalson*, 303 Fed. Appx. at 130.

166. *See id.* at 130 n.6 ("It is apparent from the record [that Jacob's ineligibility] is the real reason [Ms. Gunvalson] did not attempt to enroll Jacob in the Phase 2a trial, as Mrs. Gunvalson e-mailed a number of parties reporting her disappointment upon hearing of his ineligibility.").

nature of Jacob's claim did not sway the Third Circuit to interpret the evidence in his favor.

Third, the major bottleneck in claims for access may be neither the FDA nor the courts, but rather the drug companies themselves, who are wary of granting access in a way that may interfere with obtaining final approval for the drug in question.¹⁶⁷ Prior to initiating litigation, Jacob asked PTC to provide him the drug through "an FDA-regulated 'compassionate use' exception."¹⁶⁸ PTC refused Jacob's request because it feared that allowing individual access to PTC124 outside of the clinical trials would hinder its ability to enroll participants in the Phase 2b clinical trial and delay the approval of PTC124.¹⁶⁹ Thus, this case illustrates that because drug companies may have many reasons not to allow access, the most effective approach may be to address companies' incentives.

In sum, although informed consent documents have been interpreted to give rise to contractual obligations in some cases, this change may not forecast a rise in successful claims. Courts have generally looked unfavorably on contractual claims seeking access to experimental therapy.¹⁷⁰ Even when plaintiffs have sympathetic claims that are carefully crafted to lower their evidentiary burdens, courts are still wary of granting litigants access to unapproved drugs, as the Third Circuit decision in *Gunvalson* demonstrated. Nevertheless, there are a few exceptions to this trend, including *Dahl* and the district court's decision in *Gunvalson*.¹⁷¹ Thus, pharmaceutical companies and research sponsors may still rightly fear litigation costs, novel legal claims, and the uncertainty of litigation. In the next section, we examine the reasons for judicial reluctance to grant access and conclude that they are warranted.

167. See, e.g., George J. Annas, *Cancer and the Constitution – Choice at Life's End*, 357 NEW ENG. J. MED. 408, 411 (2007) ("[T]he major bottleneck in the compassionate-use program has never been the FDA. The manufacturers have no incentives to make their investigational products available outside clinical trials.").

168. See *Gunvalson*, 2008 U.S. Dist. LEXIS 64012, at *4.

169. See *id.* (noting that PTC denied Jacob's request for compassionate use); Defendant PTC Therapeutics' Memorandum, *supra* note 156, at 8 (arguing that allowing access outside of the clinical trials will hinder PTC's ability to enroll participants in its trials and gain FDA approval); PTC Therapeutics, PTC News, Appeals Court Rules for PTC, http://www.ptcbio.com/PTCStatement.1_news.htm (last visited Nov. 18, 2009) ("The sooner we can complete the required clinical trials and get this drug approved, the sooner all who suffer from the type of Duchenne Muscular Dystrophy (DMD) addressed by PTC124 may benefit.").

170. See *Vinion v. Amgen Inc.*, 272 Fed. Appx. 582 (9th Cir. 2008); *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006); *Suthers v. Amgen, Inc.*, 441 F. Supp. 2d 478 (S.D.N.Y. 2006).

171. See *Dahl v. HEM Pharmaceuticals Corp.*, 7 F.3d 1399 (9th Cir. 1993); *Gunvalson*, 2008 U.S. Dist. LEXIS 64012. But see *Gunvalson v. PTC Therapeutics, Inc.*, 303 Fed. Appx. 128, 129 (3d Cir. 2008) (vacating the lower court's decision to grant a preliminary injunction).

B. Why Courts Should Not Consider Contractual Claims Brought by Former or Potential Research Subjects

Courts may not be well-placed to assess whether claims for access to unapproved therapy should be granted. In fact, judges appear to be reluctant to recognize the right to medical self-defense because doing so would require the judicial branch to decide complex issues related to science and medicine.¹⁷² The Supreme Court has held that the judiciary has limited institutional competence when “making distinctions in a murky constitutional context, or where line-drawing is inherently complex.”¹⁷³ Instead, Congress and administrative agencies are deemed the appropriate governmental bodies to make controversial policy decisions in the context of scientific uncertainty.¹⁷⁴

Courts and scholars have offered various reasons why legislatures, rather than courts, generally should make complicated policy decisions. The legislature can consider the broad and long-term effects of a particular choice.¹⁷⁵ Conversely, “[the] basic function of courts is . . . the function of settling disputes” based on past facts and present law.¹⁷⁶ Legislatures may also consider a wider range of facts and evidence than courts may consider,¹⁷⁷ or they may

172. Cooper, *supra* note 77, at 40. For example, a court may be asked to determine whether a terminally ill patient truly has no treatment options other than an unapproved drug.

173. Ayotte v. Planned Parenthood of N. New Eng., 546 U.S. 320, 330 (2006); *see also* Marshall v. United States, 414 U.S. 417, 427 (1974) (“When Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad and courts should be cautious not to rewrite legislation, even assuming, *arguendo*, that judges with more direct exposure to the problem might make wiser choices.”).

174. *See* Snead, *supra* note 20, at 12 (“[A]s with other contested matters in a morally pluralistic society, this issue must be resolved in the public square through the democratic process.”).

175. *Pers. Adm’r of Mass. v. Feeney*, 442 U.S. 256, 272 (1979) (holding that Congress should consider “the manner in which a particular law reverberates in a society”); *Prentis v. Atlantic Coast Line Co.*, 211 U.S. 210, 226 (1908) (“A judicial inquiry investigates, declares and enforces liabilities as they stand on present or past facts and under laws supposed already to exist. That is its purpose and end. Legislation on the other hand looks to the future and changes existing conditions by making a new rule to be applied thereafter to all or some part of those subject to its power.”).

176. Robert F. Blomquist, *The Good American Legislature: Some Legal Process Perspectives and Possibilities*, 38 AKRON L. REV. 895, 921 (2005) (quoting HENRY M. HART, JR. & ALBERT M. SACKS, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATIONS OF LAW* 343 (William N. Eskridge, Jr. & Philip P. Frickey eds., 1994)) (internal quotation marks omitted); *see also* *Sinclair Refining Co. v. Atkinson*, 370 U.S. 195, 215 (1962) (holding that a court’s “task is the more limited one of interpreting the law as it now stands”).

177. *See* Robert A. Schapiro, *Judicial Deference and Interpretive Coordinacy in State and Federal Constitutional Law*, 85 CORNELL L. REV. 656, 701 (2000).

develop the necessary evidence by holding hearings or commissioning studies.¹⁷⁸

Congress and administrative agencies also possess the freedom to experiment with policy solutions that can later be changed; courts do not have the same degree of flexibility.¹⁷⁹ For example, if the FDA's regulations pertaining to access to unapproved drugs are inadequate, the regulations can be modified through new regulations or a change to the FDCA.¹⁸⁰ This freedom to experiment with various policy solutions may be especially useful for scientific questions, which involve continuously evolving technology. Conversely, if circumstances warrant a change in the interpretation of the law, a court must wait for an appropriate controversy to present itself before making the necessary change. Once a court has made a change, it cannot make any necessary adjustments or overturn its previous decision until a new controversy arises.

In addition, the legislature, unlike the judiciary, is directly subject to political pressure and public opinion.¹⁸¹ Through the democratic process, the public can express its disapproval of a particular policy or policies by voting legislators out of office.¹⁸² Legislative decisions, therefore, are more likely to take into account majoritarian values and contain inherent democratic legitimacy.¹⁸³ Such legitimacy may be important in situations that require the government to balance conflicting goals, such as early availability for promising new drugs and obtaining sufficient information about the safety and efficacy of pharmaceuticals.

It may be appropriate for courts to decide policy issues when the political

178. *See id.*; cf. Cooper, *supra* note 77, at 40 (noting that the FDA has unique access to the results of clinical trials, and personnel with the scientific expertise needed to evaluate the data). Additionally, these arguments may be construed as arguments in favor of judicial deference to legislative bodies. However, authors like Cooper discuss the broader policy implications of allowing courts to decide scientific and policy issues, and not the narrower legal question of whether *Chevron* deference is warranted in the face of agency expertise, and we have followed suit. *See Chevron, U.S.A., Inc. v. Natural Res. Defense Council*, 467 U.S. 837 (1984) (establishing the legal test for determining when courts should defer to administrative agencies' statutory interpretations).

179. *Ferguson v. Skrupa*, 372 U.S. 726, 730 (1963) ("Legislative bodies have broad scope to experiment with economic problems, and this Court does not sit to 'subject the State to an intolerable supervision hostile to the basic principles of our government and wholly beyond the protection which the general clause of the Fourteenth Amendment was intended to secure.'" (quoting *Sproles v. Binford*, 286 U.S. 374, 388 (1932))).

180. *See Cooper, supra* note 77, at 40.

181. *See Edward O. Correia, A Legislative Conception of Legislative Supremacy*, 42 CASE W. RES. L. REV. 1129, 1134 (1992).

182. *See id.*

183. *See id.*

process has failed.¹⁸⁴ However, in the context of medical self-defense, there is little evidence that this has occurred.¹⁸⁵ Instead, the evidence suggests that the political process has functioned appropriately to address the issue of access to unapproved drugs.¹⁸⁶ After Abigail Alliance filed suit against the FDA, a bill was introduced into the Senate that would have expanded access to unapproved drugs, and the FDA proposed new regulations that clarified and expanded its access programs, which will be discussed below.¹⁸⁷

Courts also may not be the appropriate venue for consideration of claims to access experimental therapy because they wield powerful equitable tools, including preliminary injunctions.¹⁸⁸ At the preliminary injunction stage, courts simply have to assess whether a claim is reasonably likely to succeed, and they may rule as the district court did in *Gunvalson*.¹⁸⁹ From the perspective of a patient seeking access to experimental therapy, a preliminary injunction requiring a company to provide the experimental therapy is exactly the relief desired.¹⁹⁰ This approach would be likely to result in a piecemeal approach to granting access to experimental therapy. Moreover, courts may not be well-placed to sift through data from preclinical and Phase 1 and 2 studies to determine whether receiving experimental therapy poses any risks to the litigant. The sympathetic nature of claims to access experimental therapy may lead courts to make compassionate decisions that would not work at a policy level.¹⁹¹ In *Gunvalson*,

184. See Cooper, *supra* note 77, at 41. Some might argue that the Court's intervention in *Brown v. Board of Education*, 347 U.S. 483 (1954) to move the racial integration of schools forward was an example of a judicial response to a failure of the political processes.

185. See Cooper, *supra* note 77, at 42.

186. See *id.*

187. See *id.*; see also Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147 (proposed Dec. 14, 2006) (to be codified at 21 C.F.R. § 312) (providing the text of the proposed changes to FDA's access regulations); Charging for Investigational Drugs, 71 Fed. Reg. 75,168, 75,172-73 (proposed Dec. 14, 2006) (to be codified at 21 C.F.R. § 312) (providing the text of the proposed changes to FDA's regulations concerning prices for unapproved drugs). See Sections III.A-E, *infra*, for a discussion of the proposed regulations.

188. See, e.g., *Gunvalson v. PTC Therapeutics, Inc.*, 303 Fed. Appx. 128, 128 n.3 (3d Cir. 2008).

189. See *id.*

190. Cf. Michael M. Grynbaum, *Judge Orders Drug Maker To Provide Experimental Treatment to Terminally Ill Teenager*, N.Y. TIMES, Aug. 20, 2008, at C3 (quoting *Gunvalson*'s attorney saying, "[t]his was the relief that we sought," after the district court granted the preliminary injunction).

191. See *Gunvalson*, 303 Fed. Appx. at 130 ("As we explained in open court following oral argument, we are sympathetic to the plight of Jacob and his family. . . . Nevertheless, we are constrained by the law to conclude that the Gunvalsons cannot demonstrate either a clear and

the Third Circuit appeared to have recognized the danger of these tools when it overturned the district court ruling.¹⁹²

Finally, courts should be wary of opening the floodgates of litigation. Contract law offers a variety of claims that plaintiffs can bring. Courts have now litigated claims in contract law that alleged bilateral contracts, unilateral contracts, oral contracts, and promissory estoppel.¹⁹³ The fact that these types of claims have been for the most part unsuccessful may not fully stem the tide of litigation on claims for access to experimental therapy.¹⁹⁴ The possible claims for plaintiffs are varied enough that courts should be wary of encouraging further litigation in this area. For all of these reasons, courts are appropriately reluctant to provide litigants access to unapproved drugs.

III. EXISTING LAWS AND REGULATIONS PROVIDING EXPANDED ACCESS TO UNAPPROVED DRUGS

Given that the courts may not have the institutional competence to address claims for access to unapproved therapy, a more appropriate way to handle these claims may be through regulation. After the D.C. Circuit panel decision in *Abigail Alliance*, the FDA issued a proposed rule to modify its expanded access regulations.¹⁹⁵ The FDA intended that the new rule would broaden the availability of investigational drugs through increasing awareness of expanded access programs and procedures and by “eas[ing] the administrative burdens on individual physicians seeking investigational drugs for their patients, as well as the burdens on sponsors who make investigational drugs available for treatment use.”¹⁹⁶

In August 2009, the FDA published a final version of the rule that establishes three programs through which terminally and seriously ill patients may access unapproved drugs.¹⁹⁷ The three programs are based on the size of the

definite promise or detrimental reliance, requirements for a promissory estoppel claim.”).

192. *See id.*

193. *See id.*; *Vinion v. Amgen Inc.*, 272 Fed. Appx. 582 (9th Cir. 2008); *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006); *Dahl v. HEM Pharmaceuticals Corp.*, 7 F.3d 1399 (9th Cir. 1993); *Suthers v. Amgen, Inc.*, 441 F. Supp. 2d 478 (S.D.N.Y. 2006).

194. *Cf. Mello*, *supra* note 100, at 43 (arguing that research-related litigation is likely to increase).

195. *See Expanded Access to Investigational Drugs for Treatment Use*, 71 Fed. Reg. 75,147 (proposed Dec. 14, 2006) (to be codified at 21 C.F.R. § 312); Jerry Menikoff, *Beyond Abigail Alliance: The Reality Behind the Right To Get Experimental Drugs*, 56 KAN. L. REV. 1045, 1058 (2008).

196. *Id.*

197. *See Expanded Access to Investigational Drugs for Treatment Use*, 74 Fed. Reg. 40,900

patient population seeking access: 1) treatment use (for “widespread” use), 2) intermediate-size patient population use, and 3) individual use.¹⁹⁸ The rule establishes different criteria and risk-benefit ratios for the different patient population sizes,¹⁹⁹ although it is not clear why different standards are justified.²⁰⁰ In addition to the three expanded access programs, the rule clarifies the FDA’s policy regarding what sponsors are permitted to charge expanded access patients.²⁰¹

A. General Requirements and Safeguards for Access

For a patient to legally receive an unapproved drug outside of clinical trials under the three expanded access programs, two conditions must be met. Not only must the FDA approve an expanded access application for treatment use or individual use, but the drug sponsor must agree to provide expanded access to an unapproved drug.²⁰² As mentioned above, many sponsors may believe it is not in their best interest to apply for and provide expanded access, and the FDA has no authority to mandate the provision of an unapproved drug by an unwilling sponsor.²⁰³

The final rule also outlines some requirements and safeguards that are applicable to all three programs,²⁰⁴ which are provided in Tables 1 and 2 below.

(Aug. 13, 2009) (to be codified at 21 C.F.R. § 312). Prior to the publication of the final rule, there were only two programs—treatment use and individual use—relevant to the discussion of terminally ill patients’ attempts to gain access to unapproved drugs. *See* 21 U.S.C. § 360bbb(a), (c) (2006); 21 C.F.R. § 312.36 (2008).

198. Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,900.

199. *See id.* at 40,944-45.

200. The individual use program establishes more lenient eligibility criteria than do the programs intended to provide access to larger groups of patients. However, it may be unfair to create more lenient eligibility criteria for individual patients, who, as the earliest to seek access, are likely to be relatively affluent and connected. Expanded access programs are likely not very accessible for the poor, uninformed, and unconnected. *But see* Judy Vale, *Expanding Expanded Access: How the Food and Drug Administration Can Achieve Better Access to Experimental Drugs for Seriously Ill Patients*, 96 GEO. L.J. 2143, 2161-62 (2008) (arguing that more lenient criteria for individual patients is appropriate).

201. *See* Charging for Investigational Drugs, 74 Fed. Reg. 40,872 (Aug. 13, 2009) (to be codified at 21 C.F.R. 312).

202. *See* 21 C.F.R. §§ 312.34, 312.36 (2008) (not mentioning any authority to force drug companies to provide expanded access).

203. *See id.*

204. Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,943-44.

Table 1: Requirements ²⁰⁵
1) Patients have a “serious” ²⁰⁶ or immediately life-threatening disease” ²⁰⁷ and no alternative treatment.
2) The potential benefits justify the potential risks.
3) Expanded access does not interfere with clinical trials to support marketing approval.

Table 2: Safeguards ²⁰⁸
1) A physician who treats expanded access patients is considered an investigator, and “must comply with the responsibilities for investigators.” ²⁰⁹
2) A drug company or physician who applied for expanded access on behalf of patients is a sponsor (or sponsor-investigator), and “must comply with the responsibilities for sponsors.” ²¹⁰

B. Treatment Use

Treatment use is directed at groups of patients, rather than individuals, and is intended to allow “widespread” access.²¹¹ Under the final rule, the treatment use program does not differ significantly from the treatment use program under the former regulations.²¹² The final rule suggests that drugs should not be made

205. *Id.* at 40,943.

206. A serious disease is defined as “a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.” Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,943.

207. An immediately life-threatening disease is “a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.” *Id.*

208. *Id.* at 40,943-44.

209. Investigator responsibilities include reporting adverse events to the sponsor and ensuring that informed consent requirements are met. *See id.* at 40,943.

210. Sponsor responsibilities include submitting safety reports to the FDA and ensuring physician-investigators are qualified to administer the unapproved drug. *See id.* at 40,943-44.

211. *See* Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,945.

212. *Compare* Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at

available earlier than Phase 2 clinical trials, but it does not mandate that timeline.²¹³ In addition to the general requirements, three criteria must be satisfied in order for a drug to be provided under the treatment access program: 1) the drug must be in clinical trials or clinical trials must have been completed; 2) the sponsor must be pursuing approval with due diligence; and 3) there must be sufficient scientific or clinical evidence of the safety and effectiveness of the drug to support the expanded access use. The final rule also requires sponsors to ensure that investigators comply with the research protocol and applicable regulations.²¹⁴

C. Intermediate-Size Patient Population Use

The intermediate-size patient population expanded access program represents the final rule's most significant change to the former regulations.²¹⁵ Intermediate-size patient population use is intended to provide expanded access to "a patient population smaller than that typical of a treatment [Investigational New Drug (IND)] or treatment protocol," a group of a size not mentioned in the previous regulations.²¹⁶

The final rule establishes two safeguards for intermediate use: 1) each year,

40,945 (allowing the FDA to permit widespread treatment use of experimental drugs if the patients have a life-threatening illness, the drug is being investigated in clinical trials, and the sponsor is actively pursuing marketing approval), *with* 21 U.S.C. § 360bbb(c) (2006) (allowing the granting of expanded access of an investigational new drug if there is no alternative therapy available, the drug is being investigated under clinical trials, and the sponsor of the drug is pursuing marketing approval), *and* 21 C.F.R. § 312.34 (2008) (allowing the FDA to permit treatment use of an investigational drug if there is no alternative treatment, the drug is being investigated in clinical trials, and the sponsor is pursuing marketing approval).

213. *See* Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,945.

214. *See id.*

215. *Compare* Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,944-45 (allowing the FDA to permit investigational drugs to be used for intermediate-size patient populations under certain circumstances), *with* 21 U.S.C. § 360bbb (2006) (allowing access to investigational drugs only for individual patients and widespread use), *and* 21 C.F.R. §§ 312.34, 312.36 (2008) (describing how an investigational drug may be made available to patients with life-threatening diseases in accordance with a treatment protocol or treatment IND); *see also* Alice K. Marcee, *Expanded Access to Phase II Clinical Trials in Oncology: A Step Toward Increasing Scientific Validity and Compassion*, 63 FOOD & DRUG L.J. 439, 447 (2008) (noting that the "mid-size group access is a new category").

216. Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,926; Marcee, *supra* note 215, at 447.

the FDA will reassess whether expanded access is appropriate,²¹⁷ and 2) sponsors must ensure that researchers comply with protocol requirements and relevant regulations. Table 3 outlines the three criteria for intermediate-size population use.²¹⁸

Table 3: Intermediate-Size Population Use Criteria ²¹⁹
1) "There is enough evidence that the drug is safe at the dose and duration proposed for expanded access use to justify a clinical trial" in a population similar in size to the proposed expanded access population.
2) There must be "preliminary clinical evidence of effectiveness of the drug, or of a plausible pharmacologic effect of the drug to make expanded access use a reasonable therapeutic option."
3) Sponsors must explain in their applications why patients cannot be enrolled in clinical trials, and if drug is not being developed for marketing, why this is the case.

One of the most significant changes in the final rule for intermediate-size use is that it allows "off-label" expanded access (access for patients with a disease other than the one the drug is intended to treat). Sponsors typically study an unapproved drug's safety and efficacy for one indication, even if there is reason to believe that the drug would be safe and effective for other conditions.²²⁰ Some patients like Abigail Burroughs²²¹ have diseases that are not being studied in clinical trials, and may have great difficulty obtaining access to unapproved medications. For patients like these, allowing off-label expanded access may be critically important in that it offers access to individuals who cannot obtain access through clinical trials.

In addition, the intermediate-size program allows access to drugs not being developed for marketing because they are intended to treat a particularly rare

217. In its reassessment, the FDA will consider "whether it is possible to conduct a clinical study of the expanded access use," "whether providing the investigational drug for expanded access use is interfering with the clinical development of the drug," and whether the number of patients seeking access has increased such that FDA should ask the sponsor to submit an application for a treatment use program. *See Expanded Access to Investigational Drugs for Treatment Use*, 74 Fed. Reg. at 40,945.

218. *See id.* at 40,945-46.

219. *See id.*

220. *Cf.* Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 186-87 (1999) (explaining that FDA approves drugs for particular conditions).

221. *See, e.g.,* Jacobson & Parmet, *supra* note 1, at 205.

condition.²²² This change is significant because patients with rare conditions may be unfairly barred from expanded access programs if a sponsor halts clinical trials of an unapproved drug because the market for the drug is too small to be profitable.²²³ The final rule also provides for access to approved drugs that have been taken off the market or have the same active ingredient as approved drugs.²²⁴

D. Individual Use

The final rule's individual use program establishes eligibility criteria similar to the previous individual use program.²²⁵ The final rule requires that, in addition to the general requirements, two criteria must be met for a patient to gain access to an unapproved drug through the individual use program: 1) a "physician must determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease," and 2) the patient must not be able to obtain the drug through clinical trials or another expanded access program.²²⁶

The most significant new criterion in the final rule is the second one—that a patient on the individual use program must not also be eligible to receive the unapproved drug through a clinical trial or other type of expanded access program. Although the prior regulations mandated that the FDA allow individual use only when it would not interfere with clinical trials,²²⁷ the final rule's more specific requirement that individuals be allowed expanded access only if they cannot receive the unapproved drug as a participant in a clinical trial is a stronger protection. If strictly enforced, it may help to ensure that expanded access programs will not interfere with or impede the completion of clinical trials. This addition should provide reassurance to sponsors that allowing expanded access will not delay the approval process. Protecting the integrity of clinical trials in this fashion is also important to ensure that wider access to approved drugs is not delayed or prevented by the interests of those seeking expanded access to unapproved drugs.

222. See Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,944.

223. Cf. 21 C.F.R. § 312.34(b) (2008) (permitting expanded access only if the sponsor is pursuing full marketing approval with due diligence).

224. See Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,944.

225. See 21 U.S.C. § 360bbb(b) (2006); Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,943-44.

226. Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,944.

227. See 21 U.S.C. § 360bbb(b) (2006).

The final rule also creates four additional safeguards for patients.²²⁸ First, treatment is limited to “a single course of therapy for a specified duration unless the FDA expressly authorizes multiple courses or chronic therapy.”²²⁹ Second, the FDA may require a sponsor to monitor the patient receiving individual access if the treatment lasts for an extended length of time.²³⁰ Third, if more than a few patients request individual use, the FDA may require a sponsor to submit a treatment use application.²³¹ Finally, at the conclusion of the individual use, the sponsor or investigator must provide the FDA “a written summary of the results of the expanded access use, including any adverse effects.”²³²

These additional safeguards may help to ensure the safety of the individual use patients and to encourage the collection of data provided by individual use patients. However, these safeguards are still less protective than those that have been designed for clinical trials. Clinical trials are typically subject to safety monitoring by external committees such as Institutional Review Boards²³³ and Data and Safety Monitoring Committees.²³⁴ Usually, trials must be halted if significant safety concerns arise.²³⁵ These protections are not completely replicated by the FDA’s regulations for expanded access programs and may not be possible to replicate in the context of expanded access. When a few individuals obtain access at varied locations across the country without being connected to a particular trial site, the potential for rigorous safety monitoring is greatly reduced.

E. Costs that a Drug Sponsor May Recover

One of the major goals the FDA had for the final rule was to extend its

228. See Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. at 40,944.

229. *Id.*

230. *Id.*

231. *Id.*

232. *Id.*

233. 45 C.F.R. § 46.109 (2008) (requiring Institutional Review Board review of research).

234. FOOD & DRUG ADMIN., GUIDANCE FOR CLINICAL TRIAL SPONSORS: ESTABLISHMENT AND OPERATION OF CLINICAL TRIAL DATA MONITORING COMMITTEES 3-4 (2006), *available at* <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126578.pdf> (recommending Data and Safety Monitoring Boards for “large, randomized multisite studies that evaluate treatments intended to prolong life or reduce risk of a major adverse health outcome,” and for any controlled trial of any size that will compare rates of mortality or major morbidity).

235. Michael A. Morse et al., *Monitoring and Ensuring Safety During Clinical Research*, 285 JAMA 1201, 1201 (2001) (explaining the oversight function of institutional review boards and data monitoring committees or data and safety monitoring boards).

previous charging regulations to cover all types of expanded access programs and to describe more specifically the types of costs that sponsors may recover.²³⁶ Sponsors typically are allowed to charge expanded access patients for the unapproved drug for one year from the time of FDA authorization, unless the FDA approves a different time period.²³⁷ Sponsors must meet three criteria for charging patients. First, they must justify the amount they plan to charge and obtain prior written approval from the FDA.²³⁸ Second, the sponsor must provide the FDA with “reasonable assurance that charging will not interfere with developing the drug for marketing approval.”²³⁹ Third, the sponsor cannot charge patients who are not authorized to receive unapproved drugs through the expanded access program.²⁴⁰

For all three types of expanded access programs, sponsors may recover “the direct costs of making [the] investigational drug available.”²⁴¹ For treatment use and intermediate-size patient population use programs sponsors may recover some additional costs, which are described in the following table.²⁴²

Table 4: Costs that the Sponsor May Recover for Treatment Use and Intermediate-size Patient Populations ²⁴³
1) The cost of “monitoring the expanded access protocol” and other administrative costs directly associated with the expanded access.
2) The cost of complying with reporting requirements.
3) “[O]ther administrative costs directly associated with the expanded access.”

The final rule’s charging regulation offers two benefits when compared with

236. See Charging for Investigational Drugs, 74 Fed. Reg. 40,872, 40,872 (Aug. 13, 2009) (to be codified at 21 C.F.R. § 312).

237. See *id.* at 40,899.

238. See *id.*

239. For treatment use, the assurance must include at least three items: 1) “[e]vidence of sufficient enrollment in any ongoing clinical trial(s) . . . to reasonably assure FDA that the trial(s) will be successfully completed as planned”; 2) “[e]vidence of adequate progress in the development of the drug for marketing approval”; and 3) “[i]nformation submitted under the general investigational plan specifying the drug development milestones the sponsor plans to meet in the next year.” *Id.* This provision appears to safeguard against creating a novel business model in which a company only develops drugs until the expanded access phase and never seeks full approval.

240. See *id.*

241. *Id.*

242. See *id.* at 40,899-900.

243. See *id.*

the previous regulation. First, the final rule explicitly applies to all types of expanded access regulations,²⁴⁴ while the current regulations do not explicitly address permissible charging practices for individual use.²⁴⁵ Second, the final rule provides more explicit guidance for sponsors regarding what are permissible charges. For example, the proposed regulation provides specific examples of direct costs that a sponsor may recover, including “raw materials, labor, and nonreusable supplies and equipment used to manufacture the quantity of drug” and “costs to acquire the drug from another manufacturing source, and direct costs to ship and handle (e.g., store) the drug.”²⁴⁶ The extent to which these clarifications in the final rule are truly beneficial is difficult to anticipate, but as we discuss below,²⁴⁷ it is not clear that an ability to recover costs is the major bottleneck impeding access to unapproved therapy.

F. Alternative Proposals to FDA Regulations

Some commentators have argued that the existing FDA regulations overly restrict which patients are eligible for expanded access.²⁴⁸ Scholars have offered two proposals that would deregulate expanded access to varying degrees. One proposal would allow completely open, deregulated access to unapproved drugs, while the second proposal would amend the FDCA to lessen FDA control of expanded access.²⁴⁹ Both deregulation proposals emphasize the importance of patient autonomy.²⁵⁰ Incidentally, proponents of both proposals also have argued that a constitutional right to access exists and that *Abigail Alliance* was wrongly decided.²⁵¹

244. *See id.*

245. *See* 21 U.S.C. § 360bbb (2006); 21 C.F.R. § 312 (2008).

246. Charging for Investigational Drugs, 74 Fed. Reg. at 40,899. The final rule also provides examples of indirect costs that sponsors may not recover, including “costs for facilities and equipment used to manufacture the supply of investigational drug, but that are primarily intended to produce large quantities of drug for eventual commercial sale[] and . . . other costs that would be incurred even if the . . . treatment use for which charging is authorized did not occur.” *Id.*

247. *See* discussion *infra* Section IV.B.

248. *See* Meghan K. Talbott, *The Implications of Expanding Access to Unapproved Drugs*, 35 J.L. MED. & ETHICS 316, 318 (2007); Vale, *supra* note 200, at 2160.

249. *See, e.g.,* Richard A. Epstein, *The Erosion of Individual Autonomy in Medical Decisionmaking: Of the FDA and IRBs*, 96 GEO. L.J. 559, 577-80 (2008) (describing open access and the amendments to the FDCA); Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. REG. 401, 420-22 (1994) (describing open access, existing regulations, and a contractarian model).

250. *See* Epstein, *supra* note 249; Salbu, *supra* note 249.

251. *See, e.g.,* Epstein, *supra* note 249, at 577; Robert M. Harper, *A Matter of Life and Death: Affording Terminally Ill Patients Access to Post-Phase I Investigational New Drugs*, 12 MICH. ST.

1. Open Access

A few scholars have argued for open access, in which patients may elect to take any unapproved drug that a company will provide and the FDA does not regulate expanded access at all.²⁵² Open access supporters have acknowledged that most unapproved drugs are eventually proven ineffective or unsafe.²⁵³ However, they argue that an open access model does not threaten the state's interest in promoting public health because the state's interest is limited when "the individual is terminally ill."²⁵⁴ Moreover, proponents of open access contend that the clinical trials process fails to achieve the public health goal of producing a market of safe and efficacious drugs.²⁵⁵ Consequently, they argue that the emphasis of the expanded access debate should not be on the state's public health interests but on the importance of patient autonomy.²⁵⁶ Open access supporters claim that patients are the best parties to decide whether an unapproved drug is an appropriate treatment and in their best interests.²⁵⁷

U. J. MED. & L. 265, 286-87 (2008).

252. See Epstein, *supra* note 249, at 574-80; Salbu, *supra* note 249, at 420-22. Salbu actually supports a "contractarian" model of access, which he distinguishes from open access on the assumption that open access would require drug companies to provide unapproved drugs to patients who want them. See Salbu, *supra* note 249, at 429-30. However, other scholars do not advocate an open access model that would require companies to provide unapproved drugs. Instead, they characterize open access the way Salbu characterizes the contractarian model—as a model allowing parties to contract for the sale or purchase of unapproved drugs without government interference or regulation. See Epstein, *supra* note 249, at 574-80. Thus, we do not distinguish between open access and contractarian models.

253. See Epstein, *supra* note 249, at 578.

254. Salbu, *supra* note 249, at 430. Salbu appears to limit this argument to cases in which the terminally ill patient also has no FDA-approved treatments; it is not clear that Epstein would similarly limit the argument.

255. See Epstein, *supra* note 249, at 578 ("It is easy to point to particular cases in which a fuller trial has indicated the imprudence of resorting to certain kinds of therapies. But a fuller analysis would also have to include those cases in which the gold-standard approach *confirmed* the informal field judgment but nonetheless delayed the delivery of the treatment to the market."); Salbu, *supra* note 249, at 421 ("Open-access arguments are further strengthened by the claim that the stringent drug review processes of the 1962 Amendments fail to achieve the ultimate goal of the paternalistic model: the pursuit of public health and safety."). According to open access supporters, open access to unapproved drugs may even help to enhance clinical trials by providing information about use of drugs in a larger number of patients. See Salbu, *supra* note 249, at 432.

256. Epstein, *supra* note 249, at 579.

257. See *id.*; see also Salbu, *supra* note 249, at 420 ("[T]he open-access model is built on a vision of unconstrained patient autonomy and self-determination.").

2. The ACCESS Act

Several commentators have argued that enacting the Access, Compassion, Care, and Ethics for Seriously Ill Patients Act (ACCESS Act) would best provide terminally ill patients' access to unapproved drugs.²⁵⁸ The ACCESS Act, first introduced in the Senate in 2005, would amend the FDCA to create a tiered approval process for drugs.²⁵⁹ The ACCESS Act was intended to offer a compromise position between complete patient autonomy and some FDA control of the expanded access process.²⁶⁰

Under the ACCESS Act, if Phase 1 clinical trials provided preliminary evidence of effectiveness and safety of a drug, and if the drug company was actively pursuing drug approval, the FDA could approve the drug for limited marketing.²⁶¹ The FDA could also permit the company to sell the drug for a profit.²⁶² Patients seeking access to drugs prior to full marketing approval would be required to waive their right to file suit against a drug company.²⁶³

Supporters, including Abigail Alliance, claim that adopting the ACCESS Act would appropriately balance individual autonomy and the public health need for safe and effective drugs and would also address some of the practical problems associated with expanded access programs.²⁶⁴ According to its proponents, the ACCESS Act would not interfere with enrollment in clinical trials because, in order to be eligible for early access, patients have to exhaust all available treatment and clinical trial options.²⁶⁵ ACCESS Act supporters argue

258. See Harper, *supra* note 251, at 286-87; see also Amy Heverly, *Abigail Alliance is Not the End: A Legislative Solution to a Human Problem*, 12 LEWIS & CLARK L. REV. 825, 842-47 (2008) (advocating legislation consistent with the ACCESS Act with some modifications); Linda Katherine Leibfarth, Note, *Giving the Terminally Ill Their Due (Process): A Case for Expanded Access to Experimental Drugs through the Political Process*, 61 VAND. L. REV. 1281, 1283 (2008) (endorsing the ACCESS Act with some modifications).

259. Access, Compassion, Care, and Ethics for Seriously Ill Patients Act, S. 1956, 109th Cong. (2005); see Harper, *supra* note 251, at 287.

260. See Epstein, *supra* note 249, at 577-78 ("It is clear that the structure of this bill is meant to compromise between the demands for individual access and the demands for public protection.").

261. See Harper, *supra* note 251, at 287 (noting that this option is available for sponsors seeking full marketing approval); see also Access, Compassion, Care, and Ethics for Seriously Ill Patients Act, H.R. 6270, 110th Cong. (2008).

262. See H.R. 6270.

263. See *id.*

264. See Harper, *supra* note 251, at 290.

265. See Harper, *supra* note 258, at 289-90; see also Heverly, *supra* note 258, at 844 (arguing that the ACCESS Act will not interfere with clinical trial enrollment if it is modified such that only

that it will increase drug companies' incentives to provide expanded access by allowing them to profit from expanded access sales.²⁶⁶ The ACCESS Act is also intended to decrease drug companies' disincentives to provide access by requiring patients to waive liability against drug companies and physicians administering the drugs.²⁶⁷

The ACCESS Act is the only proposal that directly addresses physician liability.²⁶⁸ Under the FDA's final rule, physicians who treat patients with unapproved drugs through expanded access protocols would be responsible for meeting various regulatory requirements, such as reporting adverse events.²⁶⁹ Ordinarily, physicians may be sued under any of the theories common to research-related litigation or under theories of malpractice for treating patients with unapproved drugs.²⁷⁰ In contrast to the FDA's regulations, the ACCESS Act would require patients to waive their right to hold physicians liable for adverse events that occur during treatment through an expanded access program.²⁷¹ It is not clear whether the ACCESS Act would also waive physicians' liability for failing to meet regulatory reporting requirements.²⁷²

These proposals for greatly expanding access to unapproved therapy would have a number of negative downstream consequences that their proponents do not fully acknowledge. In light of these consequences, we argue in the next section that these proposals are not in society's interest and that access to

the sickest patients are eligible and personal physicians cannot make clinical trial eligibility determinations); Leibfarth, *supra* note 258, at 1313-14 (arguing that the ACCESS act will not interfere with clinical trial enrollment if FDA promulgates additional regulations prohibiting patients currently enrolled in a clinical trial from leaving the trial to receive expanded access to a drug).

266. See Heverly, *supra* note 258, at 846; Abigail Alliance Website, *supra* note 6.

267. See Harper, *supra* note 251, at 289; see also Heverly, *supra* note 258, at 846 (arguing for allowing drug companies to profit from early access sales, but against a complete waiver of sponsor liability); Leibfarth, *supra* note 258, at 1311-13 (supporting the profit and waiver provisions, but arguing for some marketing restrictions additional to those in the ACCESS Act).

268. See H.R. 6270.

269. See *id.*

270. See Talbott, *supra* note 248, at 317.

271. See H.R. 6270.

272. See *id.* ("No claim or cause of action against a . . . physician who . . . supplies, distributes or prescribes a product subject to an approved Compassionate Investigational Access application shall exist in any Federal or State court for claims of property, personal injury, or death caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, efficacy, or use of a drug, biological product, or device subject to an approved Compassionate Investigational Access application.").

unapproved drugs should be offered only under very limited circumstances.

IV. AVOIDING A POLICY OF EXCEPTIONS: THE ARGUMENT FOR VERY LIMITED ACCESS TO EXPERIMENTAL THERAPY

There are two reasons why access to experimental therapies should be granted only in very limited situations, if at all. First, because there are significant safety and efficacy concerns about unapproved drugs, patients should not receive access to those drugs at early stages outside the context of clinical trials. Second, the solutions proposed attempt to further the interests of a few individuals at significant cost to society. Rather than drafting policy around these exceptional cases, it would be better to reform the general approval process for drugs. Our focus should be on testing interventions efficiently but carefully and making them available to the market as soon as that can be safely achieved.

A. Highly Uncertain Safety and Efficacy

Access to unapproved therapy should be limited because of the considerable uncertainty about the safety and efficacy of unapproved drugs. It is difficult to overstate the importance of data in determining whether and when medical interventions should be made available to the public. There are several examples of drugs or procedures that were disseminated without being tested sufficiently and resulted in large costs to our health care system, resulting in many patients being subjected to great risk for no clear benefit.²⁷³ The most prominent example is a treatment for breast cancer—high dose chemotherapy and autologous bone marrow transplant—that was effectively adopted as the standard of care before it could be validated in clinical trials.²⁷⁴ Clinicians and patients were so convinced of its effectiveness that clinical trials were delayed for many years. Yet, when clinical trials were finally conducted, it became clear that the risky procedure offered no benefit over standard, less-risky chemotherapeutic regimens and had

273. See generally David Atkins et al., *Making Policy When the Evidence is in Dispute*, 24 HEALTH AFF. 102 (2005) (discussing the controversies surrounding screening for prostate cancer, high-dose chemotherapy and bone marrow transplant for breast cancer, antibiotic use, and newborn hearing screening).

274. See generally Cynthia M. Farquhar et al., *High Dose Chemotherapy for Poor Prognosis Breast Cancer: Systematic Review and Meta-Analysis*, 33 CANCER TREATMENT REVS. 325 (2007); Michelle M. Mello & Troyen A. Brennan, *The Controversy Over High-Dose Chemotherapy with Autologous Bone Marrow Transplant For Breast Cancer*, 20 HEALTH AFF. 101 (2001); H.G. Welch & J. Mogielnicki, *Presumed Benefit: Lessons from the American Experience with Marrow Transplantation for Breast Cancer*, 324 BRIT. MED. J. 1088 (2002).

even caused harm.²⁷⁵ Another example is found in knee surgery—after many years of use, arthroscopic lavage or debridement for osteoarthritis of the knee was found to be no more effective than placebo surgery.²⁷⁶

Of all of the drugs that are tested in humans, the vast majority of potential therapeutic agents never make it through the approval process.²⁷⁷ In Europe and the United States, for every nine compounds that undergo drug testing, only one will ultimately receive regulatory approval.²⁷⁸ A given therapy may fail for a number of reasons, but the main reason that drugs fail is that they simply do not work.²⁷⁹ In 2000, the majority of drug failures were due to lack of efficacy, with safety concerns a close second.²⁸⁰ The drug approval process typically involves three phases of testing,²⁸¹ and the Abigail Alliance sought access to unapproved drugs after the first phase. Significantly, however, over 60% of treatments fail after Phase 2,²⁸² and as many as 45% fail even after entering the final phase of testing.²⁸³

Much of the litigation around expanded access involves patients suffering from cancer. However, cancer presents unique therapeutic challenges, and approval rates for oncology drugs are even lower than the average; only 5% of oncology drugs ultimately receive approval.²⁸⁴ Oncology drugs are also unique

275. See, e.g., Farquhar et al., *supra* note 274, at 332 (reporting that there were sixty-five deaths attributed to treatment toxicity among women who received the high dose chemotherapy treatment and only four such deaths among the women in control groups).

276. Shira Bender, Lauren Flicker & Rosamond Rhodes, *Access for the Terminally Ill to Experimental Medical Innovations: A Three-Pronged Test*, 7 AM. J. BIOETHICS 3, 4 (2007).

277. Robert Kinders et al., *Phase 0 Clinical Trials in Cancer Drug Development: From FDA Guidance to Clinical Practice*, 7 MOLECULAR INTERVENTIONS 325, 326 (2007) (“[L]ess than ten percent of Investigational New Drug (IND) applications for novel molecules [move] beyond the earliest stage of development.”).

278. Ismail Kola & John Landis, *Can the Pharmaceutical Industry Reduce Attrition Rates?*, 3 NATURE REVIEWS. DRUG DISCOVERY 711, 711 (2004).

279. Kinders et al., *supra* note 277, at 263.

280. Kola & Landis, *supra* note 278, at 712 (noting that together, efficacy and safety problems accounted for approximately 60% of all failures).

281. *Id.* at 712-13.

282. *Id.* at 712.

283. *Id.*

284. Kinders et al., *supra* note 277, at 326 (“[C]urrent approval rates for new oncology drugs are estimated to be no more than 5%”); Kola & Landis, *supra* note 278, at 712; see also Eric K. Rowinsky, *Curtailing the High Rate of Late-Stage Attrition of Investigational Therapeutics Against Unprecedented Targets in Patients with Lung and Other Malignancies*, 10 CLINICAL CANCER RES. 4220s, 4221s (2004) (“Even with more than 500 oncology therapeutics in active development, only a small fraction are achieving regulatory approval each year”).

because they are more likely than other classes of drugs to fail late in the testing process.²⁸⁵ Of all oncology drugs that seem promising after completing Phase 1 trials, only about one third eventually obtain approval.²⁸⁶ Thus, Abigail Alliance's proposal to allow access after Phase 1 trials would be especially problematic with regard to oncology drugs.

Even before controversy arose over allowing access to unapproved therapy, there was a longstanding debate in the literature about the ethics of including patients in Phase 1 trials. Many have argued that given the low prospects for benefit, most patients' expectations are unreasonable and it may not be ethical to allow them to enroll in research.²⁸⁷ Several studies have shown that patients in Phase 1 oncology trials are very unlikely to benefit from the study treatment—less than 6% show some response to the study treatment.²⁸⁸ One comprehensive study involving 460 Phase 1 oncology trials conducted over a period of nine years found that only 11% of research participants had a complete or partial response to experimental treatment, and most participants had no response to experimental treatment.²⁸⁹ Although clinical trials offer some chance of benefit, most people have no measurable response from receiving experimental therapy even within trials.

In addition to providing only uncertain benefits, clinical trials also carry significant risks. Approximately 38% of oncological research subjects experience

285. See, e.g., Bruce Booth, Robert Glassman & Philip Ma, *Oncology's Trials*, 2 NATURE REV. DRUG DISCOVERY 609, 609 (2003) (noting that oncology drugs "have higher average success rates than other therapeutic areas in early-stage trials (that is, Phase I and Phase II), [but] . . . a lower average success rate than other therapeutic areas at Phase III"). Oncology drugs that survive Phase 1 testing go on to fail at Phase 2 in very high rates—70% of all oncology treatments that enter Phase 2 fail at this stage. Of the oncology treatments that go on to Phase 3 trials, 59% fail at the final stage of testing. Kola & Landis, *supra* note 278, at 712.

286. Benjamin J. Falit & Cary P. Gross, *Access to Experimental Drugs for Terminally Ill Patients*, 300 JAMA 2793, 2793 (2008) (citing Joseph A. DiMasi & Henry G. Grabowski, *Economics of New Oncology Drug Development*, 25 J. CLINICAL ONCOLOGY 209 (2007)).

287. See A. Italiano et al., *Treatment Outcome and Survival in Participants of Phase I Oncology Trials Carried Out from 2003 to 2006 at Institut Gustave Roussy*, 19 ANNALS ONCOLOGY 787, 787 (2007) (noting that "many authors have expressed ethical concerns about phase 1 cancer research").

288. See *id.*

289. Elizabeth Horstmann et al., *Risks and Benefits of Phase 1 Oncology Trials, 1991 Through 2002*, 352 NEW ENG. J. MED. 895, 898-99 (2005). A partial response is defined as "an overall 50 percent reduction in the tumor, measured as the sum of the products of the two longest diameters . . . or as an overall 30 percent reduction in tumor size, measured as the sum of the longest diameters." *Id.* at 897.

toxic events,²⁹⁰ and about 14% experience the most serious category of toxic events.²⁹¹ Approximately one out of every two hundred research subjects in oncology trials dies from treatment-related side effects.²⁹² Risks such as these are not rendered trivial for patients seeking access to experimental therapy because they have few options left. People who are terminally ill may suffer more or even die sooner if they are exposed to drugs with significant and uncertain risks,²⁹³ and these are important reasons to limit access to experimental therapy.

B. Wider Access Proposals Will Not Solve Existing Problems and Are Too Costly for Society To Adopt

The existing proposals for increasing access to experimental therapy are likely to cause more problems than they solve. When powerful groups are formed to represent sympathetic interests, there is always the potential that the response will be out of proportion to the size of the problem and the risk that the new policy will devolve into a policy of exceptions.²⁹⁴ Existing proposals for expanded access are problematic for several reasons: 1) the great difficulty in limiting the scope of expanded access programs; 2) the failure of existing proposals to adequately address drug companies' incentives; 3) the fact that addressing sponsors' concerns about liability comes at too great a cost to patients; 4) the danger of slowing the approval process; 5) the risks of creating of potentially dangerous markets in unapproved therapies; and 6) the negative consequences of finding ways to fund expanded access programs.

First, there is a danger that a policy of providing access cannot be effectively limited simply by referring to "terminally ill patients" or patients with "serious" diseases. Although a common legal definition of a terminally ill patient is someone who has six months to live, this is very difficult to predict.²⁹⁵ It may

290. Italiano et al., *supra* note 287, at 791.

291. Horstmann et al., *supra* note 289, at 899.

292. Horstmann et al., *supra* note 289, at 899 (finding a treatment-related mortality rate of 0.49%); Italiano et al., *supra* note 287, at 787 (finding a potentially treatment-related mortality rate of approximately 0.5%); Thomas G. Roberts et al., *Trends in the Risks and Benefits to Patients with Cancer Participating in Phase I Clinical Trials*, 292 JAMA 2130, 2136 (2004) (finding a treatment-related mortality rate of 0.54%).

293. See Arthur Caplan, *Is It Sound Public Policy To Let the Terminally Ill Access Experimental Medical Innovations?*, AM. J. BIOETHICS, June 2007, at 1, 2.

294. See, e.g., Mello & Brennan, *supra* note 274, at 106 (observing that "[a] powerful breast cancer lobby succeeded in persuading or, in some states, forcing insurers to provide coverage for HDC-ABMT at a time when research into the treatment's effectiveness was still in its early stages").

295. See Caplan, *supra* note 293, at 2 (citing federal statute governing access to Social

also be difficult to justify distinguishing patients suffering from very debilitating but chronic diseases from those with terminal illnesses.²⁹⁶

Second, drug companies, not the FDA, are often the bottleneck for access to unapproved drugs,²⁹⁷ and addressing drug companies' incentives and interests adequately is far too costly. The FDA does not have the authority to require that drug companies provide expanded access.²⁹⁸ Drug companies may be reluctant to provide expanded access for a variety of reasons, including concerns that expanded access will place the company at increased risk for litigation from patients taking unapproved drugs, delay or prevent drug approval because of adverse events, and fail to offer enough financial incentive to merit the investment.²⁹⁹ A drug company can always choose to spend more on marketing approved drugs and is more likely to be able to obtain profits from these efforts, rather than just recovering costs. Of course, there may be public relations benefits from running an expanded access program, but these benefits would have to be significant to offset the costs of providing access to unapproved therapy.

Third, proposals to address sponsors' concerns about liability may endanger patients. The problem for sponsors is that even if most patients' lawsuits are not ultimately successful, they still cause drug companies to incur the financial costs of legal representation and, possibly, to endure negative publicity.³⁰⁰

Security benefits for children, hospice care reimbursement by Medicare, and the right to use assisted suicide in the state of Oregon under the Death with Dignity Act).

296. *See id.*

297. *See, e.g.,* Annas, *supra* note 167, at 411 (“[T]he major bottleneck in the compassionate-use program has never been the FDA. The manufacturers have no incentives to make their investigational products available outside clinical trials.”); Menikoff, *supra* note 195, at 1060 (“[T]he FDA appears to almost uniformly approve requests for compassionate-use access to a drug . . .”). *See also* Part II, *supra*, in which we discuss several cases where drug companies have declined to provide access to patients who would otherwise qualify under FDA regulations.

298. *See* 21 U.S.C. § 360bbb (2006) (providing no authority for FDA to require sponsors to provide expanded access); 21 C.F.R. § 312.34 (2008) (allowing but not requiring that sponsors provide expanded access to eligible patients); *see also* Marcee, *supra* note 215, at 453 (noting that Congress and FDA allow sponsors to choose whether to provide expanded access).

299. *See* Peter M. Currie, *Restricting Access to Unapproved Drugs: A Compelling Government Interest?*, 20 J.L. & HEALTH 309, 319 (2006) (acknowledging validity of these concerns but questioning whether “these fears justify government action to restrict access to Phase I experimental drugs”); Richard A. Epstein, *supra* note 249, at 577-80; Marcee, *supra* note 215, at 450-55; Menikoff, *supra* note 195, at 1060-64; Talbott, *supra* note 248, at 318; Vale, *supra* note 200, at 2157-74.

300. *See* Joanna R. Cerino, Comment, *The Statutory Limits of Compassion: Can Treatment INDs Provide Meaningful Access to Investigational Drugs for the Terminally Ill?*, 27 TEMP. J. SCI. TECH. & ENVTL. L. 79, 94 (2008).

Consequently, one commentator has recommended that FDA regulations contain a waiver provision that prohibits expanded access patients from “later suing for adverse and even deadly effects.”³⁰¹ If sponsors were certain that patients who received unapproved drugs would not hold them liable for negative outcomes, sponsors might be more willing to provide wider expanded access.³⁰² Some advocates for FDA’s final rule also have explicitly recommended waiving liability against physicians.³⁰³

Although a blanket waiver of liability for injuries related to expanded access would eliminate the uncertainty regarding liability resulting from providing access, it raises significant concerns. Pharmaceutical companies should not be able to obtain waivers for grossly negligent or intentional actions for several reasons.³⁰⁴ If patients are unable to hold drug companies liable for their products, drug companies may not use sufficient caution when deciding whether to provide patients risky products.³⁰⁵ Also, because sponsors conduct a great deal of preliminary research (including research that is never published), they may be in the best position to evaluate the limited data that is available about drugs at this stage and therefore in the best position to decide when to conduct clinical trials that will expose people to those risks.³⁰⁶ Those in charge of research and manufacturing should be held responsible if they test experimental therapies without sufficient data or in excessively risky circumstances. Finally, in an environment in which many individuals do not have health insurance,³⁰⁷ providing sponsors with immunity from lawsuits arising from expanded access injuries may leave uninsured individuals who are injured with no access to the

301. *See id.*

302. *See id.*

303. Talbott, *supra* note 248, at 317-18 (identifying physician liability as a problem, but not recommending liability waivers).

304. *See* Heverly, *supra* note 258, at 847 (proposing that any waivers of liability for early access to pharmaceuticals should allow patients to retain their right to hold sponsors liable for grossly negligent or malicious acts). Patient waivers of liability would not preclude FDA from holding sponsors liable for failing to meet regulatory requirements, such as sponsors’ obligation to report adverse events to FDA.

305. *See* Bender et al., *supra* note 276, at 5.

306. *See* *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 107 (E.D.N.Y. 2008) (“Because drug manufacturers often delay or suppress negative results from clinical trials they or their affiliated research institutions conduct, doctors, formulary committees, and policy makers [may base] their decisions on an unrepresentative fraction of the available scientific evidence.”) (internal quotation marks omitted).

307. *See* U.S. Census Bureau, Health Insurance Coverage: 2008, <http://www.census.gov/hhes/www/hlthins/hlthin08/hlth08asc.html> (last visited Nov. 18, 2009) (reporting that approximately 15% of the U.S. population does not have health insurance).

health care they need.³⁰⁸ Thus, waiving sponsor or physician liability in any significant way may put some patients in a very difficult position.

Fourth, expanded access has the potential to slow the approval process. Expanded access may reduce clinical trial enrollment, which in turn will slow the completion of the clinical trials needed for approval.³⁰⁹ If potential subjects had the choice to either enroll in a clinical trial with a placebo control and a 50% chance of obtaining treatment or enter an expanded access program knowing that they would receive access to the unapproved therapy, few would choose to enroll in clinical trials. Patients may have an incentive to try to manipulate the system and render themselves ineligible for clinical trials in order to obtain treatment through an expanded access program.³¹⁰ In addition, sponsors also have legitimate concerns that expanded access programs will result in more adverse events, which could in turn delay or even prevent approval.³¹¹ Finally, expanded programs will result in a larger amount of data for the FDA to review, potentially slowing the approval process.³¹² Delays to the approval process for drugs eventually found to be safe and effective not only affect sponsors' bottom lines, but, more importantly, will negatively affect the public health.³¹³

According to commentators, sponsors' fears about delays to the approval process are exacerbated by the lack of clarity in the regulations.³¹⁴ One commentator has recommended that the FDA promulgate specific regulations as to the extent a patient receiving therapy through an expanded access program will affect "the FDA's determination of the drug's safety and effectiveness in the decision to grant or deny marketing approval."³¹⁵ In its 2009 final rule, the FDA did not provide specific regulations regarding the analysis of data from the expanded access patients.³¹⁶ However, the FDA made clear that it anticipates

308. Cf. John D. Winter, *Is It Time To Abandon FDA's No Release from Liability Regulation for Clinical Studies?*, 63 FOOD & DRUG L.J. 525, 530 (2008) (describing compensation funds, such as the vaccine injury compensation fund, that require injured individuals to waive liability in order to be compensated for their injuries). Of course, if U.S. citizens were universally covered for their health care, an injury compensation fund would not be needed to justly institute waivers of liability.

309. See Cerino, *supra* note 300, at 94, Menikoff, *supra* note 195, at 1062-64.

310. Tuma, *supra* note 4, at 22.

311. See *id.* at 23.

312. See *id.* (noting that expanded access programs will create more data regarding adverse events for FDA to review).

313. Cf. Bender et al., *supra* note 276, at 4 (noting that large expanded access programs may delay clinical trial results that ultimately show the drug is ineffective).

314. See Cerino, *supra* note 300, at 94.

315. *Id.*

316. See Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. 40,900, 40,905 (Aug. 13, 2009) (to be codified at 21 C.F.R. §§ 312, 316).

expanded access data will be more useful for safety assessments than for efficacy assessments because without a control group, it is difficult to derive efficacy information from expanded access data.³¹⁷ Moreover, the FDA stated that it was unaware of any case in which adverse event data from expanded access programs caused a drug to be denied approval,³¹⁸ suggesting that sponsors' fears that expanded access data will prevent approval of their drugs may not be justified. Although the FDA has offered limited clarification regarding how it will evaluate expanded access data,³¹⁹ it is hard to imagine a new process for reviewing additional data that would not cause significant delays relative to current approval times.

Fifth, creating financial incentives for manufacturers to make unapproved therapies widely available could lead to markets in selling unapproved therapies. The costs of drug development and clinical trials are significant, and many drugs do not make it to final approval.³²⁰ Were the FDA to allow much wider access to unapproved drugs, and if pharmaceutical companies could make profits at earlier stages in the development process, companies would face perverse market incentives. Pharmaceutical companies could devise alternative and potentially lucrative business models selling unapproved drugs to terminally ill patients with few, if any, alternatives.³²¹ The prospect of a market with such a high potential for exploitation of the sickest and most vulnerable patients is troubling.

Finally, and perhaps most significantly, proposals to incentivize drug companies to provide expanded access in various ways are very problematic. Scholars have argued that drug companies' unwillingness to provide expanded access is partially caused by the costs associated with providing expanded access.³²² One commentator has advocated that sponsors be required to provide

317. *See id.*

318. *See id.*

319. *See id.*

320. *See* Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003) (finding that the total cost of pre-approval research and development of a new drug was \$802 million in 2000 dollars); Joseph A. DiMasi, *Risks in New Drug Development: Approval Success Rates for Investigational Drugs*, 69 CLINICAL PHARMACOLOGY & THERAPEUTICS 297, 303 fig.7 (2001) (finding that only 24% of drugs that enter Phase 1 trials are eventually approved).

321. *See, e.g.*, Judith Randal, *Investigational Drug Access Taken to Task in Lawsuit Against FDA*, 95 J. NAT'L CANCER INST. 1818, 1820 (2003) ("You only have to look to the world of unproven nutritional products and dietary supplements . . . to realize that Tier 1 approvals would give pharmaceutical firms less incentive to invest in research and a lot of incentive to engage in misleading advertising and promotion." (quoting Bob Erwin, President, Marti Nelson Cancer Found.) (internal quotation marks omitted)).

322. *See* Cerino, *supra* note 300, at 94-95; Marcee, *supra* note 215, at 452-53; Tuma, *supra*

expanded access as part of the drug approval process, so that sponsors cannot choose to restrict expanded access because of cost.³²³ However, this solution raises concerns about government intrusion on corporate autonomy.³²⁴ There may be cases in which it is highly inefficient for sponsors to provide access at an early stage or where a sponsor feels that safety concerns suggest that early access would be particularly risky. A blanket requirement that all sponsors provide expanded access as a condition of obtaining drug approval seems ill-considered.

Other scholars have proposed various mechanisms to fund expanded access programs as a means of incentivizing sponsors. However, successfully decreasing sponsors' expanded access costs while also appropriately using limited health care resources is a particularly difficult problem for the expanded access system. Proposed solutions include: 1) providing incentives to sponsors in the form of delayed profits that are only released upon FDA approval,³²⁵ 2) offering drug companies extended market exclusivity for a drug that is eventually approved by the FDA,³²⁶ 3) creating a private foundation to subsidize the costs of unapproved drugs,³²⁷ or 4) requiring health insurance companies to pay for unapproved drugs obtained through expanded access.³²⁸ The most complex proposal is to allow sponsors to charge expanded access patients full market price, as long as they place the proceeds in excess of direct costs in an interest-bearing escrow account until the drug is approved.³²⁹ If a drug is ultimately approved, the sponsor would gain access to the profits in the account.³³⁰ If a drug

note 4, at 19, 22; Vale, *supra* note 200, at 2165. *But see* Menikoff, *supra* note 195, at 1060-62 (arguing that fears about interference with clinical trials and FDA approval, not cost concerns, motivate drug companies' reluctance to provide expanded access).

323. *See* Marcee, *supra* note 215, at 452-53; *cf.* Nicole E. Lombard, Note, *Paternalism vs. Autonomy: Steps Toward Resolving the Conflict Over Experimental Drug Access Between the Food and Drug Administration and the Terminally Ill*, 3 J. HEALTH & BIOMED. L. 163, 185 (2007) (advocating "active involvement" of the FDA in pressuring drug companies to provide expanded access, but not explicitly advocating that the FDA require companies to provide expanded access).

324. *Cf.* Salbu, *supra* note 249, at 429-30 (discussing the potential negative effects of government mandated expanded access to HIV drugs).

325. *See* Falit & Gross, *supra* note 286, at 2794-95; Vale, *supra* note 200, at 2165-71.

326. *See* Vale, *supra* note 200, at 2165-71.

327. Cerino, *supra* note 300, at 94-95 (citing Frank Burroughs, co-founder of Abigail Alliance).

328. *Cf.* Sharona Hoffman, *A Proposal for Federal Legislation To Address Health Insurance Coverage for Experimental and Investigational Treatments*, 78 OR. L. REV. 203, 206-07 (1999) (proposing that insurance companies be required to pay for treatments provided through Phase III trials).

329. *See* Falit & Gross, *supra* note 286, at 2794.

330. *See id.*

is ultimately not approved, the profits from sales of that drug would be transferred to the federal government for health-related use.³³¹

However, many of these proposals to decrease sponsor's expanded access costs may not be adequate to incentivize sponsors to provide access. Even if sponsors sell unapproved drugs at a profit, they would likely not gain a net profit large enough to make providing expanded access attractive.³³² It is not clear that there are a large number of patients who would be financially able to purchase unapproved drugs.³³³ And even if a relatively large expanded access market did exist, drug companies might not be able to meet demand.³³⁴ Early in the drug development process, sponsors have limited production capacity because sponsors are reluctant to scale up production of a drug until Phase 3 trials, when the drug is more likely to be approved.³³⁵ In addition, drug companies would likely not charge "full price" for expanded access drugs because of fears that the public would react negatively to high prices for unapproved drugs with uncertain risks and benefits, especially in the case of terminally ill patients in highly sympathetic situations.³³⁶ Finally, since the likelihood of any given drug being approved is low, the escrow account and market exclusivity proposals may not provide drug companies with a significant incentive to provide expanded access early in clinical trials.³³⁷

In addition to concerns about sponsors' costs, commentators have raised concerns about patients' ability to pay for expanded access.³³⁸ Even if drug companies only recover the direct costs of expanded access drugs, drugs may still be too costly for some patients. Furthermore, limiting access to those who can afford to pay for it raises serious concerns about equity. Consequently, some

331. *See id.*

332. *See* Currie, *supra* note 299, at 321-23; Okie, *supra* note 14, at 440.

333. *See* Cerino, *supra* note 300, at 92, 94-95; Menikoff, *supra* note 195, at 1065-66; Okie, *supra* note 14, at 440.

334. *See* Currie, *supra* note 299, at 322; Okie, *supra* note 14, at 440.

335. *See* Currie, *supra* note 299, at 322; *see also* Kola & Landis, *supra* note 278, at 711-12 (finding that approximately 11% of drugs that enter Phase 1 trials, 38% of drugs that enter Phase 2 trials, and 55% of drugs that enter Phase 3 trials are eventually approved).

336. Okie, *supra* note 14, at 440 (quoting a representative of Pharmaceutical Research and Manufacturers of America as saying that drug companies "certainly couldn't charge full price" for post-Phase 1 drugs); *cf.* KAISER FAMILY FOUND., KAISER PUBLIC OPINION SPOTLIGHT, VIEWS ON PRESCRIPTION DRUGS AND THE PHARMACEUTICAL INDUSTRY 8 (2008), http://www.kff.org/spotlight/rxdrugs/upload/rx_drugs.pdf (finding that 74% of the U.S. public believes that the pharmaceutical industry makes "too much profit").

337. *See* DiMasi, *supra* note 320 (reporting that 20% of drugs that enter Phase 1 clinical trials are eventually approved); Kola & Landis, *supra* note 278, at 711.

338. *See* Cerino, *supra* note 300, at 94-95; Hoffman, *supra* note 328, at 206-07.

commentators have argued that health insurance should pay for expanded access when a patient has no other treatment option.³³⁹

This proposed solution would generate quite a few problems. In a context of limited health care resources, paying for potentially unsafe and ineffective drugs may not be the most appropriate use of the resources.³⁴⁰ For example, in Britain, the National Health Service does not cover some drugs that are approved, but also are expensive and provide relatively short extensions of lifespan, because purchasing such drugs is not the most effective use Britain's limited health care resources.³⁴¹ Creating a private foundation to subsidize patients' purchase of unapproved drugs similarly raises questions about how to wisely use finite resources, and, moreover, seems unlikely to occur.³⁴² Awarding market exclusivity extensions to sponsors who provide expanded access would exacerbate concerns about health care costs and resource allocation. Although drug companies would provide unapproved drugs to expanded access patients free of charge under the market exclusivity proposal, sponsors might be able to pass on the costs of expanded access programs to future patients in the form of higher drug prices.³⁴³

Devising a system that could increase health care costs for uncertain benefit seems unwise. The price of drugs already contributes significantly to increases in health care costs.³⁴⁴ The United States has the most expensive health care system in the world and spends more per person on health care than any other country.³⁴⁵ Spending on health care has increased above the rate of inflation for a number of years.³⁴⁶ High costs have led to decreased access to health care for many,³⁴⁷ and studies have shown that lack of insurance may result in as many as 18,000

339. See Hoffman, *supra* note 328, at 206-207.

340. See Falit & Gross, *supra* note 286, at 2795.

341. See Gardiner Harris, *British Balance Benefit vs. Cost of Latest Drugs*, N.Y. TIMES, Dec. 2, 2008, at A1.

342. *But see* Cerino, *supra* note 300, at 94-95 (arguing that a private foundation should be created).

343. See Vale, *supra* note 200, at 2165-71.

344. See, e.g., Thomas Bodenheimer, *High and Rising Health Care Costs. Part 2: Technological Innovation*, 142 ANNALS INTERNAL MED. 932, 932 (2005) (noting that technological innovations, including pharmaceutical innovation, contribute to rising health care costs); Zijun Wang, *The Convergence of Health Care Expenditure in the US States*, 18 HEALTH ECON. 55, 69 (2008) (finding that the cost of prescription drugs was one of the most significant factors in explaining divergence in health care costs in state programs).

345. See Bodenheimer, *supra* note 344, at 932.

346. *Id.*

347. Ezekiel Emanuel, *The Cost-Coverage Tradeoff: "It's Health Care Costs, Stupid,"* 299 JAMA 947, 947 (2008).

increased deaths a year.³⁴⁸ Rising health care expenditures also have significant economic consequences more generally, because they make it difficult for American firms to remain competitive in a global marketplace.³⁴⁹ These problems have led to significant, if unpredictable, movement in the direction of health care reform.³⁵⁰ If health care reform efforts are to succeed, there is little, if any, room for adding to our enormous health care expenditures.³⁵¹ The drive for reform may therefore have created an inhospitable climate for expanding access to unproven therapy in a way that increases health care costs.

V. PROPOSAL FOR REFORM: CHANGING CLINICAL TRIALS

The *Abigail Alliance* case and other claims for access involve terminally ill people who were unable to obtain access to clinical trials. One solution might be to change the approach to clinical trials more dramatically, perhaps by expanding the inclusion criteria for later phase (Phase 2b and 3) trials.³⁵² Scientists have argued that Phase 2 studies would be more useful if they studied a larger sample size³⁵³ and had less restrictive inclusion and exclusion criteria to broaden the pool of patients eligible to participate.³⁵⁴ Making the inclusion criteria less restrictive for Phase 2 and 3 trials and increasing the number of patients enrolled in those phases might both produce valuable scientific knowledge and prevent expanded access programs from interfering with clinical investigation.³⁵⁵ It would also ensure that individuals being exposed to unapproved drugs were provided the careful safety monitoring involved in clinical trials. Moreover, increasing the size

348. INST. OF MED., INSURING AMERICA'S HEALTH – PRINCIPLES AND RECOMMENDATIONS 8 (2004).

349. Ron Wyden & Bob Bennett, *Finally, Fixing Health Care: What's Different Now?*, 27 HEALTH AFF. 689, 690 (2008).

350. Sheryl Gay Stolberg, *Missing in Health Bills: Solutions for Rising Costs*, N.Y. TIMES, Nov. 10, 2009, at A1 (describing Congressional health care reform legislation).

351. *Id.* (noting that “[t]here are a variety of ideas for attacking costs more aggressively,” and Senators and administrative officials are focusing on containing costs, but there are important barriers to cost-cutting); see also *Transcript: Obama's Health Care Address*, WASH. POST, Sept. 9, 2009, <http://specials.washingtonpost.com/annotations/obama-health-care-address> (last visited Nov. 17, 2009) (“[O]ur health care system is placing an unsustainable burden on taxpayers. . . . Put simply, our health care problem is our deficit problem.”).

352. See Marcee, *supra* note 215, at 456 (recommending increasing the size of Phase 2 trials).

353. LAWRENCE FRIEDMAN ET AL., FUNDAMENTALS OF CLINICAL TRIALS 5 (1996); see Melissa Fazzari et al., *The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials*, 21 CONTROLLED CLINICAL TRIALS 360, 361 (2000).

354. See Fazzari et al., *supra* note 353, at 363.

355. See Marcee, *supra* note 215, at 455-57.

of Phase 2 trials might not increase drug companies' overall costs because better data earlier in the process might prevent companies from conducting some costly, but ultimately unsuccessful, Phase 3 trials.³⁵⁶ Our analysis has demonstrated that it is the research sponsors, not the FDA or the courts, who are the real bottleneck preventing individuals from receiving access to unapproved therapy. Yet, it is difficult, if not impossible, to create sound incentives for sponsors to provide access to unapproved therapy without raising concerns about the exploitation of desperate individuals who have limited treatment options. Requiring sponsors to include more individuals in clinical trials might save sponsors money while providing much-needed data on unapproved therapy, and thus may be much more effective than the proposals that have been made to date.

Of course, enrolling more subjects in clinical trials may not adequately address the concerns of individuals suffering from rare conditions or for whom off-label indications are the last resort.³⁵⁷ There may also be other important exceptions, including trials for which there are important scientific reasons not to enroll patients with complex conditions. Therefore, we do not propose that the FDA's regulations for expanded access to unapproved therapy be abandoned, but that the provisions in these regulations be interpreted in a careful and restrictive fashion.

Many clinical trials do not have sufficient numbers of subjects enrolled,³⁵⁸ and so it seems unwise to further decrease the incentives for patients to participate in clinical trials. Additionally, although tens of thousands of patients have been enrolled in expanded access programs, the data collected from these programs have been incomplete, with information about less than half of the patients involved being sent back to the FDA.³⁵⁹ The information that has been returned to the FDA has not been very useful.³⁶⁰ Unless expanded access programs can be better designed to produce data of some value (which is a proposal we would also support), they cannot substitute for clinical trials on people with complex conditions.

356. See Fazzari et al., *supra* note 353, at 367.

357. See Section III.C, *supra*; see also 21 U.S.C. § 360bbb (2006); 21 C.F.R. §§ 312.34, 312.36 (2008); Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147, 75,167 (proposed Dec. 14, 2006) (to be codified at 21 CFR § 312). Significantly, individuals seeking to enroll in trials for the off-label use of a drug may have fewer options than if the sponsor was seeking to approve the drug for use in their disease.

358. Gina Kolata, *Lack of Study Volunteers Is Said To Hobble Fight Against Cancer*, N.Y. TIMES, Aug. 3, 2009, at A1.

359. Ann T. Farrell, Food & Drug Admin., Address at Accelerating Anticancer Agent Development Workshop: FDA: Center for Drug Evaluation and Research Oncology Expanded Access (June 18, 2009).

360. *Id.*

Significantly, the idea of transforming clinical trials in this manner is not without precedent. Some have argued that “[t]he current clinical research enterprise in the United States is not consistently producing an adequate supply of information to meet the needs of clinical and health policy decision makers.”³⁶¹ In 1993, Sir Richard Peto and colleagues advocated for “large, simple trials,” involving less complex protocols, enrollment of large numbers of research subjects, limited exclusion criteria, and only a few measures on which data would be collected, for this very reason.³⁶²

In particular, clinical trials with strict exclusion criteria make it impossible to obtain systematic data on subpopulations of patients with complex conditions before a drug is released for use by the population at large.³⁶³ Researchers have advocated for clinical trials that “include a more diverse study population . . . to enroll patients in the trial with characteristics that reflect the range and distribution of patients observed in clinical practice.”³⁶⁴ Unlike smaller studies with relatively homogenous groups of people, larger, more diverse clinical trials can provide enough information to examine the effects of interventions on subgroups based on race, age, gender, and stage of disease.³⁶⁵ More information about a drug prior to widely marketing that drug is clearly preferable for public health reasons.³⁶⁶

Sponsors may be concerned that moving in the direction of large, simple trials may produce more information about the risks of a drug before the approval process is completed.³⁶⁷ Including sicker patients in clinical trials may increase

361. Sean R. Tunis et al., *Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy*, 290 JAMA 1624, 1625 (2003).

362. Richard Peto et al., *Large-Scale Randomized Evidence: Large, Simple Trials and Overviews of Trials*, 703 ANNALS OF N.Y. ACAD. SCI. 314 (1993); accord John S. March et al., *The Case for Practical Trials in Psychiatry*, 162 AM. J. PSYCHIATRY 836, 842 (2005); Tunis, *supra* note 361, at 1630.

363. Martin Fortin et al., *Randomized Controlled Trials: Do They Have External Validity for Patients with Multiple Comorbidities?*, 4 ANNALS OF FAMILY MED. 104, 104-05 (2006) (“To ensure the internal validity of their findings, many [Randomized Controlled Trials (RCTs)] exclude patients with multiple comorbid conditions. In other cases, comorbidities of patients actually enrolled in the RCTs are not reported. These trials, however, provide the data that inform the justification for use of new treatments and interventions for all patients. Excluding a subset of the population from such trials or from the final reports means important information about the proper use of a treatment or intervention for that subset is not available.”).

364. Tunis, *supra* note 361, at 1626.

365. March, *supra* note 362, at 838.

366. See Vale, *supra* note 200, at 2172.

367. Cf. Jerome Groopman, *The Right to a Trial: Should Dying Patients Have Access to Experimental Drugs?*, NEW YORKER, Dec. 18, 2006, at 40 (quoting the director of the Office of

the number of adverse events in the trial, making it more difficult to demonstrate a treatment effect.³⁶⁸ In other words, if people are so sick that the disease causes them to experience morbidity or mortality, it may be more difficult to separate which negative outcomes should be attributed to their disease and which should be attributed to the unapproved drug. One way to address these concerns is to stratify the sample into two groups: those research subjects who would traditionally fit under rigid inclusion/exclusion criteria and those who would not. The primary analysis of the data would focus on subjects who would meet traditional inclusion criteria, and secondary analyses could include information from sicker or more fragile research subjects. It is true that including sicker patients may still make it more time-consuming and difficult to interpret the data. However, as we have discussed, the current approach has been forcefully criticized for offering inadequate information for policymakers, physicians, and patients by excluding sicker patients or more representative members of the population.³⁶⁹

While these expansions probably would slow down the approval process, it is not clear that sponsors' concerns about delays to or denials of approval represent the most important concerns. Many commentators have argued that the FDA approval process is too lenient.³⁷⁰ The post-approval revelation that Vioxx³⁷¹ increased patients' risk of heart attacks by a factor of five provides a prominent example of an instance in which the FDA approval process was not adequately stringent.³⁷² If the FDA approval process is slowed in order to obtain

Oncology Drug Products as saying that many companies fear "the FDA will find some toxicity in the expanded-access program . . . and the drug will be killed").

368. See, e.g., Fortin, *supra* note 363, at 107 (noting that "depression in patients with hypertension can result in a difficult clinical course because depression may adversely affect the patients' adherence to medication and self-care regimens"); Yves Lacourcière, *A Multicenter, Randomized, Double-Blind Study of the Antihypertensive Efficacy and Tolerability of Irbesartan in Patients Aged ≥ 65 Years with Mild to Moderate Hypertension*, 22 CLINICAL THERAPEUTICS 1213, 1213 (2000) (examining the effectiveness of a drug to lower blood pressure excluding conditions that may lead to adverse outcomes such as high blood pressure, previous cardiac disease, and stroke, "as well as other preexisting or present severe medical or psychologic conditions").

369. See Fortin, *supra* note 363, at 108 ("Research devoted to generating knowledge to be applied in medical practice should take into consideration the complex reality of the situation."); March, *supra* note 362, at 838; Peto, *supra* note 362, at 378; Tunis, *supra* note 361, at 1625.

370. See, e.g., INST. OF MED., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 37 (2007).

371. Vioxx was a painkiller that was intended to provide pain relief without causing the stomach problems associated with other common painkillers such as aspirin. See, e.g., Marc Kaufman, *Merck Found Liable in Vioxx Case*, WASH. POST, Aug. 20, 2005, at A1.

372. See, e.g., Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing*

much-needed data, this is an important cost to factor into our decisionmaking, but some reasonable amount of delay may be a wise cost for the public to incur.

Finally, it is also important to note that these same arguments could have been raised against including children in research³⁷³ and are currently being made regarding the inclusion of pregnant women.³⁷⁴ The Pediatric Rule and the Best Pharmaceuticals for Children Act were passed in recognition of the fact that many drugs had not been tested in children at all before they were put into use.³⁷⁵ Many have rightly realized that when vulnerable populations are protected through exclusion from research, or when data is protected by excluding vulnerable populations, the result is ad-hoc experimentation on patients by their doctors.³⁷⁶ In this case, these protections also result in a denial of access to

(Phase IV) Study Requirements: Exception to the Rule?, 61 FOOD & DRUG L.J. 295, 365 (2006).

373. See, e.g., Kathleen C. Glass & Ariella Binik, *Rethinking Risk in Pediatric Research*, 36 J.L. MED. & ETHICS 567, 567-68 (2008) (discussing the history of pediatric research regulations); L.L. Mathis & S. Iyasu, *Safety Monitoring of Drugs Granted Exclusivity Under the Best Pharmaceuticals for Children Act: What the FDA Has Learned*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 133, 133 (2007) (“Because of features unique to the pediatric population and medication usage in this population, it may be difficult to identify adverse drug-related safety events in children.”).

374. Janice K. Bush, *The Industry Perspective on the Inclusion of Women in Clinical Trials*, 69 ACAD. MED. 708, 710 (1994) (explaining that birth defects occur naturally, and spontaneous abortion occurs in 20-30% of pregnancies, so the “dilemma is how to separate which defects might be due to drugs versus those that are just occurring naturally”); R. Alta Charo, *Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials*, 38 ST. LOUIS L.J. 135, 141, 144 (1993) (noting that some have argued that “[i]nclusion of women equals ‘noise’ in the data,” and have raised concerns about liability as a result of harm to fetuses).

375. Best Pharmaceuticals for Children Act, 42 U.S.C. § 284m (2006); Regulations Requiring Manufacturers To Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,631 (Dec. 2, 1998) (to be codified at 21 C.F.R. pts. 201, 312, 314, 601) (noting that the absence of pediatric testing and labeling may put pediatric patients at risk of adverse events or expose pediatric patients to ineffective treatments).

376. Glass & Binik, *supra* note 373, at 574 (“We strongly support an increase in pediatric research to provide the pediatric population with effective medical care, and finally to eradicate the ‘therapeutic orphan.’”); Am. Acad. of Pediatrics Comm. on Drugs, *Guidelines for the Ethical Conduct of Studies To Evaluate Drugs in Pediatric Populations*, 95 PEDIATRICS 286, 294 (1995) (“The AAP believes it is unethical to deny children appropriate access to existing and new therapeutic agents.”) (guidelines were reaffirmed in September 2005); Nat’l Insts. of Health, NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects, Mar. 6, 1998, <http://grants.nih.gov/grants/guide/notice-files/not98-024.html> (“After reviewing reports, background papers, and a study of a sample of NIH-sponsored clinical research abstracts that suggested that 10-20% inappropriately excluded children, the conveners concluded that there is a need to enhance the inclusion of children in clinical research. This conclusion is

clinical trials that could be a valuable option for people with one last hope for treatment.

One of the difficulties that our proposal cannot address adequately is that enrolling more individuals in clinical trials means that these individuals may receive placebo instead of the unapproved treatment. Our proposal does not give individuals a guarantee of receiving access to unapproved therapy. Still, the chance of a placebo is an improvement compared to any proposal which does not adequately address the most important barrier to access: the lack of incentives for drug companies to provide treatment. We have attempted to address this problem directly. Additionally, in many cases, there are significant risks posed by unapproved therapy. Because experimental therapies by definition have not been proven to be effective, placebo-controlled trials are both scientifically important and morally acceptable.³⁷⁷

It is true that the terminally ill who are seeking a chance at a cure or an extension of life have very sympathetic claims that we cannot ignore. However, there are other situations in which the law privileges societal needs over the sympathetic claims of individuals in difficult situations.³⁷⁸ For instance, witnesses may have good reason to fear that if they provide testimony in certain criminal cases, the defendants they testify against may threaten their lives or the lives of their family.³⁷⁹ However, fear for one's life is not a valid defense for contempt of court.³⁸⁰ The witness protection program was created to protect witnesses who place themselves in danger by testifying, but the witness protection program involves considerable sacrifices and does not offer a guarantee that a witness and her family will be kept safe. Justice Frankfurter justified this approach by explaining that "[e]very citizen of course owes to his society the duty of giving testimony to aid in the enforcement of the law."³⁸¹ In the case of *People v. Carradine*, the Supreme Court of Illinois explained why it

based upon scientific information, demonstrated human need, and considerations of justice for children in receiving adequately evaluated treatments.").

377. See, e.g., COUNCIL FOR INT'L ORGS. OF MED. SCIS., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS, Guideline 11 (2002), available at http://www.cioms.ch/frame_guidelines_nov_2002.htm ("Placebo may be used: when there is no established effective intervention . . ."); WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2008), available at <http://www.wma.net/en/30publications/10policies/b3/index.html> ("The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists . . .").

378. ALAN WERTHEIMER, COERCION 158 (1987).

379. *Id.*

380. *Id.*; John Lawrence Hill, *A Utilitarian Theory of Duress*, 84 IOWA L. REV. 275, 327 (1999).

381. *Piemonte v. United States*, 367 U.S. 556, 559 n.2 (1961).

upheld a contempt of court conviction of a woman too fearful to testify as follows:

[O]ne of the problems that the Court has is that unless we receive the cooperation of the citizens who see certain alleged events take place these events are not going to be rooted out, nor are perpetrators of these acts going to be brought before the bar of justice unless citizens stand up to be counted, and I think this [fear] is not a valid reason for not testifying. If it's a valid reason then we might as well close the doors.³⁸²

The court made it clear that creating an exception for witnesses to testify out of fear for their lives would come at too high a price for the legal system to bear. Proposals to permit access to unapproved drugs outside clinical trials come at a similarly high price, in this case risking the integrity of our system for evaluating the safety and efficacy of drugs.

Finally, we are in no way proposing to eliminate expanded access programs. There are likely to be circumstances in which expanded access programs are necessary. For instance, there may be cases where the Phase 1 data raises few safety concerns for a particular drug, and individuals are seeking off-label use, requesting treatment for a rare condition, or have some other need that clinical trials simply cannot meet. Although it is still important to develop ways to collect some limited data on the safety and efficacy of treatments in compassionate use programs, the FDA may appropriately decide that there is an important role for expanded access programs in these and similar instances.

CONCLUSION

The highly sympathetic nature of the claims for access to experimental therapy by terminally or seriously ill patients makes it difficult to confront the hard policy questions at the heart of this debate. Courts lack the institutional competence and policymaking expertise to address these questions, questions which are better confronted through the legislative branch. Moreover, a careful examination of the possible solutions to the problem of sponsors' incentives to provide access reveals that the proposed solutions are costly and unsound, especially given the current climate of health care reform. Instead of short-sighted proposals to modify the current health care and research system, a better approach would be to allow very limited access to unapproved drugs outside of clinical trials while expanding eligibility for clinical trials in order to ensure that more people receive access in a controlled and systematic fashion. Although our proposal may not satisfy those desperately seeking their last hope for a cure, it is

382. *People v. Carradine*, 52 Ill. 2d 231, 234 (1972) (quoting the trial court's reasoning).

time to recognize that the cost of providing broad access to unapproved therapy is far too high to bear.

Pay or Play Programs and ERISA Section 514: Proposals for Amending the Statutory Scheme

Christen Linke Young*

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INTRODUCTION

Forty-seven million Americans lack health insurance, and public opinion polls demonstrate that the electorate is increasingly interested in government action to expand access to health care.¹ Much of the debate has focused on comprehensive national legislation to reform our health care system, but over the last five years state and local governments have taken important steps to ensure that their own citizens can obtain needed health care services. One type of state law, “pay or play” health care reform, places burdens on employers in order to expand the number of adults that receive health care through their workplace. In particular, seven state and local governments have adopted laws that require employers to either “pay” a tax that is used to provide public health care services or “play” by providing health insurance for their employees.²

These state and local reform projects from Massachusetts to San Francisco stand out as examples of at least potential success in a broken and deeply fractured health care system. As national leaders work to craft a federal reform project, the Massachusetts experiment is frequently cited as an example from which important lessons can be drawn. Reformers across the country continue to point to these efforts in their attempts to expand coverage in new places.³ But, at the same time, a largely unrelated federal statute places enormous obstacles in front of this major strategy toward achieving universal health insurance.

These state and local programs are threatened by federal preemption under section 514 of the Employee Retirement Income Security Act (ERISA).⁴ The language of ERISA explicitly disallows a broad cross-section of state law affecting employer-provided benefits, which affects state pay or play laws in

1. See Kaiser Family Foundation, Kaiser Health Tracking Poll – April 2009, <http://www.kff.org/kaiserpolls/posr042309pkg.cfm> (last visited Nov. 12, 2009).

2. The seven jurisdictions include Hawaii, Maryland, Massachusetts, Vermont, New York City, San Francisco, and New York’s Suffolk County. See HAW. REV. STAT. ANN. § 393-2 (LexisNexis 2004); Fair Share Health Care Fund Act, 2005 Md. Laws 3 (codified as amended at MD. CODE ANN., HEALTH-GEN. § 15-142 (LexisNexis 2007); MD. CODE ANN., LAB. & EMPL. §§ 8.5-101 to -107 (LexisNexis 2006)); An Act Providing Access to Affordable, Quality, Accountable Health Care, 2006 Mass. Acts 77; An Act Relating to Health Care Affordability for Vermonters, 2006 Vt. Acts & Resolves 455; N.Y., N.Y., ADMIN. CODE § 22-506 (2009), available at <http://public.leginfo.state.ny.us> (follow “Laws of New York” hyperlink, then follow “ADC” hyperlink, then navigate to Title 22, Section 506); S.F., CAL., HEALTH CARE SECURITY ORDINANCE § 14.1-14.8 (2007); Retail Indus. Leaders Ass’n v. Suffolk County, 497 F. Supp. 2d 403 (E.D.N.Y. 2007) (describing the Suffolk County law).

3. Dawson Bell, *Democrats Test Water for Ballot Proposals*, DETROIT FREE PRESS, July 23, 2009, at A8, available at 2009 WLNR 15669318.

4. Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (codified as amended in scattered sections of 29 U.S.C.).

profound ways. Indeed, since its enactment in 1974, section 514—which contains ERISA’s broad preemption clause and complicated savings language—has become a case study in unintended legislative consequences.⁵ In 2006, courts concluded that a Maryland pay or play law was preempted by ERISA.⁶ Today, states continue to experiment with pay or play schemes designed to avoid ERISA preemption, and lawsuits that threaten their viability continue to make their way through the federal courts.

At the time of this writing, the Obama administration and the Democratic Congress appear well on their way toward achieving comprehensive national health care legislation.⁷ But national legislation will inevitably leave profound gaps in health care coverage—and we should look to states and localities to solve the remaining problems. One proposal circulated in the summer of 2009, for example, involved a federal mandate on individuals that required them to obtain health insurance, but no requirement on employers to contribute to their employees’ coverage.⁸ Of course, absent an amendment to ERISA, many state and local policymakers will continue to fear preemption and will face severe design constraints.

The negotiation of a national health insurance package provides an excellent opportunity to amend ERISA section 514. Scaling back ERISA preemption of state and local schemes is essential to achieving broad insurance coverage. More importantly, many of ERISA’s important stakeholders—unions, employers, indemnity insurers, and HMOs—will already be at the table to hammer out the particulars of the national health insurance bill. As this window of opportunity opens, this Note discusses the options for “fixing” section 514 to accommodate state and local schemes.

The central aim of this paper is to illustrate how section 514 might be amended in the coming years. That analysis requires an understanding of ERISA preemption and its relationship to pay or play laws. Part I introduces the debate by describing recent state experimentation with pay or play health insurance programs. It then turns to a brief overview of ERISA preemption jurisprudence and proceeds to outline the ways in which pay or play laws are inevitably ERISA-preempted. Part II embarks on the core analytic contribution of this Note, articulating and evaluating six different approaches that Congress could use to

5. See, e.g., Peter D. Jacobson, *Health Law 2005: An Agenda*, 33 J.L. MED. & ETHICS 725, 732 (2005) (calling ERISA an “interesting study in the doctrine of unintended consequences”).

6. *Retail Indus. Leaders Ass’n v. Fielder*, 435 F. Supp. 2d 481 (D. Md. 2006).

7. See Robert Pear, *Senator Takes Initiative on Health Care*, N.Y. TIMES, Nov. 12, 2008, at A18 (explaining that Obama “still considered health care a top priority, despite the urgent need to address huge problems afflicting the economy”).

8. See David Espo, *AP Sources: Senate Group Omits Employer Mandate*, ABC NEWS, July 27, 2009, available at <http://abcnews.go.com/Politics/wirestory?id=8180071>.

“fix” ERISA preemption of pay or play laws. The Note concludes with a brief comparison of the approaches offered.

I. ERISA PREEMPTION OF PAY OR PLAY LAWS

A. An Introduction to Pay or Play Health Care Reform

Health care regulation has long been an area of state dominance in America’s federalist system, and states have taken the lead in broad health care reform efforts.⁹ States have developed a number of approaches to expand their citizens’ access to health care—including public-private partnerships to develop insurance purchasing pools and creative leveraging of public funds in the Medicaid and State Children’s Health Insurance Program (SCHIP) programs—but the most comprehensive approaches focus on “pay or play” health reform, also called employer mandates.¹⁰ Under pay or play statutes, employers are given two options for every qualifying employee: either they can “pay” a state tax that subsidizes health care for the uninsured or they can “play” by providing that individual with health insurance coverage.¹¹ President Clinton’s proposed Health Security Act was a variation on the pay or play scheme, and employer mandates were a centerpiece of the Congressional reform proposals of 2009.¹²

As governments seek to expand health insurance coverage, employer mandates offer two primary advantages. First, they promise to build on the United States’ existing employer-based health system. With more than eighty percent of Americans insisting they are satisfied with their existing health insurance, health reformers must find a way to introduce change without

9. See, e.g., Eleanor D. Kinney, *Clearing the Way for an Effective Federal-State Partnership in Health Reform*, 32 U. MICH. J.L. REFORM 899, 899 (1999); Arthur Birmingham LaFrance, *Healthcare Reform in the United States: The Role of the States*, 6 SEATTLE J. FOR SOC. JUST. 199, 199 (2007).

10. See AMANDA BRODT ET AL., STATE COVERAGE INITIATIVES, STATE OF THE STATES: BUILDING HOPE, RAISING EXPECTATIONS 20-27 (2007), available at <http://www.rwjf.org/files/publications/other/StateoftheStates2007.pdf> (discussing various reform initiatives).

11. See PATRICIA A. BUTLER, NAT’L ACAD. FOR STATE HEALTH POLICY, REVISITING PAY OR PLAY: HOW STATES COULD EXPAND EMPLOYER-BASED COVERAGE WITHIN ERISA CONSTRAINTS 4 (2002), available at http://www.nashp.org/sites/default/files/ERISA_Pay_Or_Play.pdf (defining “pay or play”).

12. See, e.g., H.R. 3962, 111th Cong. §§ 411-15 (2009) (describing the employer mandate in one 2009 proposal); Kevin Fickenscher & David Kindig, *Elements of the American Health Security Act of 1993*, PHYSICIAN EXECUTIVE, Nov.-Dec. 1993, at 4 (describing the pay or play aspects of the Health Security Act).

fundamentally rocking the boat for a “satisfied majority.”¹³ Pay or play, of course, entrenches employer provided insurance, helping to ensure that things remain largely unchanged for the employer-insured population. Second, pay or play offers governments a way to expand coverage by spreading the financial burden across the private sector. By asking employers to shoulder a significant percentage of the costs of health reform, employer mandates can control the public price tag for expanded coverage. Critics of pay or play programs, on the other hand, emphasize the burden that mandates place on small businesses,¹⁴ the long-term impact on employment prospects, and the failure of mandates to tackle unsustainable growth in health insurance premiums.¹⁵

Pay or play programs vary along several dimensions. The two most important variations are: 1) the type of employer actions that qualify as “playing,” and 2) the amount of the required payment should an employer choose to “pay.” Recently enacted employer mandates in Massachusetts and San Francisco illustrate this variation.¹⁶ In particular, Massachusetts sets a very high bar for qualifying health coverage, requiring “a group health plan . . . to which the employer makes a fair and reasonable premium contribution.”¹⁷ The “play” option is thus limited to employers who offer subsidized insurance plans that meet substantive standards. Employers who fail to meet this requirement, however, are charged a very small fee: no more than \$295 per employee per year, ten percent of the average cost of qualifying coverage.¹⁸ San Francisco, by contrast, defines “playing” in very broad terms—employers must spend \$1.76 per employee-hour on health related costs, including everything from providing

13. See Rob Stein & Alexi Mostrous, *Debate Focuses on Satisfied Majority*, WASH. POST, July 28, 2009, at A4.

14. See, e.g., Robert J. Landry, III & Amy K. Yarbrough, *Global Lessons from Consumer Bankruptcy and Healthcare Reforms in the United States: A Struggling Social Safety Net*, 16 MICH. ST. J. INT'L L. 343, 363 (2007); Lin Lin, Note, *All Is Well in Massachusetts? Diagnosing the Effects of the 2006 Employer Mandate on Health Care Reform Efforts*, 25 J. CONTEMP. HEALTH L. & POL'Y 406, 410 (2009).

15. See, e.g., Landry & Yarbrough, *supra* note 14, at 363.

16. See generally An Act Providing Access to Affordable, Quality, Accountable Health Care, 2006 Mass. Acts 77; S.F., CAL., HEALTH CARE SECURITY ORDINANCE § 14.1-14.8 (2007).

17. § 47, 2006 Mass. Acts at 115 (limiting employer contribution to the use of traditional group health plans, not other tools like health savings accounts, direct reimbursement of employee medical expenses, etc.).

18. § 44, 2006 Mass. Acts at 111; see also KAISER FAMILY FOUND. & HEALTH RESEARCH AND EDUC. TRUST, EMPLOYER HEALTH BENEFITS: 2009 ANNUAL SURVEY 14 (2009), available at <http://ehbs.kff.org/pdf/2009/7936.pdf> (showing that average cost of employer-provided insurance for an individual is \$4824); Amy B. Monahan, *Pay or Play Laws, ERISA Preemption, and Potential Lessons from Massachusetts*, 55 U. KAN. L. REV. 1203, 1214 (2007) (noting the weakness of a \$295 cap).

traditional insurance to reimbursing employees directly for doctor's visits.¹⁹ Employers who fall short must make up the difference up to the full \$1.76 per employee-hour (or \$3660 per year for a full-time employee) into a city fund dedicated to the provision of health care.²⁰

Other state laws illustrate even greater diversity. Maryland's statute considered only employers' *total* spending on health expenditures, without regard to the expenditure on particular employees.²¹ Other states have counted employers' charitable contributions to community clinics or investments in on-site employee health facilities towards their health care expenditures.²² And the payment requirements are no more uniform. Some are assessed as a tax²³ and others as a fine.²⁴ Massachusetts actually assesses a variable payment based on each employer's "share" of the state's uncompensated care fund, and that share is calculated based on actual utilization of free care by individuals that work for each employer.²⁵ Thus, pay or play should be conceptualized as a general framework for involving employers in health care funding, which affords governments wide latitude to define program requirements.

To date, seven different state and local laws embodying pay or play requirements have been enacted. Hawaii enacted the country's first employer mandate in 1974, which requires employers to pay one half of their employees' health insurance costs.²⁶ In 2006, Maryland made headlines with its so-called "Walmart law," officially known as the Fair Share Act, which required private employers with 10,000 or more employees to spend eight percent of their total payroll on health insurance.²⁷ Though the statutory language targeted all large employers, in practice, Walmart was the only covered employer who was not making an adequate contribution to employee health care. Later that year, two New York local governments—Suffolk County and New York City—adopted local pay or play ordinances, requiring large retail stores to make health care

19. S.F., CAL., HEALTH CARE SECURITY ORDINANCE § 14.1.

20. *Id.*

21. *See* MD. CODE ANN., LAB. & EMPL. § 8.5-104 (LexisNexis 2006).

22. *See, e.g.,* Retail Indus. Leaders Ass'n v. Suffolk County, 497 F. Supp. 2d 403, 416-17 (E.D.N.Y. 2007).

23. *See* HAW. REV. STAT. ANN. §§ 393-2, 393-31 (LexisNexis 2004) (vesting the Director of Internal Revenue with enforcement authority).

24. *See* N.Y., N.Y., ADMIN. CODE § 22-506 (2009), *available at* <http://public.leginfo.state.ny.us> (follow "Laws of New York" hyperlink, then follow "ADC" hyperlink, then navigate to Title 22, Section 506).

25. *See* An Act Providing Access to Affordable, Quality, Accountable Health Care § 47(c)(1), 2006 Mass. Acts 77, 116. The statute also caps the required contribution at \$295 per employee. § 47(c)(10), 2006 Mass. Acts at 117.

26. *Standard Oil Co. of Cal. v. Aghsalud*, 633 F.2d 760, 760 (9th Cir. 1980).

27. MD. CODE ANN., LAB. & EMPL. § 8.5-104(b) (LexisNexis 2006).

contributions. The Massachusetts and San Francisco programs described above are the highest profile recent excursions into pay or play laws. Vermont has also implemented a plan that is similar to the Massachusetts program.²⁸ The Michigan Democratic Party recently announced that they were considering an employer mandate-based ballot initiative for the fall of 2010,²⁹ and advocates continue to prod large states to explore pay or play reforms.³⁰

Indeed, it is clear that pay or play health care reform offers state and local governments a flexible tool for shrinking the ranks of the uninsured and improving access to health care for their citizens. Moreover, employer mandates are now a staple of all comprehensive reform discussions.³¹ However, as we shall see in the next section, these laws are extremely vulnerable to challenges of federal preemption under ERISA. We turn to a brief overview of the contours ERISA jurisprudence in Section I.B, before applying these concepts to pay or play laws in Section I.C.

B. ERISA Preemption in the Courts

In the main, the Employee Retirement Income Security Act (ERISA) provides a comprehensive federal scheme regulating benefits that employers provide to their employees. The statute's regulatory scheme governs two broad categories of employee benefits: "pension plans," which provide income to employees after their retirement, and "employee welfare benefit plans," which offer short-term benefits like health or life insurance to employees.³² The law was intended to balance the needs of labor and management, offering employees a regulatory regime that would ensure access to promised benefits, while ensuring that employers would be bound by a set of uniform national laws rather than a patchwork of state pension regulations. This tradeoff required Congress to enact an explicit preemption clause, barring state law from regulating pensions and benefits.³³

28. STATE OF VT. AGENCY OF ADMIN., OVERVIEW OF VERMONT'S HEALTH CARE REFORM I (2008), available at http://hcr.vermont.gov/sites/hcr/files/Revised_Vermont_HCR_Overview_October_08__0.pdf.

29. See Dawson Bell, *Democrats Test Water for Ballot Proposals*, DETROIT FREE PRESS, July 23, 2009, at A8, available at 2009 WLNR 15669318.

30. See BRODT ET AL., *supra* note 10, at 1.

31. See, e.g., *id.* at 34.

32. See JOHN H. LANGBEIN, SUSAN J. STABILE & BRUCE A. WOLK, PENSION AND EMPLOYEE BENEFIT LAW 89-90 (4th ed. 2006).

33. Federal preemption of state law can be either express (federal legislation explicitly states that state law is preempted) or implied (legislation is silent but state and federal law cannot logically coexist). Implied preemption is further divided into two categories, conflict and field preemption. Conflict preemption refers to those cases where it is simply impossible to comply with

It is that preemption clause that threatens to swallow up states' health care reform efforts. In now-infamous language, ERISA subsection 514(a) announces the scope of federal preemption of state law in broad terms: ERISA regulation "shall supersede any and all state laws insofar as they may now or hereafter relate to any employee benefit plan described [in the Act]."³⁴ Interpretation of section 514 has turned on the contours of the phrase "relate to," and nearly thirty years of jurisprudence illustrate the difficulty of defining the scope of that term.

The overbroad language of subsection 514(a) is complicated by a series of exceptions (and exceptions to the exceptions) that have important implications for health insurance benefits. First, subsection 514(b), known as the "savings clause," importantly narrows the law's preemptive scope by saving from preemption "any State [law] which regulates insurance, banking, or securities."³⁵ Recognizing the potentially broad reach of the preemption language, Congress carved out a few distinct spheres where state regulation would be permitted—insurance, banking, and securities. But in the next subparagraph, known as the "deemer clause," Congress immediately and sharply limited the extent of the insurance/banking/securities exception. That language declares that no "employee benefit plan . . . shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company" that is subject to a state's insurance, banking, and security regulations.³⁶ Put more concretely, the deemer clause says that if an ERISA-regulated employee benefit plan does things that make it "look like" an insurance company or a bank, it is nonetheless exempt from state regulation in this area. The most relevant example is large employers who "self-insure" their employees. The self-insurance fund is covered by the statute as an ERISA plan. Thus, although these ERISA plans perform exactly the same functions as a health insurance company (paying for some but not all employee/enrollee medical expenses), the deemer clause exempts them from state regulations that apply to the rest of the insurance market.³⁷

state and federal requirements simultaneously (e.g., state law requires pension information to be presented by union representatives, but federal law requires the information be provided only by the employer). Field preemption refers to situations where it is technically possible to comply with both state and federal law, but courts determine that the federal government intended to occupy the entire "field" and displace state law (e.g., state law requires pensions to vest after a term of ten years or less, federal law requires pensions to vest after a term of fifteen years or less—while it is possible to satisfy the state law without violating the federal law, field preemption principles might dictate that the federal law ought to override the state). These concepts often overlap; for example, an express preemption clause that speaks to some but not all issues can be used to guide courts in understanding the proper scope of field preemption.

34. 29 U.S.C. § 1144(a) (2006).

35. *Id.* § 1144(b)(2)(A).

36. *Id.* § 1144(b)(2)(B).

37. See generally Russell Korobkin, *The Failed Jurisprudence of Managed Care*, 51 UCLA L.

To further complicate the statutory scheme, section 514 contains a number of other exceptions and clarifications, most of which are not relevant here.³⁸ In 1982, Congress added an important exemption applicable only to the State of Hawaii: After the Supreme Court held that Hawaii's pay or play health care reform program was ERISA preempted,³⁹ Congress specifically exempted the Hawaiian law from preemption.⁴⁰ The exemption is narrow, however, and only covers the Hawaii law as it existed in 1974, when ERISA was first enacted.⁴¹

Finally, ERISA's broad preemption language is, quite logically, not applicable to plans that are not regulated by ERISA. Section 403(b)(3) of the Act explicitly excludes from regulation any plan "maintained solely for the purpose of complying with applicable workmen's compensation laws or unemployment compensation or disability insurance laws."⁴² In this provision, Congress recognized that, while some employers voluntarily provided generous benefits associated with workplace injuries or layoffs, state governments were actively involved in ensuring a minimum level of protection through workers' compensation or unemployment benefit schemes. Thus, ERISA regulation does not apply to plans maintained "solely" to comply with these state law requirements, and the relevant state laws are not ERISA preempted. This "compliance plan" exception is decidedly under-theorized, but is nonetheless a part of the ERISA preemption landscape.⁴³

With this background in the statutory framework, I turn to ERISA preemption as it has been shaped by the Supreme Court. The discussion briefly illustrates the Court's initial approach, then offers a description of recent jurisprudence.

REV. 457, 486-88 (2003) (discussing the problem of "self-insured employers").

38. "[G]enerally applicable criminal law[s]" are not preempted by the broad language of 514(a), nor are "qualified domestic relations orders" or state tort actions dealing with the recoupment of some funds under Medicaid programs. 29 U.S.C. § 1144(b)(4), (b)(7), (b)(8) (2006).

39. See *Agsalud v. Standard Oil Co. of Cal.*, 454 U.S. 801 (1981), *summarily aff'g* *Standard Oil Co. of Cal. v. Agsalud*, 633 F.2d 760 (9th Cir. 1980).

40. See Pub. L. No. 97-473, § 301, 96 Stat. 2605, 2611 (1983) (codified at 29 U.S.C. § 1144(b)(5) (2006)).

41. See 29 U.S.C. § 1144(b)(5)(B)(ii) (2006).

42. 29 U.S.C. § 1003(b)(3) (2006).

43. A Westlaw search for works in the legal academy discussing the section of the code revealed several dozen articles discussing the existence of the compliance plan exception, mostly in the context of entities that are exempt from malpractice litigation, but only one article exploring this section of the preemption clause as a potential policy tool. See James E. Holloway, *Revisiting Cooperative Federalism in Mandated Employer-Sponsored Health Care Programs Under the ERISA Preemption Provision*, 8 QUINNIPIAC HEALTH L.J. 239, 268-69 n.207 (briefly discussing the compliance exemption and listing the handful of relevant cases).

1. Early Preemption Doctrine

ERISA preemption analysis begins with the statute's broad displacement of state laws that "relate to" ERISA-regulated benefits. Indeed, the first fifteen years of the Supreme Court's ERISA preemption jurisprudence were characterized by a rather literal interpretation of the phrase "relate to" that rendered preemption of state law "nearly automatic."⁴⁴ In 1981, the Court decided its first case, *Alessi v. Raybestos-Manhattan, Inc.*, which involved a New Jersey law that prevented employers from reducing pension plan benefits because of a workers' compensation award.⁴⁵ A unanimous Court easily concluded that the law was preempted.⁴⁶ But, foreshadowing decades of unpredictable and often bizarre jurisprudence, the Court acknowledged that the "relate to" language engendered "some confusion" when the state law at issue affects ERISA plans only indirectly.⁴⁷

In *Shaw v. Delta Air Lines, Inc.*, the Court held that ERISA preempted a state law requiring that employee benefit plans cover pregnancy disability.⁴⁸ The Court expounded on the scope of preemption when state law had an indirect effect on ERISA-regulated subjects, saying, "A law 'relates to' an employee benefit plan . . . if it has a *connection with* or *reference to* such a plan."⁴⁹ It is not abundantly clear that "connection with" provides substantially more guidance to lower courts than 514(a)'s "relate to" language, but the "connection with or reference to" test quickly became black letter law.⁵⁰ Importantly, the *Shaw* Court acknowledged that a law "may affect employee benefit plans in too tenuous, remote, or peripheral a manner to warrant" preemption,⁵¹ carving out a possible exception to their otherwise broad holding.

Nonetheless, in subsequent cases the Court relied on the "connection with or reference to" standard to conclude that numerous state laws were preempted by the federal scheme. State laws mandating coverage of mental health benefits,⁵² providing a cause of action for bad faith claim denials,⁵³ regulating benefit plan

44. Edward A. Zelinsky, *Travelers, Reasoned Textualism, and the New Jurisprudence of ERISA Preemption*, 21 CARDOZO L. REV. 807, 808 (1999).

45. 451 U.S. 504 (1981).

46. *Id.* at 505.

47. *Id.* at 523.

48. 463 U.S. 85 (1983).

49. *Id.* at 96-97 (emphasis added).

50. See LANGBEIN ET AL., *supra* note 32, at 770.

51. *Shaw*, 463 U.S. at 100 n.21.

52. *Metropolitan Life Ins. Co. v. Mass.*, 471 U.S. 724 (1985). The Court held that the law at issue "relate[d] to" ERISA plans, but was nonetheless saved by the insurance exemption. *Id.* at 746.

53. *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987).

treatment of tort suit awards,⁵⁴ and governing benefit provision to workers' compensation beneficiaries⁵⁵ were held preempted. A handful of state laws were saved from ERISA preemption, including a generally applicable state garnishment statute⁵⁶ and a state law requiring one-time severance payments to laid-off workers.⁵⁷

The Court's opinion in *Ingersoll-Rand Co. v. McClendon*⁵⁸ is emblematic of its post-*Shaw* jurisprudence. The plaintiff in that case claimed that his employer discharged him only to prevent his pension plan from vesting, which would constitute wrongful termination under state law. The Court held that the state common law claim was preempted by ERISA.⁵⁹ The holding reaffirmed the idea that a state law that only indirectly affected an ERISA-plan could nonetheless be preempted.⁶⁰ Additionally, the Court emphasized that the state law claim depended on the *existence* of a plan in order to determine liability.⁶¹ The state law was not the kind of "generally applicable statute that . . . functions irrespective of . . . an ERISA plan,"⁶² because the law only made sense in a world of employee benefit plans. Therefore, even though the state law did not place burdens on plans *qua* plans, and instead imposed burdens on employers who had plans, it was still the kind of state requirement that manifested an inappropriate "connection with or reference to" ERISA.

In sum, under the Court's initial approach, section 514 broadly preempted state law. One scholar has characterized the tortured scope of ERISA preemption, noting that state law was preempted "even if such laws [were] 'not specifically designed to affect' ERISA plans, [and] even if the effect . . . '[was] only indirect.'"⁶³ As the cases described above illustrate, ERISA section 514 presented "one of the broadest preemption clauses ever enacted by Congress."⁶⁴

54. *FMC Corp. v. Holliday*, 498 U.S. 52 (1990).

55. *District of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125 (1992).

56. *Mackey v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825 (1988). In a rather ironic holding, the Court applied the "reference to" test to preempt a small portion of the state statute. Georgia, in language clearly designed to avoid ERISA preemption, announced that the law did not apply to a "plan or program subject to ERISA," but the Court concluded this clause was preempted as an impermissible reference. *Id.* at 829-30.

57. *Fort Halifax Packing Co., Inc. v. Coyne*, 482 U.S. 1 (1987). The Court held that this one time payment was not a "plan" within the meaning of ERISA.

58. 498 U.S. 133 (1990).

59. *Id.* at 137.

60. *Id.* at 139.

61. *Id.*

62. *Id.*

63. Zelinsky, *supra* note 44, at 829 (quoting *District of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125 (1992)).

64. 953 F.2d 543, 545 (9th Cir. 1992) (citing *Evans v. Safeco Life Ins. Co.*, 916 F.2d 1437,

2. Travelers and Recent Jurisprudence

Throughout the early- and mid-1990s, commentators,⁶⁵ lower courts,⁶⁶ and even Supreme Court Justices⁶⁷ began to express frustration with the state of ERISA preemption jurisprudence. By 1995, the Court was prepared to revisit its approach to section 514.

In *New York Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*, the Court fundamentally altered its interpretation of section 514.⁶⁸ Justice Souter's unanimous opinion admitted some frustration with "uncritical literalism" in applying the "connection with or reference to" test, but did not technically overrule or even limit *Shaw*, *Ingersoll-Rand*, or any of the Court's prior section 514 decisions.⁶⁹ Nonetheless, *Travelers* is widely understood to have created a "sea change" in ERISA preemption doctrine.⁷⁰

At issue in the case was a New York state law that levied surcharges against all payers of hospital bills, except Blue Cross/Blue Shield plans.⁷¹ The law undoubtedly had an indirect effect on employee benefit plans, since their employees' medical costs were subject to the surcharge if the employer's ERISA plan self-insured or used conventional commercial insurance, but not if the plan elected Blue Cross/Blue Shield coverage. Yet the Court upheld the New York law.⁷² While the surcharge had "an indirect economic effect" on ERISA plans, it did not actually "bind plan administrators" to a particular design choice.⁷³ Nor did it "preclude uniform administrative practice"⁷⁴ since the administrative burden fell to the hospitals, not the plan. Thus, there was no impermissible connection with an ERISA plan in the law.

1439 (9th Cir. 1990)).

65. See, e.g., Gabrielle Lessard, *Conflicting Demands Meet Conflict of Laws: ERISA Preemption of Wisconsin's Family and Medical Leave Act*, 1992 WIS. L. REV. 809, 822-23.

66. See, e.g., *Gast v. State*, 585 P.2d 12, 23 (Or. Ct. App. 1978).

67. In a 1992 dissent, Justice Stevens encouraged the Court "to take a fresh look" at ERISA preemption. *District of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125, 135 (1992) (Stevens, J., dissenting).

68. 514 U.S. 645 (1995).

69. *Id.* at 656.

70. See, e.g., *Prudential Ins. Co. of Am. v. Nat'l Park Med. Ctr.*, 154 F.3d 812, 815 (8th Cir. 1998) (internal quotation marks omitted); see also Robert F. Rich, Christopher T. Erb & Louis J. Gale, *Judicial Interpretation of Managed Care Policy*, 13 ELDER L.J. 85, 92 (2005) ("[I]n the seminal case of *Travelers* the Court initiated what many today perceive to be a sea change in ERISA preemption policy and interpretation.").

71. *Travelers*, 514 U.S. at 649-50.

72. *Id.* at 650.

73. *Id.* at 659.

74. *Id.* at 660.

Subsequent cases generally followed this approach, and in particular picked up on the *Travelers* emphasis on state laws that “bind plan administrators” to particular choices. In *California Division of Labor Standards Enforcement v. Dillingham Construction, N.A., Inc.*, the Court considered a state law affecting apprenticeship programs, which are ERISA plans.⁷⁵ California allowed contractors to pay lower wages to apprentices in state-approved programs, thereby creating an incentive for apprenticeship programs to seek state approval. The *Dillingham* Court insisted that the state law was no more than an incentive and was not preempted by ERISA; it did not “bind ERISA plans to anything,” nor was it “tantamount to a compulsion.”⁷⁶ In much-quoted language, the Court concluded that the law was permissible because it “alters the incentives, but does not dictate the choices” of ERISA plans.⁷⁷

The Court’s next ERISA case dealt with a state law that acted directly (as opposed to indirectly) on an ERISA plan. In *De Buono v. NYSA-ILA Medical & Clinical Services Fund*, the Court upheld a New York law that imposed a general tax on health care facilities.⁷⁸ The law was challenged by an ERISA plan that administered its own health care facility subject to the tax.⁷⁹ Acknowledging that this law certainly had “some [direct] effect on the administration of ERISA plans,” the Court nonetheless concluded that it was not preempted by 514(a).⁸⁰ The Court described the statute as “one of myriad state laws of general applicability that impose some burdens on the administration of ERISA plans but nevertheless do not relate to them.”⁸¹ In the context of the relevant state statute and the accumulated ERISA jurisprudence, there may be some logic to this formulation. But it makes clear the linguistic absurdity in the post-*Travelers* cases: it is truly remarkable to conclude that a “burden” is “unrelated” to the object that shoulders it.⁸²

The descriptions above highlight only a few of the Court’s recent section 514 cases, and they neglect a great deal of nuance in the cases presented. But they do illustrate several themes that are important for understanding preemption of state “pay or play” laws. First, consider the Court’s emphasis on “alter[ing] the incentives” versus “dictat[ing] the choices facing ERISA plans,” which was most

75. 519 U.S. 316 (1997).

76. *Id.* at 332, 333.

77. *Id.* at 334.

78. 520 U.S. 806 (1997).

79. *Id.* at 809.

80. *Id.* at 816.

81. *Id.* at 815 (internal citations and quotation marks omitted).

82. *Cf. Zelinsky, supra* note 44, at 808 (deploring ERISA preemption jurisprudence that shows no “regard for the terms of the statute”).

clearly articulated in *Dillingham* but has its conceptual origin in *Travelers*.⁸³ Indeed, this formulation of the “test” for ERISA preemption has received a great deal of attention in the legal literature,⁸⁴ including the literature on preemption of pay or play schemes.⁸⁵ Under this approach, state laws are evaluated based on the extent to which they coerce, rather than merely incentivize, ERISA plans in order to promote desired outcomes.

But a second theme, less prominently articulated but similarly originating in *Travelers*, also underlies these cases: the locus and nature of the administrative burden associated with the state law is important. Thus, in *Travelers* the Court emphasized that New York’s hospital surcharge law did not interfere with “uniform administrative practice” for ERISA plans.⁸⁶ The law’s administrative burden instead fell to hospitals, not to an ERISA-covered entity. Justice Thomas has built on this theme, emphasizing that one impermissible law required ERISA plans to be changed to comply with the state’s requirement.⁸⁷ Clearly, that action might impair national uniformity.⁸⁸ In this view, state laws are evaluated based on the extent to which they actually “touch” ERISA plans, regardless of whether those touches are “coercive.” Indeed, this sort of analysis begins to look more like implied preemption jurisprudence, essentially ignoring the preemption clause and instead focusing on the actual effect that fifty unique state regimes might have on a federally-regulated entity.⁸⁹

83. See Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 334 (1997); N.Y. Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 659 (1995) (“An indirect economic influence, however, does not bind plan administrators to any particular choice . . .”).

84. See, e.g., Jeffrey A. Brauch, *Municipal Activism v. Federal Law: Why ERISA Preempts San Francisco-Style Domestic Partner Ordinances*, 28 SETON HALL L. REV. 925, 947, 962 (1998); Larry J. Pittman, *ERISA’s Preemption Clause: Progress Towards a More Equitable Preemption of State Laws*, 34 IND. L. REV. 207, 214-20 (2001); Alice T. Armstrong, Comment, *ERISA Preemption of “Any Willing Provider”: The Eighth Circuit Got It Right*, 7 GEO. MASON L. REV. 753, 769-73 (1999); Meridith H. Bogart, Note, *State Doctrines of Substantial Compliance: A Call for ERISA Preemption and Uniform Federal Common Law Doctrine*, 25 CARDOZO L. REV. 447, 465-66 (2003).

85. See, e.g., Monahan, *supra* note 18, at 1209-10; Edward A. Zelinsky, *The New Massachusetts Health Law: Preemption and Experimentation*, 49 WM. & MARY L. REV. 229, 251-52 (2007).

86. *Travelers*, 514 U.S. at 660.

87. See *Egelhoff v. Egelhoff*, 532 U.S. 141, 150-51 (2001).

88. *Id.* at 152.

89. Justice Scalia and Justice Ginsburg, in a pair of concurring opinions, have called upon the Court to do exactly this—abandon much of the section 514(a) jurisprudence, and hold that the statute’s preemptive scope is precisely congruent with traditional field and conflict preemption. *Id.* at 152 (Scalia, J., concurring); Cal. Div. of Labor Standards Enforcement v. Dillingham Constr.,

Finally, these cases underscore that the “connection with or reference to” framework survived the *Travelers* revolution. *Travelers*, *Dillingham*, and *DeBuono* all open by affirming this approach.⁹⁰ Thus, while *Shaw*’s “nearly automatic” approach to preemption is no longer good law, section 514 cases still develop quite deliberately by looking for “connections” and “references.” Moreover, much of the pre-*Travelers* thinking is still reflected and cited.⁹¹ For this reason, cases like *Ingersoll-Rand* are relevant to the preemption landscape, even if their precise interpretative approaches no longer reflect the Court’s thinking.⁹²

To summarize, ERISA preemption jurisprudence began with a decade in which state laws that had only the most indirect and tangential effects on ERISA-regulated subject matter were nonetheless held preempted. The Court changed course in 1995 with *Travelers*, and began to chaotically and somewhat unpredictably scale back on the scope of federal preemption. In subsequent cases, the Court appeared to focus on two kinds of issues—the extent to which state law compelled (rather than merely encouraged) ERISA plans to operate in particular ways, and the magnitude and locus of the administrative burdens. Indeed, in the last fifteen years, ERISA preemption has changed drastically, though the Court has yet to formally renounce its earlier decisions.

C. ERISA Preemption of Pay or Play Programs

These broad outlines frame potential ERISA preemption of state pay or play laws. And there is reason to be pessimistic: some observers have flatly concluded that it is “hard to envision significant state experimentation with medical coverage that does not run afoul” of ERISA’s preemption clause,⁹³ and that all employer mandates “are preempted by ERISA.”⁹⁴ Indeed, as explained below, despite the Court’s somewhat relaxed post-*Travelers* approach, it is fairly clear that state attempts to mandate employer health insurance programs generally constitute impermissible and ERISA-preempted governance of employee benefit plans.

N.A., Inc., 519 U.S. 316, 334 (1997) (Scalia, J., concurring). For a discussion of field and conflict preemption, see *supra* note 33.

90. See *Egelhoff*, 532 U.S. at 149; *Dillingham*, 519 U.S. at 323; *Travelers*, 514 U.S. at 623.

91. See generally Robert N. Covington, *Amending ERISA’s Preemption Scheme*, 8 KAN. J.L. & PUB. POL’Y 1, 9 (1999) (“Is there really a new order under ERISA? Answer: ‘Yes, BUT . . .’”).

92. See, e.g., *Egelhoff*, 532 U.S. at 149-50 (citing *Ingersoll-Rand* for the proposition that fifty dissimilar state laws would pose too steep an administrative burden on ERISA plans).

93. See Zelinsky, *supra* note 85, at 286.

94. Michael H. Bernstein & John T. Seybert, *You Can’t Get There from Here: Erisa Preemption of State Laws Mandating Employer Healthcare Contributions*, 3 ABA HEALTH ESOURCE, Mar. 2007, <http://www.abanet.org/health/esource/Volume3/07/bernstein-seybert.html>.

Courts have addressed ERISA preemption of four of the seven state and local statutes described above. Laws in Suffolk County and Maryland have been held ERISA preempted,⁹⁵ and the Supreme Court's holding that Hawaii's law was preempted led to a special congressional exception.⁹⁶ In the only ERISA opinion that has been favorable to a pay or play law, the Ninth Circuit held that San Francisco's program survived ERISA preemption; the case has been appealed to the Supreme Court.⁹⁷ New York City's law has not been challenged and remains on the books, but has not been enforced due to conflict between the mayor and city council regarding the permissibility of the statute under ERISA.⁹⁸ Meanwhile, the Massachusetts and Vermont laws have not been subject to judicial review and are currently being implemented.

As explained above, the Court's ERISA preemption jurisprudence has been anything but coherent. Therefore, it is useful to trace a number of themes that appear in the pay or play cases: exploring the dictated choices versus altered incentives framework, locating administrative burdens, and relying on the existence of an ERISA plan. These themes repeatedly appear in the reported opinions that have considered ERISA preemption of pay or play laws, and the laws that have escaped preemption challenges are vulnerable along the same dimensions.

1. Controlling the Level of Benefits: Choices and Incentives

The Court's first foray into ERISA preemption emphasized the importance of ensuring that "private parties, not the Government, control the *level of benefits*" provided under an ERISA plan.⁹⁹ Post-*Travelers*, the federal courts have attempted to define exactly what it means for a state statute to "control the level of benefits," and they have largely settled on the test articulated in *Dillingham*, distinguishing between laws that "alter[] the incentives" and laws

95. See *Retail Indus. Leaders Ass'n v. Fielder*, 475 F.3d 180 (4th Cir. 2007), *aff'd* 435 F. Supp. 2d 481 (D. Md. 2006); *Retail Indus. Leaders Ass'n v. Suffolk County*, 497 F. Supp. 2d 403 (E.D.N.Y. 2007).

96. See 29 U.S.C. § 1144(b)(5)(B)(ii) (2000) (creating an exception to ERISA preemption for Hawaii); HAW. REV. STAT. ANN. § 393-2 (LexisNexis 2004) (Hawaii's pay or play law); *Standard Oil Co. v. Agsalud*, 633 F.2d 760 (9th Cir. 1980), *aff'd mem.*, 454 U.S. 801 (1981) (holding the statute ERISA preempted).

97. *Golden Gate Rest. Ass'n v. San Francisco*, 546 F.3d 639 (9th Cir. 2008).

98. See N.Y., N.Y., ADMIN. CODE § 22-506 (2009), available at <http://public.leginfo.state.ny.us> (follow "Laws of New York" hyperlink, then follow "ADC" hyperlink, then navigate to Title 22, Section 506). The official codification notes that the law's validity is "currently a subject of disagreement between the mayor and the city council."

99. *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 511 (1981) (emphasis added).

that “dictate the choices” of ERISA plans.¹⁰⁰ Until recently, this framework has not been charitable to employer mandates.

Perhaps the best example of how this test has been applied to relevant state laws appears in the Fourth Circuit’s discussion of the Maryland “Walmart” statute. In that case, Maryland insisted that the law did not “mandate” that employers provide benefits under an ERISA plan, because employers had a choice between spending at least eight percent of their payroll on health benefits, or spending less than eight percent and paying any difference as an assessment to the state.¹⁰¹ In this view, the law was merely a *Dillingham*-like incentive, encouraging but not requiring employers to take certain actions with respect to ERISA-governed plans. The courts unequivocally rejected this view. The district court described the statute as providing a “Hobson’s choice,” since there was not “a single reason why the employer would pay the state.”¹⁰² The Fourth Circuit continued, “The only rational choice employers have . . . is to structure their ERISA healthcare benefit plans so as to meet the minimum spending threshold.”¹⁰³

Courts have also relied on legislative intent in crafting pay or play statutes, focusing on legislative sponsors’ statements regarding the consequence of the law. A court reviewing the Suffolk County statute emphasized legislators’ hope that the statute would force “Wal-Mart and the big box stores” to offer health benefits.¹⁰⁴ Similarly, the Fourth Circuit insisted that supporters “understood the [Maryland Fair Share] Act as *requiring* Walmart to increase its healthcare spending.”¹⁰⁵ Thus, even though these pay or play statutes technically offer employers a “choice,” courts have based their ERISA inquiry on the general goals underlying the pay or play statutes. Indeed, one observer has advised legislators seeking to avoid ERISA preemption to explicitly “remain neutral regarding whether employers offer health coverage or pay the tax” in order to prevent preemption.¹⁰⁶ Thus, attempts to achieve coverage expansions through employer mandates are often ERISA-preempted because they do not offer employers a meaningful choice between “paying” and “playing.”

100. Cal. Div. of Labor Standards Enforcement v. *Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 334 (1997).

101. See Retail Indus. Leaders Ass’n v. *Fielder (Fielder I)*, 435 F. Supp. 2d 481, 497 (D. Md. 2006).

102. *Id.*

103. Retail Indus. Leaders Ass’n v. *Fielder (Fielder II)*, 475 F.3d 180, 193 (4th Cir. 2007).

104. See Retail Indus. Leaders Ass’n v. Suffolk County, 497 F. Supp. 2d 403, 407-08 (E.D.N.Y. 2007).

105. *Fielder II*, 475 F.3d at 194.

106. See BUTLER, *supra* note 11, at 6-7. It is noteworthy that this advice was given *before* the decisions described above.

It is particularly instructive to consider this issue in the context of the Massachusetts and Vermont reform legislation, which have yet to be challenged on ERISA grounds. Recall that both laws require employers to make a “reasonable” contribution to precisely defined employee health care benefits, or pay a relatively small “assessment” or “fee” to the state—less than \$400 per employee per year.¹⁰⁷ Recent estimates suggest that it costs nearly \$4500 to provide annual health insurance for a single employee;¹⁰⁸ therefore, it may be easier for a court to conclude that these statutes actually do offer a choice to employers and ERISA plans. Indeed, Professor Monahan recently concluded that Massachusetts’ requirements “survive preemption [because] there is a relatively modest financial disincentive” associated with paying rather playing.¹⁰⁹ While this approach may seem plausible, in fact, Professor Zelinsky and others have persuasively argued that the modest assessment does not immunize these laws from ERISA preemption.¹¹⁰ For these statutes do not simply require states to spend a certain amount on health care or pay a much smaller fee to the state. Instead, they require employers to provide health benefits that meet certain substantive standards, like including primary care benefits, if they wish to avoid paying the fee. In this way, then, pay or play laws “regulat[e] the substance of [ERISA] plans” in an impermissible way.¹¹¹ Indeed, the laws “dictate the choices” by “expressly regulat[ing] employers and the type of benefits they provide employees.”¹¹² In other words, the Massachusetts and Vermont statutes may offer employers a choice between paying and playing. But for employers who do choose to offer health benefits, the laws impermissibly “dictate” the way in which the benefit must be provided.

Thus, pay or play statutes will often “dictate the choices” and therefore manifest an impermissible “connection” with ERISA plans. They go too far towards shaping the way employers provide benefits to employees—either by creating too stiff a penalty for failing to offer health benefits, or by impermissibly regulating how employers structure their benefits.

2. Administrative Burden

Another aspect of the “connection with” test that has survived—and even

107. See An Act Providing Access to Affordable, Quality, Accountable Health Care § 47, 2006 Mass. Acts 77, 115; STATE OF VT. AGENCY OF ADMIN., *supra* note 28, at 38.

108. See KAISER FAMILY FOUND., EMPLOYER HEALTH BENEFITS 2007 ANNUAL SURVEY 1-2 (2007), available at <http://www.kff.org/insurance/7672/index.cfm>.

109. Monahan, *supra* note 18, at 1216.

110. See, e.g., Bernstein & Seybert, *supra* note 94; Zelinsky, *supra* note 85, at 234.

111. Zelinsky, *supra* note 85, at 257.

112. *Standard Oil Co. of Cal. v. Agsalud*, 633 F.2d 760, 766 (9th Cir. 1980).

flourished—in the aftermath of *Travelers* is an inquiry into the administrative burdens associated with the state law.¹¹³ Of course, by forcing employers to comply with substantive or minimum spending requirements in the provision of health benefits, pay or play statutes create substantial administrative burdens.¹¹⁴ The laws force employers and ERISA plans to alter their benefit structures in order to either spend a certain amount on health care expenditures or comply with substantive regulations, and these alterations impede the “uniform administrative scheme” that ERISA allegedly envisions.¹¹⁵ Administrative complexity underlay the Court’s concern about Hawaii’s employer mandate—in a subsequent ERISA case the Court observed that “if Hawaii could demand the operation of a particular benefit plan, so could other States, which would require that the employer coordinate perhaps dozens of programs.”¹¹⁶ Indeed, courts have gone beyond the structural burdens imposed by pay or play laws and concluded that even the recordkeeping requirements associated with these laws constitute an impermissible administrative burden.¹¹⁷

The administrative complexity question has taken on particular significance in the context of employer mandates enacted by cities and counties, including the Suffolk County and San Francisco statutes. The New York district court emphasized that the Suffolk County law “would require that Wal-Mart make a different expenditure for employees in Suffolk County” and would thus “inhibit the administration of a uniform plan nationwide.”¹¹⁸ Similarly, one court was concerned with employers needing to “keep an eye on the minimum health care spending requirements in each locality.”¹¹⁹

But even in the statewide context, administrative complexity is a major concern of the courts. The Maryland law applied only to very large employers and operated statewide, but the courts found that the law impermissibly interfered with plan administration.¹²⁰ The Massachusetts and Vermont laws arguably

113. *Egelhoff v. Egelhoff*, 532 U.S. 141, 148 (2001) (explaining that administrative uniformity was one of the statute’s “principal goals”).

114. *Retail Indus. Leaders Ass’n v. Fielder*, 435 F. Supp. 2d 481, 495 (D. Md. 2006).

115. *Egelhoff*, 532 U.S. at 148 (citing *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9 (1987)).

116. *Fort Halifax*, 482 U.S. at 13.

117. *See Golden Gate Rest. Ass’n v. San Francisco (Golden Gate I)*, 535 F. Supp. 2d 968, 976 (N.D. Cal. 2007), *rev’d*, 546 F.3d 639 (9th Cir. 2008) (“[T]he requirements of the Ordinance have an impermissible connection with employee benefit plans because they impose on employers specific recordkeeping, inspection and other administrative burdens related to the administration of their private healthcare expenditures.”).

118. *Retail Indus. Leaders Ass’n v. Suffolk County*, 497 F. Supp. 2d 403, 418 (E.D.N.Y. 2007).

119. *Golden Gate I*, 535 F. Supp. 2d at 970, *rev’d*, 546 F.3d 639 (9th Cir. 2008).

120. *Retail Indus. Leaders Ass’n v. Fielder*, 475 F.3d 180 (4th Cir. 2007).

impose even greater administrative burdens because they regulate substantive aspects of the benefit plan, not just total expenditures. Because they seek substantive changes in employer-provided health care benefits, pay or play laws go to the core of ERISA preemption analysis by creating unacceptable administrative burdens that interfere with “nationally uniform plan administration.”¹²¹

3. *The Existence of an ERISA Plan*

In *Ingersoll-Rand*, the Court called attention to state laws that are premised on the “existence” of an ERISA plan,¹²² concluding that a statute that would not function in the absence of ERISA-governed benefits was, in effect, an impermissible “reference to” a covered plan. The *Dillingham* Court reiterated this theme, condemning statutes “where the existence of ERISA plans is essential to the law’s operation.”¹²³ Despite tortured state attempts to avoid assuming the existence of ERISA plans, pay or play programs run afoul of this requirement.

Employer mandates, by definition, require the state or municipality to determine if an employer has made a statutorily adequate contribution to employee health care. Certainly, a state law which defined its requirements specifically in terms of ERISA’s “employee welfare benefit plans” would be preempted because it specifically “references” and assumes the “existence” of ERISA entities. However, as states have taken more creative approaches to defining what constitutes “playing,” courts have taken a more functional approach to preemption. For example, some state laws that require employers to spend a fixed amount on “employee health care” also include a long definition of qualified health care expenses, which include ERISA and non-ERISA expenditures. Maryland included Health Savings Accounts and on-site employee health clinics,¹²⁴ while Suffolk County also included employers’ charitable contributions to local community health centers.¹²⁵ The Fourth Circuit essentially ignored the Health Savings Account and on-site clinic components of the statute, observing that they “simply would not be a serious means” by which employers would choose to comply with the law.¹²⁶ In reviewing the Suffolk County statute, the district court similarly found that it was “unreasonable” to expect employers

121. *Egelhoff v. Egelhoff*, 532 U.S. 141, 142 (2001).

122. *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139 (1990).

123. *Cal. Div. Labor Standards & Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1996).

124. See MD. CODE ANN., LAB. & EMPL. §§ 8.5-101 to -107 (LexisNexis 2006); 2005 Md. Laws 3 (codified as amended at MD. CODE ANN., HEALTH-GEN. § 15-142 (LexisNexis 2007)).

125. See *Retail Indus. Leaders Ass’n v. Suffolk County*, 497 F. Supp. 2d 403, 416 (E.D.N.Y. 2007) (describing the Suffolk County law).

126. *Retail Indus. Leaders Ass’n v. Fielder*, 475 F.3d 180, 196-97 (4th Cir. 2007).

to contribute to a community health center in place of an employee health plan, thus the statute relied on the existence of, and therefore impermissibly referenced, ERISA plans. The California district court nicely summarized this approach, focusing on the “undeniable fact . . . that the vast majority of any employer’s healthcare spending occurs through ERISA plans.”¹²⁷ In this view, any state law that attempts to assess health expenditures necessarily references ERISA plans. Given courts’ functional approach to the “reference to” portion of the preemption inquiry, most pay or play statutes impermissibly depend on ERISA spending in order to determine employer liability.

4. *The Ninth Circuit’s Opinion in Golden Gate Restaurant Ass’n*

As described above, most courts addressing the issue have held that pay or play statutes are barred by ERISA. The only exception is a 2008 decision in the Ninth Circuit, concluding that San Francisco’s employer mandate was not preempted.¹²⁸ In that opinion, Circuit Judge Fletcher overturned a lower court decision holding the statute preempted by ERISA. He also offered a detailed analysis of the program, which required employers to spend \$1.76 per hour per employee, or \$3500 per year for full time employees.

The court first addressed the argument that San Francisco’s law had an impermissible “connection with” employers’ ERISA-covered plans.¹²⁹ Quoting extensively from *Travelers* and emphasizing that the law did not “bind plan administrators to any particular choice,” the court rejected this assertion.¹³⁰ The court did not focus on the ways in which the statute might influence employers’ decisions about whether or not to adopt ERISA-covered health plans, which had been at the heart of the Fourth Circuit’s analysis of this issue.¹³¹ Instead, the Ninth Circuit highlighted the fact that the San Francisco ordinance had only a minimal impact on employers’ decisions about what to do *inside* their health insurance plans. San Francisco did not require or encourage particular forms of coverage, and in that respect “the influence exerted by the [San Francisco]

127. *Golden Gate Rest. Ass’n v. San Francisco (Golden Gate I)*, 535 F. Supp. 2d 968, 976 (N.D. Cal. 2007), *rev’d*, 546 F.3d 639 (9th Cir. 2008).

128. *Golden Gate Rest. Ass’n v. San Francisco (Golden Gate III)*, 546 F.3d 639 (9th Cir. 2008). This decision followed an earlier 2008 opinion in which Judge Fletcher stayed the district court’s decision overturning the ordinance. *Golden Gate Rest. Ass’n v. San Francisco (Golden Gate II)*, 513 F.3d 1112 (2008).

129. *Golden Gate III*, 546 F.3d at 654.

130. *Id.* at 656.

131. *See Retail Indus. Leaders Ass’n v. Fielder*, 475 F.3d 180 (4th Cir. 2007). The Ninth Circuit distinguished the Fourth Circuit case by emphasizing the fact that under the San Francisco law, benefits actually could accrue to employers who chose to pay, rather than play, which was not the case under Maryland’s Walmart law. *Golden Gate III*, 546 F.3d at 659-61.

Ordinance is even less direct than the influence in *Travelers*.”¹³² More broadly, because San Francisco only cared about the level of payment, not the type of benefits, there was no preemption.

The court then rejected the claim that the law’s administrative burdens rendered it ERISA-preempted. Relying on Ninth Circuit precedent, Judge Fletcher insisted that the burdens fell “on the *employer* rather than on an ERISA plan” and were thus irrelevant to the preemption inquiry.¹³³

Finally, the Ninth Circuit considered whether San Francisco’s ordinance made a “reference to” ERISA plans.¹³⁴ Using the *Ingersoll-Rand* test, which looks to a statute’s reliance on the “existence of an ERISA plan,” the court concluded that the law did not assume the existence of ERISA-governed benefits.¹³⁵ Indeed, the opinion eschewed the functional inquiry described above and instead concluded simply that employers could pay the tax to the city, and therefore the statute could “have its full force and effect even if no employer in the City has an ERISA plan.”¹³⁶ Furthermore, to the extent the San Francisco law “referenced” anything, it was a permissible “reference to the *payments* provided by the employer to an ERISA plan,” and not an impermissible “reference to the level of *benefits* provided.”¹³⁷

The Ninth Circuit analysis is certain to draw criticism, and some have argued that it would not withstand Supreme Court scrutiny.¹³⁸ Yet, even if the reasoning is durable, the core conclusion is that San Francisco’s law is permissible because it looks at nothing more than the dollar value of employers’ health care expenditures. This reasoning gives state and local governments only the bluntest tool with which to craft health care reform and does not enable a broader array of experimentation. As a simple example, states may wish to expand their safety net health care services for youth, while creating soft employer incentives to cover their employees’ children.¹³⁹ Perhaps more to the

132. *Golden Gate III*, 546 F.3d at 656.

133. *Id.* at 657 (emphasis added).

134. *Id.* at 658.

135. *Id.* at 652.

136. *Id.* at 657.

137. *Id.* at 658 (emphasis added).

138. See, e.g., Sharon Jacobs, *The Ninth Circuit Gives San Francisco’s Health Care Security Ordinance the Green Light (For Now)*, 36 J.L. MED. & ETHICS 431, 433 (2008).

139. In the events surrounding the 2007 negotiations over SCHIP, the Centers for Medicare and Medicaid Services (CMS) issued a “Dear State Health Official” letter to states that had requested permission to expand their CHIP programs. In the letter denying the states’ request, CMS emphasized that states must not expand CHIP without taking steps to prevent children with existing employer-provided coverage from being shifted into the public program. In the letter, CMS suggested states take several steps, including enacting laws that “[p]revent[] employers from changing dependent coverage policies that would favor a shift to public coverage.” See Letter from

point, Massachusetts's employer mandate explicitly requires a "group health plan" and would undoubtedly be impermissible under the Ninth Circuit's approach.

Nor is the problem limited to the pivot points in the Ninth Circuit's analysis. In the seven statutes described above, legislators have gone to absurd lengths in their attempts to survive preemption. The Maryland legislature thought it could escape ERISA preemption by including expenditures on "workplace clinics" as a qualified health care cost. Yet it is difficult to imagine that encouraging employers to provide free Band-Aids and cough syrup ought to be a crucial component of the health reform agenda. Suffolk County chose to include employer contributions to local community health centers, but, again, mandated corporate charity hardly seems like a stable solution for the forty-seven million uninsured. And Massachusetts believed it had to cap the employer payment at less than ten percent of the cost of health insurance, which will ultimately limit the effectiveness and may jeopardize the solvency of their project. In other words, states are engaged in legislative contortions to escape ERISA preemption, and courts have regularly concluded that even that is not enough.

If state and local pay or play laws are going to be a viable component of health care reform, governments must be able to avoid these absurdities and confidently design pay or play programs to meet their legitimate health system needs. Therefore, it is important to amend ERISA section 514, giving states the freedom to realistically explore their options, balance incentives, and creatively design programs. The next Part considers options for amending the statute, particularly in the context of a national health care initiative.

II. AMENDING ERISA

Despite extensive discussion of the difficulties associated with ERISA preemption jurisprudence, very little attention has been paid to the contours of a potential legislative change to section 514. Even within the growing body of literature addressing preemption of state pay or play laws, little has been said about how the federal statute might be amended. However, as a window of reform opportunity opens, it is imperative to have solutions on the table. Therefore, building on the above explanation of ERISA preemption, this Part discusses a number of approaches for amending the statute, exploring ways to restructure statutory preemption and allow state and local health insurance reform to flourish.

Dennis G. Smith, Director, Centers for Medicare and Medicaid Services, to State Health Officials (Aug. 17, 2007), *available at* <http://www.cms.hhs.gov/smdl/downloads/SHO081707.pdf>. However, it seems that any state law that complied with this term would almost certainly risk ERISA preemption.

This conversation is particularly timely, as serious discussion about national health care reform resumes for the first time in nearly fifteen years. National legislation may impose some type of federal mandate requiring employer health insurance contributions,¹⁴⁰ but it may also create, exacerbate, or simply ignore problems that states or even localities can tackle through their own programs. There will undoubtedly be gaps in the categories of employers and employees included in the federal reform and in the type of care covered. A prolonged phase-in period or a broad set of exceptions will create a larger space where state and local governments may wish to take action. States will need to mediate the relationship between any federal programs or mandates and Medicaid and other state safety net programs. A truly comprehensive program is simply not on the horizon, and there remains an important role for states and localities to play.

Furthermore, negotiations surrounding health care reform provide an ideal legislative vehicle.¹⁴¹ The nascent health care reform conversations already involve state and local governments, employers, unions, and insurance companies—all key actors in the ERISA landscape.¹⁴² This moment, then, provides a unique opportunity to amend ERISA to allow state and local governments to experiment with their own health care reform agendas.

In general, there are three different policy paths that would achieve this result. First, federal legislation could drastically alter the preemption clause and eliminate most of the current jurisprudence by repealing the “relate to” language in its entirety. Second, section 514 could be amended to carve out a narrower exception that would permit state and local employer mandates, but would, in some other respects, leave the preemption scheme largely intact. As discussed below, this could take a number of forms, relying on existing components of the statute to craft an exception. Finally, broad and continuing “relate to” preemption could be supplemented by special exceptions—legislative or administrative—for particular state or local laws.

Before turning to these options, it is useful to briefly recall the structure of ERISA section 514, the preemption clause. Subsection 514(a) contains the infamous “relate to” language, while subsection 514(b) contains a list of exemptions from preemption—the insurance/banking/securities exception and the associated “deemer clause,” the special exception for Hawaii’s employer

140. Amol Navathe et al., *Barack Obama’s Plan for a Healthy America*, Context: Pol’y & Prac., http://www.contextjournal.org/category5.php?article_id=369 (last visited Nov. 12, 2009).

141. *See generally* JOHN W. KINGDON, *AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES* 173-75 (2d ed. 1995) (discussing legislative timing and the importance of a political “window” for proposed reforms).

142. If the failed 1994 health care reform debates taught anything, it is the importance of bringing all stakeholders to the table early.

mandated health insurance law, and many others.¹⁴³

A. Repealing "Relate to"

Perhaps the most obvious approach to prevent ERISA preemption of employer mandates is to simply abandon subsection 514(a)'s "relate to" language. Following this path, courts would be left to apply traditional field and conflict preemption principles to determine the permissibility of laws affecting employee benefits plans. In other words, the Courts would be asked to determine if there were actual conflicts between ERISA's requirements and a state or local pay or play law (conflict preemption), or alternatively if the law wandered too far into an area that Congress intended to occupy (field preemption).¹⁴⁴ The "connection with or reference to" test in its various iterations would be discarded, and the post-*Shaw* jurisprudence would be obsolete.

Justices Scalia and Ginsburg, in two concurring opinions, have asked the Court to accomplish this result on its own through a narrow construction of the 514(a) language.¹⁴⁵ It is perhaps conceivable that the Court could overrule nearly three decades of ERISA holdings, and Scalia has had some success in convincing Justices Breyer and Stevens of the merits of this argument.¹⁴⁶ However, given the norm of strong statutory stare decisis and Congress's repeated reliance on the Court's current approach,¹⁴⁷ specific legislative action seems like a much more appropriate reform tool. Congress could replace the existing "relate to" language in subsection 514(a) with text that clearly indicates the intent Scalia describes. For instance, the statute might be amended as follows:

Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede ~~any and all~~ State

143. 29 U.S.C. § 1144 (2006). Subsection (d) reiterates that no federal law is preempted and subsection (e) ensures that automatic contribution laws are not prohibited by the states.

144. *See supra* note 33.

145. *Egelhoff v. Egelhoff*, 532 U.S. 141, 152 (2001) (Scalia, J., concurring); *Cal. Div. Labor Standards & Enforcement v. Dillingham Constr., Inc.*, 519 U.S. 316, 336 (1997) (Scalia, J., concurring) ("I think it would greatly assist our function of clarifying the law if we simply acknowledged that our first take on this statute was wrong; that the 'relate to' clause of the pre-emption provision is meant, not to set forth a *test* for pre-emption, but rather to identify the field in which ordinary *field pre-emption* applies—namely, the field of laws regulating employee benefit plans . . .") (internal citation and quotation marks omitted).

146. *See Egelhoff*, 532 U.S. at 153 (Breyer, J., dissenting) ("Like Justice Scalia, I believe that we should apply normal conflict pre-emption and field pre-emption principles where, as here, a state statute covers ERISA and non-ERISA documents alike.").

147. *See generally* Richard Sorian & Judith Feder, *Why We Need a Patients' Bill of Rights*, 24 J. HEALTH POL. POL'Y & L. 1137 (1999) (describing how the proposed Patients' Bill of Rights legislation relied on the Court's current interpretations of ERISA preemption).

~~laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title that conflict with or otherwise impede the operation of this subchapter, subchapter II of this chapter, or subchapter III of this chapter.~~¹⁴⁸

One might argue that it would be better to simply repeal section 514, leaving ERISA without an express preemption clause, and relying on the courts to apply field and conflict preemption on their own. However, such an approach creates serious problems given the exceptions to preemption carved out in subsection 514(b) and the other preemption guidance appearing in subsections 514(d) and (e).¹⁴⁹ Indeed, despite the confusing “relate to” language, other parts of ERISA preemption clause offer sensible instructions and should be left intact. Therefore, it is wise to use an amended subsection 514(a) to set a general tone for preemption and allow the remainder of the statute to build around that.

Still this approach poses significant drawbacks. To begin, ERISA plans have legitimate concerns regarding administrative uniformity. In a labor market that is increasingly freed from geographic limitations, the administrative costs of complying with myriad state and local laws (reaching well beyond health benefits) could be tremendous. Field preemption principles would provide some limit to state regulation, especially within a statute that clearly evinces the need for administrative simplicity,¹⁵⁰ but there would undoubtedly be tremendous uncertainty. For instance, states would obviously be barred from regulating appeals from pension denials, since there is a large body of ERISA law on the subject, but appeals related to health insurance denial would be in uncertain waters. Furthermore, uncertainty itself is an important drawback to this approach. Preemption jurisprudence is notoriously unpredictable. Inviting a new generation of state law in a field that has been largely closed to state regulations for more than thirty years will cause confusion. On balance, these drawbacks may be outweighed by a legislative conclusion that “relate to” preemption was a failed experiment, but it is important to explore more limited alternatives.

B. A Statutory Space for Pay or Play

Rather than eliminating “relate to” and all of the associated jurisprudence, it may be more feasible or more desirable to simply carve out a narrower exception that allows state and local governments to experiment with pay or play statutes. There are three potential ways to create such an exception—bifurcating subsection 514(a) to separate pension plans and welfare benefit plans, expanding

148. See 29 U.S.C. § 1144(a) (2006).

149. *Id.* § 1144(b), (d)-(e).

150. See *Aetna Health Inc. v. Davila*, 542 U.S. 200, 208 (2004) (“The purpose of ERISA is to provide a uniform regulatory regime over employee benefit plans.”).

the insurance/banking/securities exception in subsection 514(b), or expanding the “compliance plan” exception. Each of these approaches is discussed below.

1. Pensions Plans and Welfare Benefit Plans

One way to create an exception for state employer mandates would be to focus on the different kinds of benefits regulated under the statute. Recall that ERISA regulates two broad categories: pension plans and welfare benefit plans. Pension plans provide post-retirement income to former employees and therefore require a complex set of rules governing how benefits accrue and vest over the course of an employee’s career. Indeed, ERISA’s 1974 enactment was motivated by the desire to create comprehensive national standards to ensure that pension funds were sustainably and fairly administered, and to provide a federal guarantee of pension plans’ solvency.¹⁵¹ Welfare benefit plans, on the other hand, include temporary benefits like health insurance and life insurance. While there was certainly some perceived need for federal regulation in this area, the substantive provisions of ERISA place far fewer burdens on welfare benefit plans than they do on pension plans.¹⁵²

Yet, section 514’s preemption scheme applies equally to pension and welfare benefit plans. The Third Circuit has reasoned that “it is unlikely that Congress intentionally created this so called ‘regulatory vacuum,’ in which it displaced state-law regulation of welfare benefit plans while providing no federal substitute.”¹⁵³ Professor Conison has offered a convincing account of the origins of this approach.¹⁵⁴ Conison argues that Congress was primarily concerned with fiduciary issues like pension plan vesting and funding, but the inclusion of welfare benefit plans in the broad preemption language was nonetheless intentional.¹⁵⁵ In particular, a 1974 state court ruling in Missouri affecting welfare benefit plans and subjecting them to state insurance regulation¹⁵⁶ sensitized ERISA’s drafters to the “potential for state interference with the proposed law.”¹⁵⁷ Thus, Congress was aware of the impact that subsection 514(a) would have on regulation of welfare benefit plans and deliberately elected such an approach.

Despite original congressional intent, however, it is relatively easy to build a

151. See LANGBEIN ET AL., *supra* note 32, at 77-89.

152. *Id.* at 90-92.

153. *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 467 (3d Cir. 2003) (Becker, J., concurring).

154. Jay Conison, *ERISA and the Language of Preemption*, 72 WASH. U. L.Q. 619 (1994).

155. See *id.* at 646-650.

156. *State ex rel. Farmer v. Monsanto Co.*, 517 S.W.2d 129, 133 (Mo. 1974).

157. Conison, *supra* note 154, at 648.

case for treating non-federal regulation of pension plans and welfare benefit plans differently. Imagine an employee who begins a twenty-year career with a single employer in Ohio, spends fifteen years working in Michigan, and transfers to Florida eighteen months before retirement. When this employee retires, disparate pension regulations in Ohio, Michigan, and Florida could cause profound uncertainty and conflict over the terms of his pension benefits, creating a strong imperative for federal preemption. However, when the employee seeks an annual physical under his employer-sponsored health insurance in Ohio, Michigan, or Florida, there is no conflict.¹⁵⁸ His health benefits are only subject to the regulations of one state at a time, and his transfer out of Michigan terminates any effect that Michigan law might have on his coverage.

Following this logic, subsection 514(a) could be amended to apply broad “relate to” preemption to pension plan benefits, but not employee welfare benefit plans. New language might read:

Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee *pension* benefit plan described in section ~~1003(a)~~ 1002(2) of this title and not exempt under section 1003(b) of this title.

With no explicit preemption language affecting ERISA’s welfare benefit plans, traditional field and conflict preemption principles would apply. Functionally, this approach may be indistinguishable from an effort to remove the “relate to” language from the statute entirely. All of the major ERISA preemption cases have considered laws that allegedly “relate to” welfare benefits, not pensions, and the supremacy of the comprehensive federal scheme in pension benefit regulation is largely undisputed. Nonetheless, approaching preemption reform in this way might be more palatable to key ERISA stakeholders, including employers and plan administrators, because it continues federal preemption in important parts of the market.

It is important to distinguish this approach from the “reasoned textualism” approach to preemption under the current statute that has been advocated by Professor Zelinsky.¹⁵⁹ He focuses attention on the distinction between pension and welfare benefit plans, but he does so in order to draw the preemption analyses closer together, rather than to separate them from one another. In particular, a “reasoned textualist” approaches preemption as follows:

[I]f ERISA affirmatively regulates a particular facet of pension plans (e.g., the employees who must be covered by such plans), the combination of section 514

158. Cf. LANGBEIN ET AL., *supra* note 32, at 118-19 (providing a similar example).

159. See Zelinsky, *supra* note 44, at 808.

and ERISA's silence on that subject as to welfare plans consigns that subject to employer autonomy. Thus, as to a state law impacting upon the substance of welfare plans, the Court should ask whether such law intrudes upon the zone of employer autonomy defined by reference to ERISA's regulation of pension plans. If the challenged state law intrudes upon the zone of employer autonomy so defined, the law is ERISA-preempted and the zone thereby preserved from state as well as federal regulation.¹⁶⁰

In other words, the "relate to" language is used to broadly define the field of regulation occupied by ERISA with respect to welfare plans. If Congress chose to regulate an aspect of pension benefits but left welfare benefits unregulated in that area, then any state or local law touching on welfare benefits in that way must be ERISA preempted. On the other hand, if the law affects an aspect of welfare benefit plans for which Congress is also silent with respect to pension benefits, the law is permissible. This "reasoned textualist" approach, whatever its merits, undoubtedly leaves most pay or play laws preempted.¹⁶¹ These laws mandate employer contributions to certain benefit plans and therefore impermissibly affect employer action. By contrast, the approach described above detangles pension and welfare benefit plan preemption, focusing the inquiry only on the way in which Congress separately regulates each type of benefit, and creates broader space for pay or play legislation.

2. Insurance/Banking/Securities Exception

Separating pensions from welfare benefit plans, while technically leaving the "relate to" language partially intact, still creates a tremendously large exception for regulation of all welfare benefit plans. A narrower change to ERISA's preemption language might focus more specifically on employers' health insurance benefits. A logical approach begins with subsection 514(b)(2)'s insurance/banking/securities exception. This language allows states to "regulate[]" insurance, banking, or securities," but with one important caveat—no ERISA-covered plan shall *itself* be subject to state regulation of insurance, banking, or securities.¹⁶² This limitation, codified in the "deemer clause," has created a surprisingly large loophole, allowing employers to "self-insure" rather than purchase insurance products, thus exempting them from state insurance regulation. Without digressing too far into the health insurance and HMO controversies of the late 1990s and early 2000s, it is worth noting that ERISA and its deemer clause played a central role in states' early inability to effectively

160. *Id.* at 840.

161. *See id.* at 845-46 (discussing *District of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125 (1992)); *see also* Zelinsky, *supra* note 85, at 232.

162. *See* 29 U.S.C. § 1144(b)(2) (2006).

regulate HMOs in the face of consumer complaints.¹⁶³ The proposed federal “Patients Bill of Rights” was one reaction to this gap in regulation, but subtle, post-*Travelers* changes in ERISA jurisprudence eventually alleviated some, though not all, of this tension.¹⁶⁴ This conflict undoubtedly lies in the background of any attempt to rework subsection 514(b)(2).

Nonetheless, carefully targeted modifications could extend this statutory language to include pay or play statutes. Combined with changes to section 514’s definitional section, the subsection could be amended as follows:

(b) Construction and application (2)(A) Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities, *or which requires provision of health care benefits*. (B) Neither an employee benefit plan described in section 1003(a) of this title, which is not exempt under section 1003(b) of this title (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies. . . .

(c) Definitions. For purposes of this section (3) *The term “health care benefits” shall include benefits provided under an employee benefit plan described in section 1003(a) of this title, only insofar as those benefits affect the protection or maintenance of a beneficiary’s health or wellness.*

This language allows states to do two things. First, they can require that employers make minimum health care expenditures or provide a minimum guarantee of health care coverage. This sort of revision does indeed create a broad safe harbor for employer mandates, allowing broad and creative state experimentation. At the same time, this language also reaches a very different kind of state regulation. Under the proposal, states can require that employers cover certain benefits, like pregnancy or vaccinations—requirements that have long been applied to standalone insurers, but that self-insured employers have been able to avoid through ERISA’s deemer clause.¹⁶⁵ While this is certainly a controversial extension of states’ regulatory power, this approach creates a sensible expansion.

The language above does include important limitations on states’ new

163. See LANGBEIN ET AL., *supra* note 32.

164. See Covington, *supra* note 91, at 6.

165. See LANGBEIN ET AL., *supra* note 32, at 770.

authority. First, the proposed language exempts only state laws that “require the provision of” health benefits, not laws which “regulate” those benefits, thus limiting the extent to which states can affect plan conduct. Furthermore, the proposed revision leaves the actual text of the deemer clause intact, even while neutralizing some of its effects. Nonetheless, under this scheme, self-insured employers continue to be exempt from state regulations affecting the “business” of health insurance (e.g., solvency requirements),¹⁶⁶ and states are only able to reach the substantive content of self-insured health plans in the same way that they regulate standalone insurance. At the same time, the definitional language in subsection 514(c)(3) could be narrowed, perhaps excluding mental health benefits and eschewing the controversial debate over mental health parity (e.g., “protection or maintenance of a beneficiary’s *physical* health or wellness”), or otherwise limiting the scope of the exception. Finally, note that, unlike solutions described above, this language applies only to states, not localities, and schemes like the one in San Francisco would continue to risk ERISA preemption.

Further, the interests lined up to support the deemer clause—large employers and most insurers—are substantial, and narrowing the loophole subjects them to a vast body of state regulation. While this may be entirely justifiable from a policy perspective, it may be politically infeasible, or it may simply be a battle that reformers choose not to fight. In that case, there is a third approach that would extend an even narrower safe harbor to certain kinds of employer mandates. As discussed below, this proposal does not rely on an amendment to section 514 and instead proceeds from the “compliance plan” exception in ERISA’s general definitional section.

3. *Compliance Plan Exception*

Broadly speaking, not all kinds of employee benefits are regulated under ERISA. Laws affecting benefits that are unregulated are therefore not preempted, for they do not “relate to” any ERISA-governed subject matter.¹⁶⁷ For instance, “excess benefit plans,” which provide benefits beyond some ERISA requirements, are outside the regulatory scheme;¹⁶⁸ governments are free to regulate these plans as they choose.¹⁶⁹ Leveraging this feature of the statute relies on amending ERISA so that benefits provided to comply with state and local pay

166. Regulation on the “business” of health insurance includes provisions creating minimum asset requirements or creating fiduciary responsibilities, exactly the sort of regulation ERISA was meant to preempt.

167. *See generally* 29 U.S.C. § 1144(a) (2006) (preempting state laws that “relate to any employee benefit plan described in section 1003(a) of this title *and not exempt* under section 1003(b) [ERISA section 403(b)] of this title”) (emphasis added).

168. *See id.* §§ 1002(36), 1003(b)(5).

169. *See id.* § 1144(a).

or play laws are not considered regulated welfare benefits. While this may seem improbable, given that health insurance benefits are a central ERISA-governed welfare benefit plan, the Act does open up a narrow opportunity for action.

Specifically, subsection 403(b)(3), known as the “compliance plan” exception, provides:

(b) The provisions of this subchapter shall not apply to any employee benefit plan if . . . (3) such plan is maintained solely for the purpose of complying with applicable workmen’s compensation laws or unemployment compensation or disability insurance laws¹⁷⁰

This language leaves the states and localities free to design workers compensation and unemployment benefit schemes, with mandated employer contributions, without risking ERISA preemption. Pay or play laws could potentially be worked into this framework, though the result would necessarily limit the form of state and local regulation. Following this approach, subsection 403(b)(3) could be amended to read as follows:

(b) The provisions of this subchapter shall not apply to any employee benefit plan if . . . (3) such plan is maintained solely for the purpose of complying with applicable workmen’s compensation laws, ~~or~~ unemployment compensation or disability insurance laws, *or health care contribution laws*

Under this exception, governments could design stand-alone “health care contribution” programs and require employer provision of benefits without coming under ERISA’s umbrella. However, this sort of scheme would look very different from employer mandates that state and local governments have recently enacted. Note that the exception applies only to plans that are maintained “solely” to comply with relevant laws. Pay or play laws, on the other hand, have tended to look to employer contributions under existing ERISA-covered health care benefit plans. If non-federal health care reform is going to escape preemption through the compliance plan exception, then new forms of employer mandates will need to be developed.

The Massachusetts health care reform statute suggests one design that may be effective. Under that law, employers who choose to “pay” are not assessed a fixed per-employee fee, but are instead required to compensate the state for a percentage of the uncompensated health care sought *by their employees*.¹⁷¹ A statute that placed a similar assessment on employers across the state could be designed so that contributions were funneled into a plan “maintained solely for

170. *Id.* § 1003(b) (2006).

171. *See* An Act Providing Access to Affordable, Quality, Accountable Health Care § 44, 2006 Mass. Acts 77, 111-13.

the purpose of complying.”¹⁷² Thus, while not technically creating an employer mandate, this approach would accomplish the same result, since individuals generally seek uncompensated care only if they lack employer-provided insurance.

Approaching pay or play preemption in this way has tremendous practical advantages—it creates a narrow exception that only reaches a very specific kind of statute. Yet it also drastically limits how governments design their reform programs, potentially placing off-limits many innovative public-private partnership approaches providing expanded access to health insurance. By requiring that pay or play statutes operate from an employer benefit that exists “solely” to comply with state or local law, new regulation might arguably be more disruptive by requiring the establishment of new kinds of benefits.

C. Case by Case De-Preemption

None of the narrow approaches described above are entirely satisfactory—the more expansive safe harbors may be impossible to enact and may risk intolerable uncertainty, while the more limited approaches may be too restrictive to allow effective experimentation. Similarly, repealing the “relate to” language may prove unwise or insurmountably challenging. The third potential policy path, case by case de-preemption of particular laws, certainly does not escape these concerns. Instead, it may recombine the trade-offs in a different way, thus creating an alternative set of opportunities for reformers.

This Section describes two somewhat related tools for achieving such case by case de-preemption, where federal actors evaluate particular state and local pay or play laws and exempt them from ERISA preemption at their discretion. It begins by describing a purely legislative approach based on ERISA’s exception for the state of Hawaii and then explores how this approach might be modified in light of the Clean Air Act’s scheme for establishing fuel economy standards for consumer vehicles. It then sketches the outline of a more comprehensive and flexible scheme based on federal agency discretion.

1. The Hawaii Route

In 1974, shortly before ERISA was enacted, Hawaii’s state legislature passed the Prepaid Health Care Act of 1974, effectively requiring employers to pay at least fifty percent of their employees’ health care costs.¹⁷³ The Hawaii statute reaches beyond even the most ambitious proposals in the modern debate, covering any employee working more than twenty hours a week, and capping

172. 29 U.S.C. § 1003(b)(3) (2006).

173. HAW. REV. STAT. ANN. § 393-13 (LexisNexis 2004).

employee contributions to insurance premiums at 1.5% of their salary.¹⁷⁴ In a 1980 decision that was affirmed by the Supreme Court per curiam, the Ninth Circuit held the statute preempted by ERISA.¹⁷⁵ Two years later, after an aggressive campaign by Hawaii's congressional leadership,¹⁷⁶ Congress amended ERISA's preemption clause to specifically exclude the Hawaii statute.¹⁷⁷ The exception only extends to the statute as crafted in 1974 and does not allow Hawaii to modify its program in any way.¹⁷⁸ Therefore, Hawaii employers are still required to comply with the state's broad health care coverage mandate; however, any other state attempting to replicate the program would face certain ERISA preemption.

Some have argued that Massachusetts should explore a similar legislative exception for its own health care reform program.¹⁷⁹ While the state's program has not been challenged in federal court, and observers continue to argue that the law is effectively tailored to escape ERISA preemption, the threat of preemption litigation still hangs over administration of the state law. A statutory exception like Hawaii's would eliminate this concern. Of course, given Massachusetts's tortured efforts to escape ERISA preemption—limiting employers' assessments to \$295 per year and tracking employer data for uncompensated care patients—it would be ironic to find that these compromises were moot. More importantly, a Hawaii-like provision would lock Massachusetts into its current program design, flying in the face of rhetoric touting the program as an experiment in need of tinkering and modification.¹⁸⁰ And, perhaps most significantly, an exception for the state of Massachusetts would do nothing to promote employer mandates in San Francisco, Vermont, and other states and cities contemplating reform. In fact, a legislative exception for Massachusetts would actually undermine the argument that other programs were not ERISA-preempted.

Some of these concerns can be better understood by looking to an entirely unrelated area of federal law: the Clean Air Act's Corporate Average Fuel

174. *Id.* § 393-3, -13; see also Sylvia A. Law, *Health Care in Hawai'i: An Agenda for Research and Reform*, 26 AM. J.L. & MED. 205, 206-07 (2000) (attributing Hawaii's broad coverage to numerous factors, including decades of Democratic political control and the state's unique cultural history).

175. *Standard Oil Co. of Cal. v. Aghsalud*, 633 F.2d 760 (9th Cir. 1980), *aff'd mem.*, 454 U.S. 801 (1981).

176. Shelley K. Hubner, *State "Pay or Play" Employer Mandates: Prescribed or Preempted?*, HEALTH L., Aug. 2008, at 15, 19.

177. See 29 U.S.C. § 1144(b)(5) (2006).

178. See *id.* § 1144(b)(5)(B)(ii).

179. David A. Hyman, *The Massachusetts Health Plan: The Good, the Bad, and the Ugly*, 55 U. KAN. L. REV. 1103, 1110 (2007). The same logic certainly applies to programs in Vermont, San Francisco, and other places.

180. See *id.* at 1116-17.

Efficiency (CAFE) Standards, governing fuel efficiency standards for automakers.¹⁸¹ In 1970, Congress created the first federal standards for consumer automobiles. In the process, legislators were forced to grapple with the fact that California had already adopted its own more stringent standards for cars sold within its boundaries.¹⁸² The compromise that emerged allowed California to keep its own standards, and to amend those standards subject to approval by the Environmental Protection Agency.¹⁸³ Furthermore, other states were free to adopt the California standards if they chose; they could not, however, create their own fuel economy standards.¹⁸⁴

By analogy, imagine how the ERISA preemption scheme could adopt some of these features. The statute could be amended to, first, de-preempt the Massachusetts law; second, give Hawaii and Massachusetts the option of seeking federal approval for changes to their statutes; and third, allow other states to adopt wholesale the Hawaii or Massachusetts programs. But even this brief thought experiment exposes profound flaws with such an approach in the context of health care reform. To begin, fuel efficiency standards create a single-variable regulatory scheme and the core cost-benefit calculation is clear: the cost of dirtier air against the expense of more efficient cars. Pay or play statutes, on the other hand, are comprehensive programs that involve dozens, or even hundreds, of decision points and weigh a daunting array of interests. Fuel efficiency standards are simply a number, but employer mandate-based health reform affects an entire system, and an either/or approach in this context is difficult to justify. Additionally, in the context of CAFE standards, California has some non-arbitrary claim to special status—it is a large state and its consumers purchase enough cars to garner substantial market power.¹⁸⁵ No similar logic applies in the health care reform debate; Hawaii and Massachusetts are only advantaged

181. See 49 U.S.C. § 32,902 (2006).

182. See Patrick Parenteau, *Lead, Follow, or Get Out of the Way: The States Tackle Climate Change with Little Help from Washington*, 40 CONN. L. REV. 1453, 1466-67 (2008).

183. Until recently, EPA approval was largely considered a rubber-stamp process, and the EPA had never denied a waiver to California; however, the Bush Administration denied the most recent application in 2007. See Press Release, Environmental Protection Agency, America Receives a National Solution for Vehicle Greenhouse Gas Emissions (Dec. 19, 2007), available at <http://www.epa.gov/newsroom/newsreleases.htm> (follow “By Date” hyperlink, then follow “2007” hyperlink, then navigate to 12/19/2007). In the first week of the new administration, President Obama ordered the EPA to reconsider the issue. See John M. Broder & Peter Baker, *Obama’s Order Is Likely to Tighten Auto Standards*, N.Y. TIMES, Jan. 25, 2009, at A1.

184. 42 U.S.C. § 7543(a) (2006).

185. See generally Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 732-33 (2008) (discussing the business community’s preference for preemption because of the way it simplifies trade across state lines). Were Nebraska to attempt similar legislation, one could imagine that automakers would simply refuse to sell cars in the state.

because of their first-mover status, and there is no particular reason to think that these programs would work well in other states.¹⁸⁶ Finally, in the health care context, this approach would largely eliminate the broad and creative experimentation that is needed to find meaningful health care reform options.

Indeed, none of this is to suggest that the CAFE model should be seriously explored in the context of ERISA reform. But it does highlight an alternative to the statutory reforms discussed in the preceding Section, which attempt to define a specific sandbox in which non-federal actors can create pay or play structures. Instead, there are models in the modern administrative system that begin by preempting state law but nonetheless allow states and localities to advance their own regulatory interests on a federally-controlled playground. The next Subsection explores a different, more apt analogy in administrative law and uses that to trace an approach for amending ERISA section 514.

2. A Role for Federal Agencies

A more workable model would provide state and local governments a flexible way to seek ERISA de-preemption of health care reform legislation. Starting with a presumption of today's broad (though somewhat uncertain¹⁸⁷) ERISA preemption of pay or play statutes, states and localities could apply to a federal agency, which would then review their program and grant an exception from preemption. Such a system would give governments the ability to design flexible programs, while allowing a federal actor to assess the administrative burden placed on employers. Thus, Massachusetts's comprehensive and carefully administered statewide reform program could be treated differently than the haphazard New York City law applying only to employers with more than 12,500 square feet of retail grocery sales.¹⁸⁸ Moreover, employers would be provided with clear notice of any non-federal law that may affect their provision of health care benefits, arguably lessening the administrative complexity for multi-state employers.

In fact, a 1976 Food and Drug Administration (FDA) statute, the Medical Device Amendments,¹⁸⁹ operates in a very similar way. The statute provides a

186. See Sidney D. Watson et al., *The Road from Massachusetts to Missouri: What Will It Take for Other States To Replicate Massachusetts Health Reform?*, 55 U. KAN. L. REV. 1331 (2007) (explaining the myriad ways that health reform must vary state-to-state).

187. Cf. *Golden Gate Rest. Ass'n v. San Francisco*, 546 F.3d 639 (9th Cir. 2008) (constituting the only decision upholding a pay or play law).

188. See N.Y., N.Y., ADMIN. CODE § 22-506 (2009), available at <http://public.leginfo.state.ny.us> (follow "Laws of New York" hyperlink, then follow "ADC" hyperlink, then navigate to Title 22, Section 506).

189. See Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 15 U.S.C. § 55 and in scattered sections of 21 U.S.C.).

comprehensive federal regulatory scheme for medical devices, and in broad language preempts any state law governing the “safety or effectiveness” of a regulated device.¹⁹⁰ However, the statute also provides that the FDA may exempt laws from preemption, “[u]pon application of a State or a political subdivision” and review by the agency.¹⁹¹ Today, the *Code of Federal Regulations* contains a long list of exempted state laws.¹⁹² Like the fuel efficiency standards compromise, this legislative scheme was born of an era when states entered a regulatory field before the federal government, and legislators were forced to design a system that would allow federal supremacy while accommodating existing state law.¹⁹³

There are a number of unresolved questions and substantial problems with using this approach to create an ERISA de-preemption scheme. First, which agency would be responsible for administering the program? ERISA largely falls under the purview of the Department of Labor, but that agency has very little special expertise in the complex issues affecting employer provision of health care. Some even argue that the Department’s own engagement in ERISA cases is at least partly responsible for today’s complicated ERISA jurisprudence.¹⁹⁴ Another choice might be the Centers for Medicare and Medicaid Services (CMS), an office within the Department of Health and Human Services that is responsible for assessing state compliance with the federal Medicaid statute.¹⁹⁵ States are accustomed to seeking CMS approval for changes to their Medicaid programs,¹⁹⁶ and pay or play reforms are often coupled with expansion of or alterations to the state’s health care safety net services.¹⁹⁷ Thus, states may

190. 21 U.S.C. § 360k(a)(2) (2006).

191. *Id.* § 360k(b) (2006).

192. *See* 21 C.F.R. § 808.1 (2009).

193. *Cf.* Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 526 (1988) (discussing the history of the MDA).

194. *See, e.g.,* William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from Chevron to Hamdan*, 96 GEO. L.J. 1083, 1113-14 (2008) (discussing the Supreme Court’s deference to the Department of Labor in ERISA cases). *But see* *Golden Gate Rest. Ass’n v. San Francisco*, 546 F.3d 639 (9th Cir. 2008) (lower court did not defer to the Department of Labor).

195. *See* Centers for Medicare & Medicaid Services, Overview, <http://www.cms.hhs.gov/History> (last visited Nov. 12, 2009).

196. All states must have a Medicaid “State Plan” on file with CMS, and states must seek approval for all changes, either as “State Plan Amendments” or federal “waivers.” *See generally* Julia Gilmore Gaughan, *Institutionalization as Discrimination*, 56 U. KAN. L. REV. 405, 408-12 (2008) (providing a description of the Medicaid state plan process).

197. *See* Mark E. Douglas, *An Overview of the Recent State Rally for Health Care Reform*, 5 IND. HEALTH L. REV. 277, 291-93 (2008) (describing how the Massachusetts reform plan interacts

already be working with CMS to obtain approval for their reform legislation, and expanding that process to cover ERISA de-preemption could be a starting point. However, CMS has no expertise in employee benefits, the private insurance market, state insurance regulation, or other related issues, making it difficult to imagine putting the entire process in their hands. One could also envision a hybrid scheme where CMS evaluates the program and makes a recommendation to the Department of Labor, in much the same way that the Department of Justice and Department of Health and Human Services collaborate on the “scheduling” of drugs under the Controlled Substances Act.¹⁹⁸

Yet even if one resolves the question of agency authority, there is still the vexing concern of inappropriate agency politicization of these decisions. After all, both of the de-preemption schemes discussed above—CAFE standards and the MDA—have been thrust into newspaper headlines and federal courts in recent years, as state and private actors allege that the agency involved has asserted its authority in impermissible ways.¹⁹⁹ One of the goals of pay or play reforms is to fill gaps at the interstices of federal health care reform, and inserting the federal bureaucracy into these decisions may frustrate this aim.

Finally, any system of federal agency de-preemption would require statutory criteria by which state or local programs could be evaluated. This forces a conversation about the specific goals of ERISA preemption, and reaching a consensus may be even more politically challenging than the legislative reforms discussed above. Furthermore, statutory criteria would need to draw boundaries around the type of state or local law that would be eligible for de-preemption. If the option is targeted to only reach the archetypal employer mandate, experimentation may be unnecessarily closed, but a broader focus may make de-preemption administratively impossible. Nonetheless, despite all of these concerns, an administrative de-preemption scheme creates a possible alternative and may allow more middle ground than a purely statutory change.

CONCLUSION

This Note has argued that most state and local pay or play laws are preempted by ERISA. Even when health care reform is tailored to survive a challenge, the preemption jurisprudence places such hurdles in front of program design that it impedes the ability to create flexible and creative reform structures. As health care reform is thrust into the national spotlight, legislators are

with the Medicaid program).

198. See 21 U.S.C § 811(b) (2000).

199. See *Riegel v. Medtronic*, 128 S. Ct. 999, 1012 (2008) (Stevens, J., concurring) (discussing the MDA and FDA’s de-preemption authority); Broder & Baker, *supra* note 183 (discussing the California CAFE controversy).

presented with an opportunity to amend ERISA's preemption clause as part of a health care reform bill, yet little attention has been paid to the contours of such legislative reform. Thus, this Note has proposed and analyzed a number of specific amendments that would allow health care reform at the state and local level.

One obvious possibility is to simply remove the controversial "relate to" language from the statute and leave ERISA to traditional field and conflict preemption principles.²⁰⁰ Another approach continues expansive "relate to" preemption for ERISA regulation of pension plans, but leaves state and local law affecting welfare benefit plans without an express preemption clause.²⁰¹ Alternatively, reforms could graft new exceptions onto existing components of ERISA's preemption clause—the insurance/banking/securities exception,²⁰² or the compliance plan exception.²⁰³ State and local governments could also seek specific congressional amendments exempting their particular employer mandates, as Hawaii did in 1982.²⁰⁴ Finally, the Note explored a proposal for ERISA de-preemption moderated by a federal agency.²⁰⁵

Each of these proposals has different advantages. Abandoning the "relate to" language, in its entirety or as applied to welfare benefit plans, is the only alternative that offers states and localities complete flexibility in program design. Yet these approaches may place intolerable administrative burdens on employers and may be politically impossible. At the same time, more targeted and politically palatable reforms—including modification of the compliance plan exception or agency-based de-preemption—may so constrain the design of pay or play reforms that they are hardly better than the current scheme. Administrative de-preemption is further hampered by program complexity and important questions about its feasibility, but if successfully implemented, it could provide a compromise option that promoted state and local experimentation while satisfying some employer concerns.

Perhaps the best alternative is to add health care reform to the insurance/banking/securities exception. The types of employer mandates covered by this change are reasonably broad, but employers are exposed to state regulation in a more narrow and predictable area. This proposal has the further advantage of mitigating some of the more pernicious concerns associated with employers' use of the "deemer clause" to escape state regulation of health

200. See *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 335 (1997) (Scalia, J., concurring); *supra* Section II.A.

201. See *supra* Subsection II.B.1.

202. See *supra* Subsection II.B.2.

203. See *supra* Subsection II.B.3.

204. See *supra* Subsection II.C.1.

205. See *supra* Subsection II.C.2.

insurance benefits,²⁰⁶ though that fact in and of itself may pose political difficulties.

Indeed, it is hardly obvious where negotiations to amend ERISA's preemption clause will lead. The process will have to tackle concerns that reach well beyond the context of pay or play health care reform, and those topics are outside the scope of this Note. But if nothing else, this begins a conversation about how ERISA can be amended by placing possibilities on the table and providing a sense of the trade-offs and concerns in play. And the time for action is now: presented with a once-in-a-generation opportunity to reform our health care system, national leaders can make it possible for states to pick up where their efforts leave off. Through swift action, Congress can ensure that state and local governments are empowered to create successes from whatever small failures the national health reform project is forced to endure.

206. See *supra* notes 35-37 and accompanying text.

