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Loyola University Chicago School of Law

BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW

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**THE *ONLINE* HEALTH POLICY AND LAW REVIEW OF
LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW**

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VOLUME 18, ONLINE ISSUE 2

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ANNALS OF HEALTH LAW
ADVANCE DIRECTIVE
Editor's Note

The *Annals of Health Law* is proud to present the second Issue of our online journal, *Advance Directive*. Consistent with our goal of promoting student health law scholarship, Part I of this Issue features the winning entry from the first annual Illinois Association of Healthcare Attorneys' student writing contest. In her article, "No-Fault Solutions to the Problems of Medical Injuries: A Focus on Sweden as a Model," Sarah Hoffman explores the inadequacies of the U.S. medical malpractice tort system in deterring unsafe practices and compensating injured individuals. She turns to Sweden's "no fault" system as a viable alternative.

Part II of this Issue focuses on the theme of law and public health. We begin with the pressing topic of public health and the economy. Our authors explore the potential risks of putting healthcare reform on the back burner because of the economic crisis; the burgeoning practice of medical tourism as an alternative to expensive health care treatment in the United States; and whether a national mandate for autism insurance coverage is too onerous in the current economic climate.

Next our authors tackle public health regulation: vaccines, immunizations, and FDA food safety inspections. Our authors propose a workable standard for vaccine exemptions to address "misplaced fears" of vaccines; suggest strategies to combat well-documented ethnic disparities in influenza immunization rates; and explore the hazards of the FDA relying on the regulatory scheme of the importing country to inspect imported food.

We then address the critical topic of access to medications and mental health treatment. Our authors propose an orphan drug patent pool to incentivize research into orphan diseases and improve access to the resulting drugs; and then

suggest ways to reduce juvenile recidivism by increasing access to mental health treatment for juvenile offenders.

The Issue then turns to public health litigation, analyzing a recent Supreme Court decision, *Altria Group, Inc. v. Good*, which may give hope to numerous plaintiffs in class action lawsuits who are claiming harm from misleading advertising involving “light” cigarettes.

Finally, the Issue delves into public health legislation, where our authors analyze controversies surrounding Illinois state legislation to protect medical marijuana users; New York state “fat tax” legislation designed to reduce obesity rates while generating revenue for health programs; federal legislation to combat the rising incidence of chronic Lyme disease; and federal “conscience clauses” that allow healthcare providers to refuse to perform medical procedures based on religious or moral beliefs.

We would like to thank Claire St. Aubin, our Technical Production Editor, and Tiffany Gehrke and Alexis Shrawder, our *Advance Directive* Senior Editors, for their invaluable contributions in launching this Issue. We also are grateful to our *Annals* Executive Board members—Adam Larson, Tamara Forys and Angela Epolito—for their editorial assistance. Our *Annals* members deserve a special recognition for writing timely, thoughtful articles and for editing the work of their peers. Finally, we extend our warmest appreciation to the Beazley Institute and our faculty advisors, Professors Lawrence Singer and John Blum, for their continued support, encouragement, and mentorship.

We hope you enjoy our second Issue of *Advance Directive*.

Sincerely,

Ann Weilbaecher
Editor-in-Chief
Annals of Health Law
Loyola University Chicago School of Law

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No-Fault Solutions to the Problem of Medical Injuries: A Focus on Sweden as a Model*

Sarah Z. Hoffman **

The medical malpractice tort system in the United States is based on three main goals: deterrence of unsafe practices, compensation for injured persons, and corrective justice.¹ The tort system is not accomplishing these goals. Recurring medical injuries, uneven payment of damages, and a lack of clearly defined success and fairness in the justice system render the current medical malpractice system largely ineffective.

In 2000, the Institute of Medicine reported that medical errors in hospitals cause as many as 98,000 deaths per year. This report and others² call attention to the question of whether or not the tort system properly deters medical error.³ The

* This article is the winner of the 2008 Illinois Association of Healthcare Attorneys' Law Student Writing Competition.

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¹ Randall R. Bovbjerg & Frank A. Sloan, *No-Fault for Medical Injury: Theory and Evidence*, 67 U. CIN. L. REV. 53, 57 (1998); see also David M. Studdert, Michelle M. Mello, & Troyen A. Brennan, *Health Policy Report: Medical Malpractice*, 350 NEW ENG. J. MED. 283, 283 (2004).

² See Jeremy Coylewright, *No Fault, No Worries...Combining a No-Fault Medical Malpractice Act a the National Single-Payer Health Insurance Plan*, 4 IND. HEALTH LAW REVIEW 31, 37 (2007) (citing a Harvard study showing that only 12.5% of injured patients actually filed suit against their providers, and only a fraction of those claimants "actually recover any form of economic compensation..."); see also Studdert, Mello, & Brennan, *supra* note 1, at 285 (stating that a Harvard Study found "alarming estimates of the burden of medical injury...").

³ See Studdert, Mello, & Brennan, *supra* note 1, at 285 ("[E]vidence that the system deters medical negligence can be characterized as limited at best.").

litigation process is often lengthy and expensive.⁴ The injured are not always fairly compensated; awards frequently vary for similar injuries.⁵ Often doctors' malpractice insurance is so high they are forced to leave the practice of medicine, or alternatively practice in a different state with lower premiums.⁶ The adversarial nature of litigation pits patient against provider, which weakens the doctor-patient relationship. Injured persons may not receive justice and fairness because they may not be compensated equitably and within a reasonable amount of time after being injured.

An optimal medical liability system improves patient care and safety, works to prevent medical errors, and compensates injuries.⁷ Myriad solutions have been proposed as alternatives to the existing tort system.⁸ A no-fault solution to the problem of medical injuries would radically change the current mindset regarding medical injury in the United States. No-fault poses an interesting, and perhaps viable, alternative to the current tort system.

Section I of this article discusses the concepts of a no-fault system for medical injuries, including legislative reform, contract reform, and the pros and cons to such a system. Section II focuses on Sweden's no-fault model of compensation for medical injury. Finally, Section III analyzes how this system would work in the United States and the prospects of no-fault solutions for the problem of medical injuries in the United States.

⁴ See RANDALL R. BOVBJERG & BRIAN RAYMOND, KAISER PERMANENTE INST. FOR HEALTH POLICY, PATIENT SAFETY, JUST COMPENSATION AND MEDICAL LIABILITY REFORM 8 (2003), available at http://www.kpihp.org/publications/docs/patient_safety.pdf (stating that the average litigation time period for medical malpractice cases was 45 months); see also Jeffrey O'Connell, *Neo-No-Fault Remedies for Medical Injuries: Coordinated Statutory and Contractual Alternatives*, 49 LAW & CONTEMP. PROBS. 125, 125 (1986) [hereinafter *Neo-No-Fault Remedies*].

⁵ BOVBJERG & RAYMOND, *supra* note 4, at 9 ("[R]elatively minor injuries tend to be overcompensated relative to economic loss and more serious injuries under-compensated."); see also Jeffrey O'Connell, *A "Neo No-Fault" Contract in Lieu of Tort: Preaccident Guarantees of Postaccident Settlement Offers*, 73 CAL. L. REV. 898, 899 (1985) [hereinafter *Neo No-Fault Contract*] (characterizing the tort system as a "lottery").

⁶ BOVBJERG & RAYMOND, *supra* note 4, at 4.

⁷ David M. Studdert & Troyen A. Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, 286 JAMA 217, 219 (2001) [hereinafter *Error Prevention*].

⁸ Studdert, Mello, & Brennan, *supra* note 1, at 288-89 (citing different reforms or overhauls of the tort system that have been implemented or considered, including mediation, medical courts, arbitration, damages caps, attorney fee limits, and enterprise liability).

I. CONCEPTS OF A NO-FAULT SYSTEM FOR MEDICAL INJURIES

A no-fault compensation system (NFCS) for medical injuries would completely overhaul the current tort liability system. The claimant must prove four elements in the tort-based model for medical injury: duty, injury, causation, and negligence.⁹ The Restatement (Third) of Torts, in speaking to the negligence doctrine, states that "[a]n actor ordinarily has a duty to exercise reasonable care when the actor's conduct creates a risk of physical harm."¹⁰ Thus, doctors have a duty to exercise reasonable care to avoid causing physical harm to their patients. Patients bring injury claims based on this negligence doctrine when they believe a doctor has violated the duty owed to the plaintiff patient through this negligence standard of conduct which, for a physician, is the requirement to exercise the "knowledge, skill and care ordinarily possessed and employed by members of the profession..."¹¹ Many of these injury claims either "never reach the courts or, if litigated successfully, result in recovery which is not rationally related to the nature and scope of the wrong."¹² In addition, the negligence-based malpractice system results in prohibitive costs for provider malpractice insurance, which increases the costs of medical care.¹³

The goal of no-fault is to "improve upon the injury resolution of tort liability by replacing the existing fault remedy and liability insurance with a new no-fault alternative..."¹⁴ NFCSSs "eliminate the requirement of proving negligence."¹⁵ Further seeking to improve upon compensation and justice for those injured, no-fault's broadened eligibility scheme covers more individuals and eases access by "lowering the difficulties for asserting a claim."¹⁶ No-fault may

⁹ *Error Prevention*, *supra* note 7, at 219.

¹⁰ RESTATEMENT (THIRD) OF TORTS: LIAB. PHYSICAL HARM § 7 (2005).

¹¹ W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 187 (5th ed. 1984).

¹² Josephine Y. King, *No Fault Compensation for Medical Injuries*, 8 J. CONTEMP. HEALTH L. & POL'Y 227, 228 (1992).

¹³ Studdert, Mello, & Brennan, *supra* note 1 at 286 (discussing that tort law increases costs and encourages defensive medicine, including ordering of tests and procedures that are of marginal or no medical benefit).

¹⁴ Bovbjerg & Sloan, *supra* note 1, at 64.

¹⁵ *Error Prevention*, *supra* note 7, at 219.

¹⁶ Bovbjerg & Sloan, *supra* note 1, at 65,

also improve deterrence of injuries, as better monitoring of injuries, “expert resolution of claims,” and “systematic case finding,” including improved incentives for doctors and hospitals, may prevent injuries.¹⁷ A NFCS offers an appealing alternative to the current system by better achieving the goals of compensation, deterrence, and justice. A NFCS could be implemented through legislative channels, private contract, or a comprehensive no-fault system. Sweden’s comprehensive no-fault payment system for medical injuries is a useful model to examine. While opponents of no-fault cite excessive cost, causation issues, and lack of deterrence for arguments against such a system, policymakers in the United States can draw on Sweden’s experience to reform our current tort system.

A. Legislative Reform

No-fault legislative reform could take a number of approaches, from covering only certain types of injuries to a comprehensive medical liability scheme. Congress has proposed statutory no-fault compensation plans in the past.¹⁸ For example, a healthcare provider facing a potential tort claim would have the option to foreclose any claim for personal injury against him or her by offering, within a brief fixed time, periodic payments toward the claimant’s net economic loss.¹⁹ By statute, this tendered offer would foreclose any personal injury claim.²⁰ Such a statute either could be implemented on a state-by-state or national level. The statute could be designed to give a potential plaintiff the option to choose between a definite recovery of net economic loss or pursue a claim in tort.²¹ Alternatively, the statute could give the potential claimant no

¹⁷ *Id.*

¹⁸ *Neo-No-Fault Remedies*, *supra* note 4, at 129.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

option to refuse the tendered offer.²² The logistics would depend on the legislature and the proposal.²³

B. Private Contract

A no-fault system would be a controversial change from the current tort system. Because legislatures, both state and national, are reluctant to pass contentious statutes, private contract reform may offer a less divisive and challenging mechanism for implementing a no-fault system. Jeffrey O'Connell is the primary proponent of what he calls a "neo no-fault contract," agreed upon before a medical intervention, which would guarantee a post-medical intervention settlement offer.²⁴ At the time a patient meets with a doctor, the provider would "bind itself to offer no-fault benefits for economic . . . loss in the event of a resulting personal injury."²⁵ Prior to treatment, the patient would sign a contract with the doctor or organization accepting the no-fault benefits in lieu of a tort claim if he or she subsequently was injured.²⁶ The patient would be fully informed of his or her waiver of the right to sue in tort. The contract could be structured to exclude smaller cases; for example, "the contract could include a deductible of \$10,000 of actual medical expense or wage loss below which the tender need not be made."²⁷

This scheme would not place blame on the provider or serve as an admission of fault because the patient and doctor agreed beforehand to tender the offer in case of an adverse outcome.²⁸ Insurance companies might embrace this scheme because they would not be at risk of paying large, outlying awards won in litigation for pain and suffering. They also would improve their ability to predict

²² *Id.*

²³ See *Neo-No-Fault Remedies*, *supra* note 4, at 134-35 (discussing several parts to such plans, including exclusion of smaller claims before a provider makes a tender offer and including reasonable attorneys' fees in connection with the payment).

²⁴ *Neo No-Fault Contract*, *supra* note 5, at 906-07.

²⁵ *Id.* at 906.

²⁶ *Id.*

²⁷ *Id.* at 909.

²⁸ See *id.* at 910.

payments. Patients would bargain for the opportunity to receive faster payment for their injuries without the uncertainty of litigation. Doctors may appreciate the ease of payment and lack of blame for their actions. As the settlement offer is no longer discretionary, a “defendant [doctor] or an insurer need not fear that the offer to cover net economic loss will be perceived simply as an opening bid or as a signal of weakness,” which in the current system can encourage plaintiffs and attorneys to delay proceedings to obtain a larger settlement.²⁹

In contrast to a binding contract, an injured party could be given the option to accept the tendered offer for net economic loss within a certain time period or file a tort claim.³⁰ It is unclear if this method would result in adverse selection, with those parties with greater injuries and stronger claims pursuing the claim in tort, thus negating the positive effects the private contract method would have on the existing malpractice tort system and insurance.³¹ However, parties who have suffered injuries may be averse to risk and therefore choose to accept certain, prompt payment over uncertain, delayed awards.³²

With either statutory or contractual no-fault, the system could be designed to impose the duty to tender an offer upon the injuring party or allow the injuring party the opportunity to choose to tender or risk a tort suit.³³ Similarly, either system could compel the injured party to accept the tendered offer by pre-determined agreement or allow the party to accept or reject the offer for net economic loss and pursue in tort.³⁴ The designer of the individual proposal would determine which options to apply.

²⁹ *Neo-No-Fault Remedies*, *supra* note 4, at 132.

³⁰ *Id.*

³¹ *Neo No-Fault Contract*, *supra* note 5, at 911.

³² *Id.*

³³ *Neo-No-Fault Remedies*, *supra* note 4, at 135-36.

³⁴ *Id.* at 136.

C. Comprehensive No-Fault Compensation

In a comprehensive no-fault compensation system, “the injurer must tender, and the injured party must accept.”³⁵ This scheme makes medical providers strictly liable “for reimbursing losses due to preventable injury, completely eliminating the requirement for any injured patient to prove provider negligence in court.”³⁶ Patients would be entitled to compensation when they suffer a disability caused by medical treatment “irrespective of whether the treatment was negligent.”³⁷ The compensable event is based on preventability instead of negligence.³⁸ However, questions such as “just what constitute[s] an injury, how noneconomic loss such as pain and suffering [will] be determined and quantified, and how . . . [damages will] be apportioned among multiple participants in the course of treatment” remain.³⁹ The NFCS could use a medical panel to determine what constitutes an injury and if the injury was preventable, or the system could rely on a pre-determined list of avoidable class of events to make such a decision.⁴⁰

An enterprise liability system would help solve the problem of damage apportionment and also would improve patient safety. It has been documented that the “aberrant behavior of individual providers is a relatively infrequent explanation for harm,” and instead the “greatest potential for patient safety advances” lie in “institutional... accountability.”⁴¹ Many comprehensive no-fault schemes suggest an enterprise liability system “whereby the hospital [or healthcare provider] is responsible for the no-fault premiums.”⁴² In such a system, doctors affiliate with a hospital or other healthcare organization, and this

³⁵ *Id.*

³⁶ BOVBJERG & RAYMOND, *supra* note 4, at 20.

³⁷ Paul C. Weiler, *The Case for No-Fault Medical Liability*, 52 MD. L. REV. 908, 920 (1993).

³⁸ BOVBJERG & RAYMOND, *supra* note 4, at 20.

³⁹ COMMITTEE TO STUDY ALTERNATIVES TO THE PRESENT SYSTEM, PHYSICIAN INSURERS ASSOCIATION OF AMERICA, A COMPREHENSIVE REVIEW OF ALTERNATIVES TO THE PRESENT SYSTEM OF RESOLVING MEDICAL LIABILITY CLAIMS 52 (1989).

⁴⁰ BOVBJERG & RAYMOND, *supra* note 4, at 20.

⁴¹ *Error Prevention*, *supra* note 7, at 221.

⁴² Chandler Gregg, Comment, *The Medical Malpractice Crisis: A Problem with No Answer?*, 70 MO. L. REV. 307, 332 (2005).

entity becomes the principal target of liability.⁴³ Individual doctors would no longer “bear the costs associated with an injury.”⁴⁴ The enterprise—in this case the hospital, health plan, or other physician-employing organization—“would be ‘strictly liable’ in both a legal and economic sense by meeting the costs of liability premiums for all affiliated staff.”⁴⁵ The hospital takes out insurance and becomes exclusively liable for injuries that occur within the hospital. The hospital or organization then implements safety measures based on the doctors’ individual reporting of events and can take a proactive approach internally to evaluate their doctors without passing the “fault” of the injurious event onto the doctors themselves.⁴⁶ The hospital or provider organization will assume the fault for the medical error, rather than the physician. Doctors should have greater incentive to report events because they will not face the negative image of a malpractice lawsuit.

Enterprise liability has the potential to greatly improve patient safety as well. Errors are best addressed not with each individual physician, but with a holistic approach, focusing on the entire system in which health care delivery takes place. The “benefits of knowledge about preventable events outweigh the costs associated with short-term premium increases” because the hospital can design system improvements to reduce error, which will “lead to lower premiums in the long run.”⁴⁷ Systematic error reduction will be realized by addressing the “environment in which individuals doctors and nurses work.”⁴⁸ Hospitals and large “health care organizations are in a far better position than individuals providers to see opportunities to improve patient safety and to act on those insights.”⁴⁹ Enterprise liability thus theoretically incentivizes doctors to report

⁴³ Weiler, *supra* note 37, at 920.

⁴⁴ *Error Prevention*, *supra* note 7, at 221.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ Philip G. Peters, Jr., *Resuscitating Hospital Enterprise Liability*, 73 Mo. L. REV. 369, 379 (2008).

⁴⁹ *Id.* at 378.

errors and improves patient safety, paving the way for a comprehensive no-fault compensation system.

The process for a NFCS would be relatively straightforward. After a patient is injured as a result of medical treatment, he or she would submit a claim through an administrative process, perhaps to a medical screening panel, to determine whether the treatment caused the injury.⁵⁰ Administration of this scheme “would reside in a specialized and accessible tribunal that would utilize explicit criteria and schedules to decide what events are compensable and what payments are appropriate.”⁵¹

Designated compensable events (DCEs) have been proposed as a way to determine which medical procedures and injuries are compensable.⁵² DCEs are “formulas that spell out that if a patient undergoes a certain medical procedure . . . and later displays a particular outcome . . . , the latter injury would automatically be compensable to the extent it produces the kinds of disabling loss that are covered by the plan’s benefit schedule.”⁵³ Administrators can use DCEs to save time by applying the formulas to stated claims, “saving them from having to conduct a full-scale inquiry about medical causation in each individual case.”⁵⁴ DCEs lower costs by reducing time spent on determining compensable injuries and damages.

D. Pros and Cons to No-Fault

There are strong arguments for and against a NFCS for medical injuries. Proponents of the system cite the fair, more efficient compensation. No-fault allows more claimants to receive damages for their injuries because it removes the barrier of requiring a finding of negligence before compensating for an injury.⁵⁵

⁵⁰ See Weiler, *supra* note 37, at 928-29.

⁵¹ *Id.* at 920.

⁵² *Id.* at 933.

⁵³ *Id.* at 932.

⁵⁴ *Id.*

⁵⁵ PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION 147 (1993) (“[C]urrently only a tiny fraction of

A claimant is compensated for an injury regardless of negligence, thus enveloping many more injured parties into the scheme.⁵⁶ Injured parties receive the compensation more quickly and efficiently through a streamlined administrative body, rather than through the slow and costly tort system.⁵⁷ Proponents also point to benefits for physicians, such as lower malpractice premiums and a less adversarial arrangement between patient and provider.⁵⁸ Physicians and injured parties are spared the uncertainty and indignity of a trial. Physicians can focus on practicing medicine, instead of worrying about whether their insurance premiums will become prohibitive to their practice.

Opponents of the no-fault scheme often cite excessive cost as a negative factor. While the system may not save a great amount, as it compensates more total claimants, no-fault payments could be capped at a pre-determined dollar amount, or could “concentrate liability dollars on victims of longer-term injuries...”⁵⁹ It is also important to note that “the size of any one damage award would typically be more modest than the magnitude of damages paid under the current open-ended regime of tort damages for both financial losses and pain and suffering,” revealing further potential for cost savings.⁶⁰ Total costs depend on the individual system design. However, administrative and legal expenses are greatly reduced in a no-fault system, offsetting other cost increases brought about by increased claimants or severely injured claimants.⁶¹

In addition, some compensation plans target funds to the most significantly disabled victims to save costs, with a deductible based either on duration of disability or dollar amount of loss.⁶² Excluding “more numerous short-lived disabilities” and focusing on the “longer-lasting disability[ies] that

negligently injured patients . . . ever realize on their tort right to compensation for . . . injuries.”) [hereinafter MEASURE OF MALPRACTICE].

⁵⁶ See *Error Prevention*, *supra* note 7, at 220.

⁵⁷ See *supra* note 4 and text accompanying notes 54-56.

⁵⁸ See *supra* notes 50-51 and accompanying text.

⁵⁹ MEASURE OF MALPRACTICE, *supra* note 55, at 145.

⁶⁰ *Id.* At 147.

⁶¹ Weiler, *supra* note 37, at 926.

⁶² See *id.* at 923.

affect far fewer patients” would lower costs by decreasing administrative burdens and would allow other private sources, such as insurance or employers granting sick leave, to pay the bill.⁶³ There are other ways to reduce costs of the program through specific award provisions.⁶⁴ It is unclear whether a no-fault medical liability model in the United States would be less affordable than the current tort model, but some research and experience indicates that no-fault would be affordable.⁶⁵ In any case, using disability and loss thresholds could be a structural safeguard against prohibitive costs.

Opponents to a NFCS also reference the problem of causation. Critics argue that “finding the true cause of a patient’s disability would typically be as difficult as determining the doctor’s fault under the current malpractice system.”⁶⁶ It can be difficult to prove that medical treatment caused a patient’s injury because a “patient who enters a hospital may already be suffering from an underlying illness which itself may be the cause of the eventual disability.”⁶⁷ When assessing liability, the disability after medical treatment must “fall outside the range of intended or expected consequences of the treatment.”⁶⁸ However, tort law requires a finding that “a doctor was at fault in the standard of care provided” and “must then make a second determination of whether the medical negligence was actually the cause of harm to the patient.”⁶⁹ A NFCS would reduce these steps to the determination of whether the injury was an unexpected result. DCEs could additionally help determine “problems of medical injury

⁶³ MEASURE OF MALPRACTICE, *supra* note 55, at 80.

⁶⁴ Weiler, *supra* note 37, at 924 (stating that “only a designated proportion of net lost wages should be replaced” and “mandatory patient compensation should reimburse only those losses not covered by other sources of public and private loss insurance”).

⁶⁵ *Id.* at 925 (noting the “Harvard Study” found that no-fault would be affordable compared to the present costs of malpractice insurance and states could purchase this comprehensive plan for “roughly the same amount of money they are now spending on the existing malpractice insurance system”).

⁶⁶ *Id.* at 927-28.

⁶⁷ *Id.* at 928.

⁶⁸ *Id.* at 928-29.

⁶⁹ *Id.* at 932.

causation by identifying those treatment-outcome relationships” that meet the compensable injury requirement for unexpected or avoidable adverse events.⁷⁰

One of the most cited criticisms of a no-fault plan is that its “superiority as a sensible mechanism for compensating . . . patient injuries is outweighed by its deficiency as an instrument for preventing future patient injuries.”⁷¹ Essentially, these critics argue that current tort law serves a deterrent function by inducing doctors to treat patients more carefully, and doctors will no longer have a “legal motivation to avoid substandard patient care.”⁷² These critics believe no-fault may result in a decreased incentive for high quality care and an increase in medical injuries.

On the contrary, a NFCS may actually result in greater deterrence of injuries than the existing tort system. Combined with enterprise liability, medical no-fault “retains legal incentives for injury prevention because it imposes liability for compensating claimants upon the institutional providers responsible for patient care.”⁷³ While no-fault “sacrifices the injury-prevention potential of litigation focusing on individual blame,” the system creates financial incentives for institutions to “control careless behavior of individual providers” and to innovate “advanced and safer medical techniques for avoiding currently ‘unavoidable’ adverse outcomes.”⁷⁴ Organizations would employ either self-insurance or outside insurance, and “any institution in which more injuries occurred would bear a correspondingly higher financial burden.”⁷⁵ Hospitals and other provider organizations thus have incentives to “look for patterns of injury causation” to ultimately decrease accidents and increase patient safety.⁷⁶

In addition, a no-fault program could improve patient safety. If doctors are no longer personally liable for a medical injury, they may have an incentive to

⁷⁰ *Id.* at 933.

⁷¹ Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 434 (1994).

⁷² Weiler, *supra* note 37, at 940.

⁷³ Abraham & Weiler, *supra* note 71, at 434.

⁷⁴ *Id.* at 434-35.

⁷⁵ MEASURE OF MALPRACTICE, *supra* note 55, at 148.

⁷⁶ *Id.*

report injuries more readily, thus promoting an open forum for evaluating safety within an institution.⁷⁷ This openness and accountability will ideally trigger investment in “research and innovation in safer medical techniques.”⁷⁸

II. SWEDEN’S NO-FAULT MODEL OF COMPENSATION AND ITS APPLICABILITY TO THE UNITED STATES

New Zealand and four Scandinavian countries (Sweden, Finland, Denmark, and Norway) have implemented some form of a comprehensive no-fault payment system for medical injuries.⁷⁹ Sweden’s no-fault approach may be the most attractive among the international models due to the abundance of research on this country’s system and the degree of physician involvement in the claims process.⁸⁰ Sweden has a system of national health insurance financed by tax revenues, where most private healthcare providers are included in the national system.⁸¹ Tort law is seldom used in connection with medical services; instead, Sweden has created a universal no-fault compensation system.⁸² In 1997, Sweden implemented the Patient Damages Act, a compulsory insurance scheme for every caregiver.⁸³ The providers’ differing insurance companies form a Patient Insurance Alliance, which delegates the investigation and adjustment of patients’ claims to the company called Patients Damages Adjustment, translated as “PSR.”⁸⁴

⁷⁷ This has been the case in Sweden. See Weiler, *supra* note 37, at 927 (stating that “if the experience in Sweden is any indication, some doctors will often help their patients secure disability benefits for treatment-related injuries, rather than fight tooth-and-nail against such an outcome”).

⁷⁸ MEASURE OF MALPRACTICE, *supra* note 55, at 148-49.

⁷⁹ Error Prevention, *supra* note 7, at 219.

⁸⁰ *Id.*; see also M. Studdert et al., *Can the United States Afford a “No-Fault” System of Compensation for Medical Injury?*, 60 LAW & CONTEMP. PROBS. 1 (1997) [hereinafter *Can the United States Afford?*]

⁸¹ Lotta Wendel, *Compensation in the Swedish Health Care Sector*, in 8 TORT AND INSURANCE LAW: NO FAULT COMPENSATION IN THE HEALTH CARE SECTOR 367, 367 (Jos Dute, Michael G. Faure & Helmut Koziol eds., 2004).

⁸² *Id.*

⁸³ *Id.* at 368 (noting that beginning in 1975 Sweden had a voluntary system of no-fault compensation but changed to a compulsory system because of a significant rise in the number of private care providers who did not join the system).

⁸⁴ *Id.* at 370.

The Patient Damages Act covers harm that is caused “in connection with medical care or treatment performed in Sweden.”⁸⁵ The caregiver, a government entity or a private provider, is responsible for obtaining insurance,⁸⁶ and employing doctors. In the United States, the caregiver would be comparable to a hospital or other provider organization.⁸⁷ Pamphlets describing the Swedish compensation fund are available to all patients treated in Swedish hospitals.⁸⁸ The application for benefits is available in clinics and hospitals.⁸⁹ After the patient files the claim, the treating physician completes a report on the alleged injury.⁹⁰ Physicians actively participate in approximately sixty percent to eighty percent of claims by notifying patients of possible medical injuries, referring patients to social workers for assistance, and “even helping patients [file] claims.”⁹¹ A national central claims office then decides “whether the injury was caused by the treatment and whether the injur[y] could have been avoided.”⁹²

The Swedish patient does not have to prove negligence but must “prove a causal connection—a considerable likelihood—that the damage was caused by the health care.”⁹³ The patient bears the burden of proof that the damage is due to medical examination, care, or treatment.⁹⁴ This burden of proof encompasses four steps: (1) whether there is a causal connection between the medical treatment and the injury; (2) whether the treatment was medically motivated; (3) whether the chosen method was made in accordance with scientific knowledge and professional experience; and (4) whether it would have been possible to avoid the injury if another method or treatment had been used.⁹⁵ The assessment of whether

⁸⁵ *Id.*

⁸⁶ *Id.* at 371.

⁸⁷ Wendel, *supra* note 81, at 372.

⁸⁸ *Can the United States Afford?*, *supra* note 80, at 6.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Error Prevention*, *supra* note 7, at 219.

⁹² Kristie Tappan, *Medical-Malpractice Reform: Is Enterprise Liability or No-Fault a Better Reform?*, 46 B.C. L. REV. 1095, 1109 (2005).

⁹³ Wendel, *supra* note 81, at 372.

⁹⁴ *Id.*

⁹⁵ If the patient first proves there is a connection between the medical treatment and the injury, the system proceeds to the second step. The patient is compensated if the treatment was not medically

the injury could have been avoided is reviewed against the standard of an experienced specialist provider under similar circumstances, which in practice very much appears to evaluate “whether the care provider has made a mistake, although less emphasis is placed on the issue of individual blame.”⁹⁶ This standard does not differ markedly from the assessment criteria used in a tort liability system, but it is less individualized and has less stringent requirements on proving the causal link.⁹⁷

Physical as well as psychological damages are compensated.⁹⁸ “The patient is entitled to economic compensation for loss of income . . . and compensation for non-pecuniary loss,” such as physical suffering.⁹⁹ In 1998, the PSR received 8552 claims, forty-five percent of which resulted in compensation.¹⁰⁰ Awarded amounts ranged from \$120 to \$883,000; the average compensation was approximately \$9900.¹⁰¹ The total cost for the insurance in 1998 was approximately \$31.4 million.¹⁰² Decisions made by the PSR can first be appealed to the Board on Patients Damages and then either to an arbitration board or to a court, but, according to the PSR, less than ten cases are brought in

motivated. If the treatment was medically motivated, the PSR considers whether the chosen method was medically correct. The patient is compensated if the method was not in accordance with scientific knowledge and professional experience. Finally, if the treatment was in accordance with the standard knowledge and experience, the company considers whether an injury could have been avoided with another method. “[T]here is seldom a different method which would have been possible to use without any risk,” and if there was not, the patient does not receive compensation. *Id.* at 372-73.

This method appears complicated, but essentially the patient is compensated if the injury resulted from medical treatment, the treatment was medically justified, and the outcome was avoidable. Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1627 (2002).

⁹⁶ Jos Dute, *A Comparison of No-Fault Compensation Schemes*, in 8 TORT AND INSURANCE LAW: NO FAULT COMPENSATION IN THE HEALTH CARE SECTOR 444, 479 (Jos Dute, Michael G. Faure & Helmut Koziol eds., 2004).

⁹⁷ *Id.*

⁹⁸ Wendel, *supra* note 81, at 374.

⁹⁹ *Id.* at 383.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* Converted amounts to U.S. dollars based on an exchange rate of one U.S. dollar to 8.06 Swedish kronor. XE, <http://www.xe.com> (last visited April 16, 2009) [hereinafter Converted to U.S. dollars].

¹⁰² Wendel, *supra* note 81, at 383; Converted to U.S. dollars, *supra* note 101.

court each year.¹⁰³ An injured party is not precluded from recovering in tort against the provider after recovering pursuant to the Patient Damages Act.¹⁰⁴ The Swedish government considered barring injured persons from pursuing a claim in court, but assumed it would be “natural for a claimant to use the faster and cheaper path towards compensation first, before considering court.”¹⁰⁵

The Swedish fund imposes an injury threshold.¹⁰⁶ A patient must have spent at least ten days in the hospital or accumulated at least thirty sick days before being eligible for compensation.¹⁰⁷ This demarcation demonstrates that the Swedish system intends to compensate only the most seriously injured patients.

Criticism of the Swedish system includes its lack of publicity, which prevents many patients from receiving the compensation to which they are entitled and has led to calls for a more open and transparent system.¹⁰⁸ Generally, the Swedish population seems to agree that “compensation for medical malpractice should be based on a no-fault principle.”¹⁰⁹

III. PROSPECTS FOR NO-FAULT SOLUTIONS IN THE UNITED STATES

The Swedish NFCS approach is an attractive alternative to the current tort system in the United States. An optimal medical compensation scheme will retain the goals of the tort system: compensation, deterrence, and justice. A well-designed system also will reduce medical errors and effectively compensate resulting injuries.¹¹⁰ The Swedish system better fulfills these goals than the current tort system in the United States. Sweden’s model of no-fault, premised on the criteria of avoidability and implemented through an enterprise liability structure, reduces error and compensates injured parties effectively.

¹⁰³ Wendel, *supra* note 81, at 370, 383.

¹⁰⁴ *Id.* at 384.

¹⁰⁵ *Id.*

¹⁰⁶ *Can the United States Afford?*, *supra* note 80, at 8.

¹⁰⁷ *Id.*

¹⁰⁸ Dute, *supra* note 96, at 474.

¹⁰⁹ Wendel, *supra* note 81, at 386.

¹¹⁰ C Vincent, Editorial, *Compensation as a Duty of Care: The Case for “No Fault,”* QUALITY & SAFETY HEALTH CARE, Aug. 2003, at 240, 240.

Essentially, the Swedish approach compensates adverse events that are avoidable.¹¹¹ As stated earlier, an injury is compensable under the Swedish approach if the injury resulted from the medical treatment, the treatment was medically justified, and the outcome was avoidable.¹¹² The concept of avoidable errors “invokes the idea of error reduction through changes in *systems* of care, whereas the concept of negligence suggests that errors can be reduced” by individual action.¹¹³ The current tort system, based on negligence, encourages providers to hide errors, while the concept of avoidable adverse events “overcomes the problem of moral condemnation and encourages” a system-wide approach to error prevention and patient safety.¹¹⁴

A NFCS in the United States could adopt Sweden’s caregiver-insurance-purchasing model, which is similar to the enterprise liability model. Under this model, hospitals, rather than the treating physicians, would pay for medical errors.¹¹⁵ Compensation would require a finding that the injury was avoidable, rather than a finding of negligence.¹¹⁶ An administrative body would process claims and make compensation decisions rather than a court of law.¹¹⁷ “Patients [w]ould be permitted to opt into a no-fault model at the point of receiving care by choosing a participating physician or hospital.”¹¹⁸ If a patient was injured during the course of treatment, he or she would fill out a compensation request at the hospital, similar to the Swedish system.¹¹⁹ The patient’s request would be submitted to a board or administrative body to determine if the injury was avoidable, and the provider organization would be liable for any avoidable adverse outcome.¹²⁰

¹¹¹ Mello & Brennan, *supra* note 95, at 1627.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.* at 1628.

¹¹⁵ See Kristie Tappan, *Medical-Malpractice Reform: Is Enterprise Liability or No-Fault a Better Reform?*, 46 B.C. L. REV. 1095, 1110 (2005).

¹¹⁶ *Id.* at 1110-11.

¹¹⁷ *Id.* at 1111.

¹¹⁸ *Error Prevention*, *supra* note 7, at 222.

¹¹⁹ *Id.* at 219.

¹²⁰ *Id.* at 219-20.

In designing a no-fault scheme for the United States, the cost of the system will depend on the number of claims awarded, the average amount paid, and the administrative expenses.¹²¹ Designers can structure the system as they choose with regard to full compensation for losses, pecuniary versus non-pecuniary costs, deductibles on damages, or thresholds for injury or losses.¹²² A disability threshold, as utilized in Sweden, would make costs more predictable and equitable, as compared to the current tort system, where damage awards are often unpredictable and unfair.¹²³ Use of deductibles and injury thresholds would help reduce costs and fund the most seriously injured parties.¹²⁴ In addition, DCEs would help lower administrative costs and increase efficiency by providing a pre-determined list to help an administrative body decide when and how much compensation is appropriate.¹²⁵ Cost estimates vary, but one study estimated the national costs of compensating avoidable medical injuries in the range of \$37.6 billion to \$50 billion—thereby not increasing the total cost of the liability system “relative to the status quo.”¹²⁶

Embracing a “Swedish-style approach could lead to a system that is both affordable and positioned to compensate a considerably larger proportion of medically injured patients than the current malpractice system manages or even allows.”¹²⁷ It appears that patients have easier access to no-fault compensation systems than to the courts, and care providers will be “more likely to inform patients of the possibility of submitting injury claims under a no-fault system.”¹²⁸ Therefore, using an avoidability standard similar to Sweden’s and an administrative claims processing mechanism will compensate more injuries than under the present system.¹²⁹

¹²¹ Dute, *supra* note 96, at 468.

¹²² *Id.* at 469; *see also supra* notes 62-63 and accompanying text.

¹²³ See Tappan, *supra* note 115, at 1121-22.

¹²⁴ See *supra* notes 62-63 and accompanying text.

¹²⁵ See *supra* text accompanying notes 52-54.

¹²⁶ Mello & Brennan, *supra* note 95, at 1632.

¹²⁷ *Can the United States Afford?*, *supra* note 80, at 33.

¹²⁸ Dute, *supra* note 96, at 467.

¹²⁹ Mello & Brennan, *supra* note 95, at 1634.

Additionally, the Swedish no-fault system would deter future errors in the United States by encouraging doctors to report errors. Doctors would more readily report injuries because they would no longer be directly liable for medical errors and would not face exorbitant malpractice premium increases every time an adverse event occurred.¹³⁰ In an enterprise liability system, hospitals or other provider organizations would be responsible for payment if medical errors occur.¹³¹ Hospitals and health care organizations are in the best position to initiate system-wide improvements in health care delivery; therefore, if they are strictly liable for medical errors, they will have an incentive to improve safety and reduce errors and injuries.¹³² By reporting injuries more effectively, the no-fault system also encourages hospitals to educate their providers on patient safety and other problems that arise in patient care.¹³³

The no-fault compensation scheme promotes justice as well. Injured parties should be compensated more quickly and fairly under a NFCS, especially if the system utilizes DCEs or a similar process to streamline the claims process. The administrative system ensures a more even and consistent spread of damages among the injured, rather than depending on the uncertainty of a trial to determine what an injured party will receive.¹³⁴ As already stated, the NFCS also would compensate a greater number of injured parties than the current tort system, and it could focus on the more seriously injured through threshold disability levels, thus promoting justice for the most deserving parties.

Both physicians and patients probably would benefit from a NFCS similar to Sweden's system. Physicians resent the current malpractice litigation system, and they likely would prefer the "rational and honest approach" used in identifying avoidable adverse events.¹³⁵ This approach would appeal to

¹³⁰ See Tappan, *supra* note 115, at 1116-17.

¹³¹ See *id.* at 1117.

¹³² *Id.* at 1116.

¹³³ Tappan, *supra* note 115, at 1117.

¹³⁴ See MEASURE OF MALPRACTICE, *supra* note 55, at 4-5 (describing the "unpredictability" of medical malpractice awards); see also BOVBJERG & RAYMOND, *supra* note 4.

¹³⁵ Mello & Brennan, *supra* note 95, at 1629.

physicians “who are bound by ethical precepts to disclose errors . . . but face a conflict of interest under the current negligence-based system in doing so.”¹³⁶ Also, patients would appreciate the rapid compensation and transparency in reporting errors in addition to the increased trust between provider and patient.¹³⁷ The NFCS allows the care provider to remain the patient’s ally instead of becoming an adversary when injuries occur during treatment.¹³⁸ However, the provider will have to change his or her outlook on reporting errors; he or she must express a greater willingness to report errors and consent to “greater transparency in the institutional processes that analyze medical errors.”¹³⁹ Patients also must relinquish their “shot at the ticket in the litigation lottery” and be more willing to accept a no-fault form of payment, even if it is less than they *might* have received under the current tort system.¹⁴⁰

One main barrier to implementing a NFCS in the United States is the lack of a highly developed social security system that compensates injured patients, whereas this type of system exists in New Zealand and the aforementioned Scandinavian countries.¹⁴¹ The Swedish system relies on its social security to compensate parties in addition to the Patient Damages Act.¹⁴² Thus, a NFCS should be combined with an extensive social security structure for maximum economic and care benefits.¹⁴³

Another barrier to implementing a Swedish-like NFCS is the availability of tort remedies. If patients are allowed to recover under both systems of liability, there is almost no doubt that they will take advantage of this aspect and recover under both no-fault and tort remedies. The no-fault system should retain the option to sue under tort law, as the Swedish system does, because this is a stalwart of the United States’ compensation system and would be difficult to eliminate

¹³⁶ *Id.*

¹³⁷ *See id.*

¹³⁸ Dute, *supra* note 96, at 473.

¹³⁹ Coylewright, *supra* note 2, at 56.

¹⁴⁰ *Id.* at 55.

¹⁴¹ Dute, *supra* note 96, at 448.

¹⁴² *Id.*

¹⁴³ Wendel, *supra* note 81, at 385.

altogether for political reasons. The Association of Trial Lawyers of America is not likely to support a no-fault compensation scheme, as members benefit from protracted legal battles and large tort settlements. This group can be expected to lobby extensively against any no-fault plan.¹⁴⁴ Attorneys who bring medical malpractice claims “probably stand to lose the most if a no-fault system were implemented,” as they would no longer be needed for patients to receive compensation for medical errors.¹⁴⁵ Thus, these attorneys will be a powerful opposition force to NFCS for medical injuries.

However, the no-fault compensation must be attractive enough to lure injured parties away from pursuing claims in tort and entice them to accept the risk-free and fair no-fault compensation, foreclosing future tort claims.¹⁴⁶ Access to the traditional tort system should remain available for “suits alleging willful and wanton behavior on behalf of medical providers.”¹⁴⁷

The Swedish no-fault scheme provides a helpful model for creating a comprehensive no-fault solution for the problem of medical injuries in the United States. Many features of a NFCS make it an attractive alternative to the tort liability system. Overall, the current system could benefit from no-fault’s improvement on compensation, deterrence, and justice for medical injuries.

¹⁴⁴ Mello & Brennan, *supra* note 37, at 1628-29.

¹⁴⁵ Tappan, *supra* note 115, at 1126-27.

¹⁴⁶ See *supra* notes 104-105 and accompanying text.

¹⁴⁷ Coylewright, *supra* note 2, at 46.

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Health Care in a Time of Financial Crisis: Is the Economic Downturn a Sufficient Excuse to Delay Health Reform Once Again?

*Kristin Savov**

In his address to Congress on February 24, 2009, President Obama expressed his commitment to achieving healthcare reform within the next year as one of his top three priorities.¹ In order to achieve this, President Obama's budget proposal sets aside \$633.8 billion over the next ten years for a Health Reform Reserve Fund;² however, the recent economic downturn could inhibit this ambitious proposal, as many argue that, in light of America's economic situation, healthcare reform can wait.³ Yet, health care and the economy are intertwined. In 2009, health care is expected to reach 17.6% (\$2.5 trillion) of the U.S. gross

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¹ President Barack Obama, Address to Joint Session of Congress (Feb. 24, 2009) (transcript available at http://www.whitehouse.gov/the_press_office/remarks-of-president-barack-obama-address-to-joint-session-of-congress).

² SENATE BUDGET COMM., BRIEF ANALYSIS OF PRESIDENT OBAMA'S FY 2010 BUDGET BLUEPRINT 10 (Feb. 27, 2009), available at http://budget.senate.gov/democratic/statements/2009/Obama%20FY%202010%20Budget%20Brief%20Analysis_022709.pdf.

³ See 49% Say Obama Should Delay Health Care Reform Until Economy is Better, RASMUSSEN REPORTS, Mar. 2, 2009, <http://www.rasmussenreports.com/content/view/full/18671>; see also Conservatives for Patients' Rights, <http://www.conservativesforpatientsrights.com/> (last visited Mar. 11, 2009); Jim Kuhnhenn, *Obama Says Long-Term Investments Cannot Wait*, ASSOCIATED PRESS, MAR. 12, 2009, http://www.google.com/hostednews/ap/article/ALeqM5hEx3tiPJhZQLVqjNmHR_oP6FZMuwD96SMG200.

domestic product (GDP) and by 2018 will reach 20.3% (\$4.4 trillion);⁴ this rapid growth in healthcare costs is not sustainable.⁵

The recession only exacerbates underlying problems in America's healthcare system. As unemployment rises, so too does the number of uninsured Americans, resulting in increased financial strain on state Medicaid programs.⁶ As many Americans are one pink slip away from losing their employer-based health benefits, these issues continue to increase in importance and urgency. The United States cannot ignore the financial problems of over 45 million⁷ uninsured Americans; rather, the failing system must be reformed.

I. HEALTH CARE COSTS AND THE INEFFICIENT ALLOCATION OF RESOURCES IN THE CURRENT SYSTEM

The United States spends more on health care per capita than any other country.⁸ Despite higher spending, Americans are, on average, no healthier than people in other developed countries,⁹ and tens of millions of Americans are uninsured.¹⁰ These uninsured Americans without access to affordable health care impose substantial costs on the U.S. economy;¹¹ lack of insurance has been linked to shorter life spans, educational and developmental impairments in children, poor health, and decreased productivity in the workplace.¹² As a consequence of

⁴ Andrea Sisko et. al., *Health Spending Projections Through 2018: Recession Effects Add Uncertainty to the Outlook*, 28 HEALTH AFF. (WEB EXCLUSIVE) w346, w346-w347 (2009).

⁵ GOV'T ACCOUNTABILITY OFFICE, HEALTH CARE: UNSUSTAINABLE TRENDS NECESSITATE COMPREHENSIVE AND FUNDAMENTAL REFORMS TO CONTROL SPENDING AND IMPROVE VALUE 1, 3-6 (2004), <http://www.gao.gov/new.items/d04793sp.pdf>.

⁶ VERNON SMITH ET AL., KAISER COMM'N ON MEDICAID & THE UNINSURED, HEADED FOR A CRUNCH: AN UPDATE ON MEDICAID SPENDING, COVERAGE, AND POLICY HEADING INTO AN ECONOMIC DOWNTURN 8 (2008), available at <http://kff.org/medicaid/upload/7815ES.pdf>.

⁷ KAISER COMM'N ON MEDICAID & THE UNINSURED, FIVE BASIC FACTS ON THE UNINSURED 1 (2008) [hereinafter FIVE BASIC FACTS], available at <http://kff.org/uninsured/upload/7806.pdf>.

⁸ KAISER FAMILY FOUND., HEALTH CARE SPENDING IN THE UNITED STATES AND OECD COUNTRIES (2007), <http://www.kff.org/insurance/snapshot/chcm010307oth.cfm>.

⁹ KAISER FAMILY FOUND., *supra* note 8.

¹⁰ FIVE BASIC FACTS, *supra* note 7, at 1.

¹¹ JACK HADLEY ET AL., KAISER COMM'N ON MEDICAID & THE UNINSURED, KEY FACTS ABOUT COVERING THE UNINSURED IN 2008: CURRENT COSTS, SOURCES OF PAYMENT, AND INCREMENTAL COSTS 1 (2008), available at <http://kff.org/uninsured/upload/7810.pdf>.

¹² *Id.*

unaffordable medical care, the uninsured indirectly cost the U.S. economy an estimated \$100 to \$200 billion in 2006.¹³

Direct costs are also high. The uninsured pay for approximately \$30 billion of the care they receive, while government programs and other sources of charitable care pay \$56 billion.¹⁴ An additional \$5.1 billion aimed toward reimbursing hospitals for uncompensated care (care not paid for by an individual or an insurer)¹⁵ is “misallocated to hospitals that provide little care to the uninsured.”¹⁶ Some health care providers may further offset uncompensated care by charging insured patients higher rates.¹⁷ However, this effect is minimal, with private insurance premiums estimated to be only 1.7% higher as a result of this cost-shifting.¹⁸

In addition, many non-profit hospitals receive tax benefits that are grossly disproportionate to the amount of charity care actually provided.¹⁹ For instance, Minnesota hospitals provided only \$80 million in charitable care in 2005, while receiving tax-benefits totaling \$482 million.²⁰ The total value of tax exemptions given to non-profit hospitals in exchange for providing charity care reached approximately \$10 billion in 2006,²¹ a recent IRS report, however, found that uncompensated care only accounted for 56% of the “community benefit” reported by non-profit hospitals claiming a tax-exemption.²² Further, this care was unevenly distributed among hospitals, with 14% of hospitals providing 63% of the

¹³ *Id.*

¹⁴ Jack Hadley et al., *Covering the Uninsured in 2008: Current Costs, Sources of Payment, and Incremental Costs*, 27 HEALTH AFF. (WEB EXCLUSIVE) w399, w411 (2008).

¹⁵ *Id.* at w405.

¹⁶ *Id.*

¹⁷ *Id.* at w406.

¹⁸ *Id.*

¹⁹ John D. Colombo, *Federal and State Tax Exemption Policy, Medical Debt and Healthcare for the Poor*, 51 ST. LOUIS U. L.J. 433, 449 (2007).

²⁰ Anna Wolke, *Community Benefit and Tax Exemption Come Under the Microscope*, ST. HEALTH NOTES (Nat'l Conference of State Legislatures/Forum for State Health Policy Leadership, Wash., D.C.), Jan. 7, 2008, at 1, available at <http://www.ncsl.org/print/health/shn/shn506.pdf>.

²¹ Colombo, *supra* note 19, at 450.

²² INTERNAL REVENUE SERV., IRS EXEMPT ORGANIZATIONS HOSPITAL STUDY: EXECUTIVE SUMMARY OF FINAL REPORT 2 (2009), available at http://www.irs.gov/pub/irs-tege/execsum_hospprojrept.pdf.

uncompensated care to the uninsured.²³ Much of the federal funding that is already being spent could be used far more efficiently by reallocating funds to finance insurance for all Americans.²⁴ Expanding full-year coverage to all uninsured Americans would cost an estimated \$122.6 billion.²⁵ This means that providing universal coverage would increase total health care spending by only 5.1%, a lower figure than the annual increase in health care spending (7.6%).²⁶

II. HEALTH CARE INITIATIVES PASSED IN RECENT LEGISLATION

In February 2009, sizeable investments in healthcare were made when the Children's Health Insurance Program Reauthorization Act of 2009²⁷ (CHIPRA) and the American Recovery and Reinvestment Act of 2009²⁸ (ARRA) were signed into law. CHIPRA invests \$33 billion over the next four and one-half years to expand eligibility and simplify enrolment in the State Children's Health Insurance Program (previously known as SCHIP, now known as CHIP).²⁹ Prior to this legislation, Medicaid and SCHIP provided coverage to one fourth of all children in America (29 million children under Medicaid and 7 million children under SCHIP).³⁰ The new expanded CHIP program extends coverage to 4.1 million of the 9 million remaining uninsured low-income children in America.³¹

Unlike CHIPRA, the initiatives passed in the ARRA do not expand coverage for uninsured Americans.³² Rather, ARRA creates temporary solutions aimed at preventing increases in the number of uninsured Americans, and long

²³ *Id.* at 3.

²⁴ Hadley et al., *supra* note 14, at 412-413.

²⁵ *Id.* at w411.

²⁶ *Id.*

²⁷ Children's Health Insurance Program Reauthorization Act of 2009, Pub. L. No. 111-3 (2009) (to be codified at 42 U.S.C. §1396 et.seq.).

²⁸ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5 (2009).

²⁹ KAISER COMM'N ON MEDICAID & THE UNINSURED, KEY FACTS, CHILDREN'S HEALTH INSURANCE PROGRAM REAUTHORIZATION ACT OF 2009 (CHIPRA) 1 (2009), available at <http://www.kff.org/medicaid/upload/7863.pdf>.

³⁰ *Id.*

³¹ *Id.*

³² KAISER COMM'N ON MEDICAID & THE UNINSURED, AMERICAN RECOVERY AND REINVESTMENT ACT (ARRA): MEDICAID AND HEALTH CARE PROVISIONS 2 (2009) [hereinafter KAISER, AMERICAN RECOVERY ACT], available at <http://kff.org/medicaid/upload/7872.pdf>.

term investments aimed at reducing health care costs over time.³³ Though ARRA's provisions may slow the increase in uninsured Americans and may reduce the long-term costs of health care, they are not a substitute for comprehensive health care reform.³⁴

A. *Temporary Increases in FMAP and Subsidies for COBRA*

The ARRA includes \$86.6 billion in temporary relief³⁵ to combat a collective \$350 to \$370 billion state budget shortfall projected over the next three fiscal years.³⁶ This temporary relief funds the federal portion of joint Federal-State Medicaid programs by increasing the Federal Medical Assistance Percentage (FMAP) in States burdened by high unemployment and, consequentially, high Medicaid enrollment.³⁷ A 1% increase in unemployment increases Medicaid and SCHIP enrollment by 1.1 million and increases costs by \$3.4 billion.³⁸ Thus, the additional funding is critical, since the combination of high unemployment rates with budget shortfalls have strained existing Medicaid programs and forced states to cut benefits³⁹ to meet budget requirements. States with an increase in unemployment of at least 1.5% over a three month period since January 1, 2006 qualify for the temporary increase in their FMAP.⁴⁰ However, in order to receive federal funding, states must restore Medicaid funding to July 1, 2008 levels, and are prohibited from making additional cuts to Medicaid funding.⁴¹ Also, states

³³ KAISER, AMERICAN RECOVERY ACT, *supra* note 32, at 2.

³⁴ *Id.*

³⁵ *Id.*

³⁶ KAISER COMM'N ON MEDICAID & THE UNINSURED, RISING UNEMPLOYMENT MEDICAID AND THE UNINSURED: A MULTI-YEAR SNAPSHOT OF STATE FINANCING EFFECTS 1 (2009), available at http://www.kff.org/uninsured/upload/7850_FS.pdf.

³⁷ KAISER, AMERICAN RECOVERY ACT, *supra* note 32, at 1.

³⁸ KAISER COMM'N ON MEDICAID & THE UNINSURED, MEDICAID, SCHIP, AND ECONOMIC DOWNTURN: POLICY CHALLENGES AND POLICY RESPONSES (EXECUTIVE SUMMARY) 5 (2008) [hereinafter KAISER, POLICY CHALLENGES], available at <http://www.kff.org>.

³⁹ Amy Goldstein, *States Cut Medicaid Coverage Further*, WASH. POST, Dec. 26, 2008, at A1; Jane Zhang, *States Take Aim at Medicaid*, WALL ST. J., Jan. 28, 2009, available at: <http://online.wsj.com/article/SB123311516946923241.html>.

⁴⁰ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §5001(c) (2009).

⁴¹ *Id.*

must meet prompt payment requirements to receive increased Federal funds.⁴² These payment requirements may prove problematic for states such as Illinois, which owes providers for a huge backlog of Medicaid payments.⁴³

Though increased Medicaid enrollment strains state budgets, cutting Medicaid funds in a faltering economy tends to worsen economic downturns by preventing Medicaid from acting as a buffer that can automatically stimulate a weakening economy.⁴⁴ Medicaid is the second largest item in states' budgets and brings more federal dollars into states than any other budget item.⁴⁵ Medicaid payments not only support health care services and providers, but also provide indirect support to vendors and suppliers of health care firms.⁴⁶ These outside federal funds generate billions in economic activity within states and support tens of thousands of jobs.⁴⁷

In response to the economic downturn of 2003 to 2004, Congress passed the Jobs and Growth Tax Relief Reconciliation Act, another temporary solution, which provided an extra \$20 billion to state Medicaid programs and prevented states from reducing Medicaid benefits.⁴⁸ While this act had positive results,⁴⁹ it is inefficient to enact new emergency legislation for state Medicaid programs with each recession because such legislation often comes too late.⁵⁰ A long-term, proactive solution to this problem is to permanently alter the FMAP formula so that

⁴² *Id.* at §5001(f)(2).

⁴³ Steve Stanek, Illinois Bill Payment Backlog 'Potentially Catastrophic', *Budget & Tax News*, Feb. 2009, available at http://www.heartland.org/publications/budget%20tax/article/24477Illinois_Bill_Payment_Backlog_Potentially_Catastrophic.html.

⁴⁴ Kaiser, Policy Challenges, *supra* note 38, at 5-6.

⁴⁵ KAISER COMM'N ON MEDICAID & THE UNINSURED, THE ROLE OF MEDICAID IN STATE ECONOMIES: A LOOK AT THE RESEARCH 1 (2009), available at http://www.kff.org/medicaid/upload/7075_02.pdf.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ KAISER, POLICY CHALLENGES, *supra* note 38, at 6.

⁴⁹ *Id.* at 6.

⁵⁰ Vic Miller, *Stabilizing Medicaid Financing During Economic Downturns*, CTR. FOR CHILDREN & FAMILIES, GEORGETOWN UNIV. HEALTH POLICY INST., POLICY PAPER NO. 2, at 1 (2007), available at <http://ccf.georgetown.edu/index/cms-filesystem-action?file=ccf%20publications/federal%20medicaid%20policy/stabilizing%20medicaid.pdf>.

federal funding is based on a state's unemployment level⁵¹ instead of on a state's per capita income.⁵²

The second largest health care investment included in the ARRA is a \$24.7 billion dollar plan to subsidize Consolidated Omnibus Budget Reconciliation Act (COBRA) insurance coverage for recently unemployed workers.⁵³ Two-thirds of workers, should they lose their jobs, are eligible to extend their employer-subsidized insurance through COBRA at an unsubsidized rate.⁵⁴ However, 91% of eligible unemployed Americans cannot afford COBRA premiums.⁵⁵ Thus, without subsidies, the unemployed join the ranks of the uninsured, and, for many uninsured Americans, an illness or injury can lead to financial ruin.⁵⁶ Under the ARRA, workers laid-off between September 1, 2008 and December 31, 2009 can receive a 65% subsidy for COBRA premiums for up to nine months.⁵⁷ However, this may be insufficient, as it is estimated that a subsidy would need to cover approximately 75% to 85% of premiums in order to equal the costs borne by workers under an employee-sponsored plan.⁵⁸ As with FMAP, the COBRA provision in the ARRA is merely a temporary solution,⁵⁹ a response to this economic crisis; it is not a long-term solution for unemployed Americans who lose their employer-based insurance along with their jobs.

B. Long-Term Investments to Reduce Costs

The ARRA also invests in long-term initiatives designed to reduce future health care costs.⁶⁰ Specifically, the bill includes \$19.2 billion in funding for

⁵¹ *Id.* at 3.

⁵² KAISER, AMERICAN RECOVERY ACT, *supra* note 32, at 1.

⁵³ *Id.*

⁵⁴ MICHELLE M. DOTY ET AL., COMMONWEALTH FUND, MAINTAINING HEALTH INSURANCE DURING A RECESSION: LIKELY COBRA ELIGIBILITY 1 (2009).

⁵⁵ *Id.*

⁵⁶ LESLIE E. LINFIELD, INST. FOR FIN. LITERACY, WHO WENT BANKRUPT IN 2006? A DEMOGRAPHIC ANALYSIS OF AMERICAN DEBTORS, 21 (2007).

⁵⁷ KAISER, AMERICAN RECOVERY ACT, *supra* note 32, at 2.

⁵⁸ DOTY ET AL., *supra* note 54, at 1.

⁵⁹ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5 §3001(b)(c)(3) (2009).

⁶⁰ KAISER, AMERICAN RECOVERY ACT, *supra* note 32, at 1-3.

health information technology (health IT).⁶¹ Under the ARRA the government is required to establish an Office of the National Coordinator for Health Information Technology.⁶² This Health IT Office is charged with setting standards and policies for health IT,⁶³ distributing grants and funding for the establishment of health IT,⁶⁴ and meeting the goal of providing every American with an electronic health record by 2014.⁶⁵ The ARRA also strengthens privacy laws related to the protection of personal information in health IT.⁶⁶ However, ARRA does not explicitly state what these new standards are.

In a controversial provision, ARRA invests \$1.1 billion in “comparative effectiveness” research.⁶⁷ This research focuses on reducing costs by prescribing only the most effective treatments.⁶⁸ However, the pharmaceutical industry strongly opposes this research.⁶⁹ Further, cost savings are difficult to predict and it may take ten years before any cost reductions are realized as a result of this research.⁷⁰

III. CONCLUSION

Though substantial investments in health care have already been made in CHIPRA and the ARRA, these efforts are not a substitute for comprehensive health care reform. It is not yet clear what shape health care reform will take, and the proposed plans could take the country in radically different directions.⁷¹

⁶¹ *Id.*

⁶² American Recovery and Reinvestment Act §3001(b)(c)(3)).

⁶³ *Id.*

⁶⁴ *Id.* at §3001.

⁶⁵ *Id.* at §3001(C)(6)(E).

⁶⁶ *Id.* at §§ 13401-24.

⁶⁷ KAISER, AMERICAN RECOVERY ACT, *supra* note 33.

⁶⁸ CONG. BUDGET OFFICE, RESEARCH ON THE COMPARATIVE EFFECTIVENESS OF MEDICAL TREATMENTS 29 (2007).

⁶⁹ Alicia Mundy, *Drug Makers Fight Stimulus Provision*, WALL ST. J., Feb. 9, 2009, available at <http://online.wsj.com/article/SB123423024203966081.html>.

⁷⁰ CONG. BUDGET OFFICE, *supra* note 68, at 30.

⁷¹ Compare, Healthy Americans Act, S. 391, 11th Cong. (2009) (a bipartisan bill that would eliminate tax exemptions for employer-sponsored health plans and mandate that individuals purchase insurance through national or regional pools) and Robert Pear & Sheryl Gay Stolberg, *Obama Says He is Open to Altering Health Plan*, N. Y. TIMES, Mar. 5, 2009 (describing Obama's

While any plan for reform comes at a high cost, such an investment would bring about innumerable benefits for millions of Americans. Through a patchwork of programs, billions⁷² are already being spent each year to offset uncompensated care provided to over 45 million⁷³ uninsured Americans, and a good portion of these funds could be redirected to help fund a plan to provide health care for all Americans. Even amidst this recession, Americans cannot afford to ignore the health care crisis. As the number of uninsured rises with the number of unemployed, the need for action on these issues becomes even more urgent.

willingness to compromise on his plan to offer a national health plan alongside private insurance plans in a national health exchange, so long as eight key principles are met), *with* Jay Newton-Small, *Bipartisan Senate Group Makes Health Care Progress*, TIME, Mar. 13, 2009 (describing the efforts of a bipartisan group of senators known as “the gang of nine” to reach consensus on a health care reform bill).

⁷² Hadley et al., *supra* note 14, at w411.

⁷³ FIVE BASIC FACTS, *supra* note 7, at 1.

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Medical Tourism: An Informed Choice May Present a Safe and Realistic Alternative to Expensive Treatment at Home

*Adrienne Sevilla**

The number of uninsured and underinsured Americans has burgeoned to forty-five million,¹ and comprehensive healthcare reform is on an ever-distant horizon. The phenomenon of medical tourism, however, may provide a financially viable and safe alternative to seeking certain medical treatment within the United States. Currently, medical tourism costs account for less than two-percent of total U.S. healthcare spending.² Nonetheless, that figure will certainly increase as patients' confidence grows and U.S. based insurance companies begin covering treatments in other countries. Additionally, interest in medical tourism will increase as the Joint Commission International, an internationally reputable accreditation body, accredits more hospitals around the world.

Medical tourism occurs when a person travels internationally to obtain medical procedures.³ The rising costs of health care in the U.S. have spurred an increase in this type of tourism.⁴ The procedures that patients travel abroad for vary greatly. Approximately half of procedures sought outside of the U.S. are

¹ Kristen Boyle, *A Permanent Vacation: Evaluating Medical Tourism's Place in the United States Healthcare System*, 20 *HEALTH L.* 42, 42 (2008).

² AMA COUNCIL OF MEDICAL SERVICES, REPORT OF THE COUNCIL ON MEDICAL SERVICE 2 (2008), <http://www.ama-assn.org/ama1/pub/upload/mm/372/a-08cms1.pdf> [hereinafter AMA REPORT].

³ JOSEF WOODMAN, PATIENTS BEYOND BORDERS 6, (Faith Brynie ed., Healthy Travel Media 2008).

⁴ AMA REPORT, *supra* note 2, at 5.

medically necessary, while the other half are elective procedures.⁵ Examples of potential treatments include: abdominoplasties in Brazil, heart valve replacements in Thailand, hip resurfacing in India, addiction recovery in Antigua, fertility diagnosis and treatment in South Africa, thalassotherapy in Hungary, or restorative dentistry in Mexico.⁶ Patients who traveled abroad for the aforementioned procedures only paid between thirty- and ninety-percent of the total that these procedures would have cost them in the U.S.⁷

In 2005, an estimated 500,000 Americans traveled abroad for medical treatment, and that is expected to triple by 2020.⁸ By the end of 2008, that number had already swelled to an estimated 750,000.⁹ To accommodate this growing demand, many foreign countries are financially motivated to offer high quality care to potential medical tourists because the medical tourism industry earned over \$20 billion internationally in 2005, and will earn a projected \$40 billion in revenue by 2010.¹⁰

In the face of rising costs in the U.S., public interest in medical tourism continues to grow.¹¹ Globally, an estimated two million patients seek treatment at hospitals and clinics outside their home countries each year.¹² In a 2006 survey of families with at least one currently ill member, twenty- to forty-percent of respondents expressed a willingness to have major, non-urgent surgery at a “very good hospital” outside the U.S., by a surgeon trained in the U.S., England, or Canada who speaks the patient’s language, if they could save at least \$10,000.¹³

⁵ *Id.* at 2.

⁶ WOODMAN, *supra* note 3, at 7.

⁷ Chen May Yee, *Wellpoint Soon Will Offer Some Medical Travel Benefits*, STAR TRIBUNE, Nov. 14, 2008, at 1D.

⁸ Boyle, *supra* note 1, at 43.

⁹ Mark Tutton, *Medical Tourism: Have Illness, Will Travel*, CNNHEALTH.COM, Mar. 26, 2009, <http://www.cnn.com/2009/HEALTH/03/26/medical.tourism/?iref=mpstoryview>.

¹⁰ Boyle, *supra* note 3, at 43.

¹¹ *Id.*

¹² WOODMAN, *supra* note 3, at 8.

¹³ AMA REPORT, *supra* note 2, at 2-3.

I. BENEFITS OF MEDICAL TOURISM

The cost of medical procedures in foreign countries is lower than in the U.S. for a variety of reasons. First, physicians and other health care workers have comparatively lower wages.¹⁴ Additionally, global providers of medical devices, supplies, and pharmaceuticals charge significantly lower prices in foreign countries.¹⁵ Furthermore, malpractice insurance costs are substantially lower overseas as compared to the U.S.¹⁶

A report by the American Medical Association's ("AMA") Council on Medical Services included a summary of the potential cost savings for a sampling of medical services in India, Thailand and Singapore:¹⁷

Procedure	U.S. Insurer's Price	U.S. Retail Price	India	Thailand	Singapore
Angioplasty	\$26K - \$37K	\$57K - \$83K	\$11K	\$13K	\$13K
Gastric Bypass	\$28K - \$40K	\$48K - \$69K	\$11K	\$15K	\$15K
Heart Bypass	\$55K - \$70K	\$122K - \$177K	\$10K	\$12K	\$20K
Hip Replacement	\$18K - \$26K	\$44K - \$63K	\$9K	\$12K	\$12K
Knee Replacement	\$18K - \$25K	\$41K - \$59K	\$8.5K	\$10K	\$13K
Spinal Fusion	\$25K - \$37K	\$63K - \$91K	\$5.5K	\$7K	\$9K

The U.S. insurer's price included at least one day of hospitalization, while these retail prices for the foreign countries included not only hospitalization, but also airfare and hotel room costs.¹⁸ The potential for savings is obviously enormous.

Many medical tourists report that the savings are not the only benefit of travelling abroad for health care services – personal attention and quality of care are additional benefits. For example, Joshua Kurlantzick, a writer for the *New*

¹⁴ *Id.* at 4.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Unmesh Ker et al., *Outsourcing Your Heart*, TIME, May 29, 2006, at 44.

¹⁸ AMA REPORT, *supra* note 2, at 2-3.

York Times, recently found himself seriously ill while traveling in Thailand.¹⁹ He was “put at ease” and treated by an English-speaking, U.S. trained physician,²⁰ who was one of the one-hundred plus physicians at the hospital board-certified by U.S. medical specialty groups.²¹ The bill for admittance to the emergency room, consultation, a room, and every medication the physician prescribed totaled \$100.²² The high quality care and borderline luxurious facilities (Bumrungrad’s lobby features marble floors, bellhops, five-star restaurants, and a Starbucks) left Kurlantzick “longing for Bumrungrad” when he returned home to the U.S.²³

Kurlantzick’s experience with the quality, personal attention, and low cost is ubiquitous through the accounts of medical tourists. For example, Kevin Miller, a self-employed and uninsured chiropractor from Louisiana, turned to Bumrungrad after learning of the \$90,000 cost to repair a herniated disk and neck injury.²⁴ After researching the internet, Miller opted to travel to Bumrungrad where a U.S.-trained surgeon successfully performed the operation.²⁵ Miller’s hospital bill was less than \$10,000, and he expressed his overall satisfaction saying, “I wouldn’t hesitate to come back for another procedure.”²⁶

II. POTENTIAL DISADVANTAGES OF MEDICAL TOURISM

Despite the prolific stories of cost-savings and luxury abroad, medical tourism is not without potential disadvantages. Concerns remain about quality of care, post-operative care, and the lack of legal ramifications for malpractice.

Patients’ concerns are justified. In the U.S., patients derive confidence from the federal and state government’s oversight of hospitals, an oversight that

¹⁹ Joshua Kurlantzick, *Sometimes, Sightseeing Is a Look at Your X-Rays*, NY TIMES, May 20, 2007, at §5, Column 1.

²⁰ *Id.*

²¹ Howard D. Bye, Esq., *Shopping Abroad for Medical Care: The Next Step in Controlling the Escalating Health Care Costs of American Group Health Plans?*, 19 HEALTH L., April 2007, at 30, 31 (2007).

²² *Id.*

²³ *Id.*

²⁴ Ker et. al, *supra* note 15.

²⁵ *Id.*

²⁶ *Id.*

does not exist in the same form outside the U.S.²⁷ When abroad, patients cannot rely on the same governmental oversight, and the safety standards of foreign hospitals sometimes fall far below those in the U.S. due to either the absence of regulation or a lack of regulation enforcement.²⁸

Lack of extensive oversight and regulation can have disastrous consequences. For example, many patients from California have traveled to Mexico to undergo procedures by unlicensed doctors in inadequate facilities and subsequently found themselves in an American emergency room.²⁹ Unlicensed Mexican plastic surgeons operating in unaccredited facilities have caused disfigurement and fatal infections.³⁰ Also, German patients who received kidney transplants in India and Pakistan suffered higher mortality rates than those who had kidney transplants in their home country.³¹

The maintenance of adequate records and the coordination of post-operative care are essential due to complications that may arise during and after the patient travels home. The patient must coordinate post-operative care with a physician at home before undergoing any procedure outside of the U.S..³² Additionally, patients may be forced to stay longer in the foreign country (potentially missing more work than expected) because their physicians at home may be unwilling to provide post-operative care.³³ Further, medical records must be transported to and from the destination treatment center in a manner that complies with HIPAA guidelines to avoid privacy problems when the patient returns to the U.S.³⁴

Furthermore, patients who fall victim to medical malpractice in another country do not have the same opportunities for legal recourse as in the U.S.³⁵ It

²⁷ WOODMAN, *supra* note 3, at 192.

²⁸ AMA REPORT, *supra* note 2, at 5.

²⁹ Boyle, *supra* note 1, at 46.

³⁰ *Id.*

³¹ *Id.* at 45.

³² AMA REPORT, *supra* note 2, at 6.

³³ Boyle, *supra* note 1, at 45.

³⁴ AMA REPORT, *supra* note 2, at 6.

³⁵ WOODMAN, *supra* note 3, at 158.

may be impossible for a U.S. court to exercise jurisdiction over a foreign hospital.³⁶ Moreover, even if a U.S. court enters a judgment against a foreign hospital, it will be difficult for a patient to recover any damages.³⁷ Hospitals in Bangkok, for example, require patients to sign a waiver barring all legal action against the hospital and its agents.³⁸ Although a patient may choose to sue the hospital in the country where it is located, the inconvenience and cost may outweigh any potential recovery. Furthermore, very few countries allow punitive damages for medical malpractice suits, so any recovery will most likely be less than the injured patient might expect.³⁹

III. ADDRESSING THE DISADVANTAGES

The JCI is the international counterpart to the Joint Commission on Accreditation of Healthcare Organizations.⁴⁰ The JCI evaluates foreign hospitals similarly to U.S. hospitals.⁴¹ The evaluation standards have been altered for global applicability, however, meaning they are neutral to any specific country's laws and regulations.⁴² Although foreign accreditation standards are comparable to domestic standards, the standards do not include the additional protection U.S. local and national laws provide.⁴³ The JCI published its most recent edition of accreditation standards in January 2008, encompassing six patient safety goals: (1) identify patients correctly; (2) improve effective communication; (3) improve safety of high-alert medications; (4) ensure correct-site, correct-procedure and

³⁶ *Id.*

³⁷ *Id.*

³⁸ Boyle, *supra* note 1, at 46.

³⁹ WOODMAN, *supra* note 3, at 159

⁴⁰ Elizabeth Gluck, *Incredible [Accreditable] India: Trends in Hospital Accreditation Co-Existent with the Growth of Medical Tourism in India*, 1 St. Louis Univ. J. of Health L. & Pol'y 459, 479 (2008).

⁴¹ AMA REPORT, *supra* note 2, at 3.

⁴² KAREN TIMMONS, JOINT COMMISSION INTERNATIONAL, STANDARDS DEVELOPMENT: AN INTERACTIVE WORKSHOP, Slide 13 (2008), http://www.isqua.org/isquaPages/ISQua_Accreditation_JCI_KarenTimmons.pdf.pdf.

⁴³ AMA REPORT, *supra* note 2, at 5.

correct-patient surgery; (5) reduce the risk of healthcare-associated infections; and (6) reduce the risk of patient injury from falls.⁴⁴

Although JCI accreditation does not guarantee patient safety or a one hundred-percent successful outcome, the President of the JCI, Karen Simmons, pointed out that going to a JCI-accredited hospital is “essentially a risk-reduction activity.”⁴⁵ According to Timmons, hospitals that seek and successfully achieve accreditation “demonstrate[] to the international community that the hospital has voluntarily sought an independent review of its commitment to safety and quality, and has met standards that contribute to good patient outcomes.”⁴⁶ Some potential medical travelers see accreditation as “a powerful symbol of a health care organization’s commitment to high quality health care, continuous improvement across all aspects of patient care and services, and patient safety.”⁴⁷ Furthermore, insurance companies like Wellpoint and Blue Cross Blue Shield of South Carolina are now offering medical tourism coverage to augment domestic plans.⁴⁸ Wellpoint insures one out of nine Americans,⁴⁹ and such a prolific insurer offering this benefit will help increase faith in travel for medical care for the consumers are likely to trust in the insurer’s evaluation and vetting of the participating foreign institution.

Wellpoint’s program, the Global Health Care Partnership, offers non-emergency procedures to employees of Serigraph, Inc., a Wisconsin-based printing company, beginning in January of 2009.⁵⁰ Currently, only certain facilities in India are participating, and those facilities are JCI-accredited.⁵¹ Before seeking healthcare abroad, Wellpoint plans to assign Serigraph employees

⁴⁴ Gluck, *supra* note 36, at 480.

⁴⁵ Posting of Avery Comarow, *Saving on Surgery by Going Abroad*, U.S. News & World Report Website, <http://health.usnews.com/articles/health/special-reports/2008/05/01/saving-on-surgery-by-going-abroad.html?PageNr=1> (May 1, 2008).

⁴⁶ Gluck, *supra* note 36, at 479.

⁴⁷ *Id.*

⁴⁸ Chris Meehan, *Wellpoint is Latest Blues Plan to Invest in Medical Tourism*, AIS’s HEALTH BUSINESS DAILY, Jan. 7, 2009, <http://www.aishealth.com/Bnow/hbd010709.html>.

⁴⁹ Wellpoint Our Business, <http://wellpoint.com/business/default.asp> (last visited Feb. 15, 2009).

⁵⁰ Meehan, *supra* note 49.

⁵¹ *Id.*

to a case manager who will address pre- and post-operative challenges and help with travel arrangements for the patient and the patient's travel companion.⁵² Wellpoint will not cover any travel expenses, but employers like Serigraph may choose to offer financial incentives to employees to encourage them to use the benefit if there are large potential cost-savings for the company.⁵³

With the current state of the U.S. health care system and the rising levels of costs and the uninsured, medical tourism remains a viable option despite its potential disadvantages. Accreditation by the JCI will inspire confidence among potential patients and lead to a uniform high quality of care. Insurance companies offering medical tourism as a benefit will lead consumers to see it as a more established and reputable option. These efforts will encourage medical travel, aid the dissemination of information among potential patients, and increase confidence levels in foreign health care institutions.

⁵² *Id.*

⁵³ *Id.*

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Autism Insurance Coverage: Is the Cost of a National Mandate Too Burdensome in an Uncertain Economy?

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Autism, or autism spectrum disorder (ASD), is the term used to describe a series of complex neurobiological disorders involving language, social, and sensory processing problems.¹ ASDs include autistic disorder, Asperger syndrome, and pervasive developmental disorder—not otherwise specified (PDD-NOS, including atypical autism); while symptoms may appear the same amongst individual disorders, the symptoms differ in severity, onset of occurrence, and specific nature.² The Centers for Disease Control and Prevention estimates that 1 in 150 eight-year-old children have autism, and advocates claim that autism is the “fastest-growing serious developmental disability in the U.S.”³ Autism affects all racial, ethnic, and socioeconomic groups and is four times more likely to occur in boys than girls.⁴ Disagreement exists within the mental health community as to whether the rise in diagnosis of children with autism is the result of better diagnostic testing, more inclusive classification, or an actual increase in the

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¹ Trudy Steuernagel, *Increases in Identified Cases of Autism Spectrum Disorders*, 16 J. OF DISABILITY POL’Y STUD., 138, 138 (2005); AUTISM SPEAKS, ARGUMENTS IN SUPPORT OF PRIVATE INSURANCE COVERAGE OF AUTISM-RELATED SERVICES 4 (Oct. 24, 2007), http://www.autismvotes.org/atf/cf/%7B2A179B73-96E2-44C3-8816-1B1C0BE5334B%7D/arguments_for_private_insurance_coverage.pdf.

² CTRS. FOR DISEASE CONTROL & PREVENTION, AUTISM INFORMATION CENTER: AUTISM SPECTRUM DISORDERS OVERVIEW (Feb. 9, 2007), <http://www.cdc.gov/ncbddd/autism/overview.htm> [hereinafter CDC].

³ CDC, *supra* note 2; AUTISM SPEAKS, *supra* note 1, at 4.

⁴ CDC, *supra* note 2.

prevalence of the disorder.⁵ Research has shown that autism can be detected as early as eighteen months and early intervention will significantly improve a child's development.⁶

Until recently, the high cost of diagnosing and providing subsequent therapies was not covered by insurance, and many families needed to make significant financial sacrifices so that they could afford treatment.⁷ According to the Autism Society of America, a family could spend as much as \$5 million caring for a child with autism during the child's lifetime.⁸ The Harvard School of Public Health tallies the lifetime cost of autism treatment at about \$3.2 million per person, totaling \$35 billion per year to care for all persons with autism.⁹ Autism Speaks, a national advocacy group and proponent of state mandated insurance coverage, remarks that the financial burden may require these families to take out second mortgages, live with other family members, and possibly file for bankruptcy in order to pay for treatment and therapy.¹⁰

Members of Autism Speaks, who are integral players in the push for autism insurance coverage mandates, have personal connections to the disorder and experience the frustrations associated with the high cost of treatment, which families sometimes simply cannot afford.¹¹ For instance, Autism Speaks Illinois

⁵ Steuernagel, *supra* note 1, at 138.

⁶ CDC, *supra* note 2; see also Autism Society of America, Characteristics of Autism, http://www.autism-society.org/site/PageServer?pagename=about_whatis_char (last visited Mar. 29, 2009) ("[C]hildren with autism can learn and function normally and show improvement with appropriate treatment and education.").

⁷ See Val Willingham, *Parents Press for Autism Insurance Coverage*, CNN, <http://www.cnn.com/2008/HEALTH/conditions/10/17/autism.insurance/index.html> (last visited Mar. 29, 2009).

⁸ *Id.*

⁹ Barbara Kantrowitz & Julie Scelfo, *Growing Up with Autism; Teenagers and Young Adults are the Emerging Face of Autism as the Disorder Continues to Challenge Science and Unite Determined Families*, NEWSWEEK, Nov. 27, 2006, available at http://autism.pbisillinois.org/IATTAP_newsweek_growing_up_with_autism27NOV06.pdf; Press Release, Harvard School of Public Health, Autism Has High Costs to U.S. Society (Apr. 25, 2006) (on file with Harvard School of Public Health), available at <http://www.hsph.harvard.edu/news/press-releases/2006-releases/press04252006.html>.

¹⁰ Willingham, *supra* note 7; see AUTISM SPEAKS, *supra* note 1.

¹¹ Telephone Interview with Lee Jorwig, Illinois Chapter Advocacy Chair for Autism Speaks, in Chicago, Ill. (Feb. 12, 2009). Lee Jorwig is the current Advocacy Chair for Autism Speaks and was formerly President of the Chicago Chapter of Autism Speaks and President of Cure Autism

Chapter Advocacy Chair Lee Jorwic and his wife Teri have spent approximately \$25,000 to \$30,000 per year on treatment for their son Christopher, who was diagnosed with autism in 1993.¹² Christopher's treatment encompassed over four and a half years of private therapy, including more than forty hours per week of personal Applied Behavioral Analysis (ABA) therapy.¹³ ABA, a particular method of one-on-one therapy, is costly and controversial, yet most promising for those children who are diagnosed at an early age.¹⁴ ABA is highly repetitive and intensive, (requiring up to eight hours a day, forty hours a week), and estimates of costs vary greatly.¹⁵ Parents lobbying for coverage of this therapy argue that autistic children who receive ABA will be able to care for themselves, even if only the basic activities of daily living.¹⁶ As a result, these children may be less dependent on public aid such as Medicaid as they grow older.¹⁷

Only a handful of states require private insurance companies to provide coverage for behavioral treatment services for autism, such as ABA therapy.¹⁸ Amongst those states that have mandates in place, the coverage limits and maximum ages of eligibility for benefits vary.¹⁹ Due to this partial or complete lack of coverage, Autism Speaks launched a grass-roots campaign in several states.²⁰ Its latest success occurred on December 12, 2008, when Illinois passed Public Act 95-1005 (215 ILCS 356z. 14) requiring all group and individual health insurance policies and HMO contracts to provide "coverage for the diagnosis and

Now. He has been working on the grass-roots campaign in Illinois for insurance coverage for the past six years. Mr. Jorwic's reason for becoming such a prominent advocate for autism and insurance coverage is simple, clear, and humbling: "Teri and I have met people [who] over the years just get devastated by [the high cost of ABA therapy] . . . I wanted to do something for other people, because so many people are devastated...." *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ John Donvan, *Insurance vs. Autism: For Parents, Insurance is a Personal Fight*, ABC NEWS, Mar. 24, 2008, <http://abcnews.go.com/Health/story?id=4515825>; Willingham, *supra* note 7.

¹⁵ Donvan, *supra* note 14; Willingham, *supra* note 7.

¹⁶ Donvan, *supra* note 14.

¹⁷ Donvan, *supra* note 14; See also Kantrowitz & Scelfo, *supra* note 9.

¹⁸ HOLLY BORTFELD, TALK ABOUT CURING AUTISM, INSURANCE COVERAGE FOR BIOMEDICAL & TRADITIONAL AUTISM TREATMENTS 25 (Oct. 2008), <http://www.tacanow.org/resources/autism-insurance-insurance-coverage-for-autism.pdf>.

¹⁹ *Id.*

²⁰ Telephone Interview with Lee Jorwic, *supra* note 11.

treatment of autism spectrum disorders for children under 21, establishing an annual benefit of \$36,000 for services....”²¹ According to Jorwic, Autism Speaks focused on Illinois as a pivotal state because of the prevalence of major insurance companies based in the state.²² Autism Speaks hopes that passing the law in Illinois will be the tipping point, and the arguments and information which persuaded Illinois legislators will be nationally disseminated and serve as a catalyst for the enactment of similar laws in other states.²³

Nevertheless, the main opponent of autism advocate groups will continue to be the insurance industry, according to Jorwic.²⁴ Specifically, the Council for Affordable Health Insurance argues that passage of such mandates will inevitably lead to increased cost of insurance premiums and therefore put the cost of coverage out of the reach of many already struggling Americans.²⁵ The Joint Legislative Audit and Review Commission (JLARC) of Virginia reported that insurance premiums would increase by \$4.88 per month if the state were to pass its version of the autism insurance mandate.²⁶ Critics argue the increase, which may not appear significant in theory, will overburden small-business owners in reality since they already are finding it difficult to provide quality health insurance for their employees.²⁷

Autism advocates argue that coverage will impact insurance premiums minimally at best—for instance, Indiana premiums only increased between .5% and 1% after the passage of the state legislation.²⁸ Additionally, such advocates

²¹ ILL. DEP’T. OF FIN. & PROF’L REG., ILLINOIS INSURANCE FACTS; INSURANCE COVERAGE FOR AUTISM (Dec. 2008), <http://www.idfpr.com/DOI/pressRelease/pr08/AutismFactSheet.pdf>.

²² Telephone Interview with Lee Jorwic, *supra* note 11.

²³ *Id.*

²⁴ *Id.*

²⁵ Carla K. Johnson, *Parents Press States for Autism Insurance Laws*, ABC NEWS, Oct. 20, 2008, available at <http://abcnews.go.com/Health/wireStory?id=6068425>.

²⁶ JOINT LEGISLATIVE AUDIT & REVIEW COMMISS’N, EVALUATION OF HOUSE BILL 83: MANDATED COVERAGE OF AUTISM SPECTRUM DISORDERS 8 (Sept. 29, 2008), <http://jlarc.state.va.us/Meetings/Other/Autism.pdf>.

²⁷ Keith D. Cheatham, *Time for Autism Insurance? – No*, RICHMOND TIMES-DISPATCH, Jan. 4, 2009, available at http://www.timesdispatch.com/rtd/news/opinion/columnists/article/CHEATHAM105_20090102-204431/167616/.

²⁸ Telephone Interview with Lee Jorwic, *supra* note 11.

argue that states with the highest maximum yearly benefits only will see a modest increase in the cost of annual premiums, approximately \$50 per policy holder.²⁹

According to a study conducted by the American Association on Mental Retardation, children with autism were more likely to encounter problems accessing specialty care from a medical doctor than children with mental retardation.³⁰ Over a quarter of the children with autism reportedly had health plan-based and provider-based access problems, including the inability to find “skilled and experienced specialty doctors.”³¹ Further, under the current system, even when a person with autism lives in a state that has implemented a mandate, coverage is not necessarily guaranteed.³² A federal mandate providing one comprehensive, cohesive plan throughout the country, such as then Senator Obama’s draft bill entitled the Autism Treatment Acceleration Act of 2008, would minimize the complexities and ease the confusion associated with interpreting varying state mandates for employers, plan providers, doctors, other medical providers, and parents so that autistic children could be treated adequately.³³

A federal mandate does not constitute socialized medicine nor an attempt to further burden American workers or small business owners with exorbitant insurance premiums. Rather, a community of healthcare advocates, parents, and concerned citizens views a national law as a vehicle to provide the best available treatment for special needs children.³⁴ Children who never are given the opportunity to learn necessary life skills will become adults who are not self-sufficient and likely will rely upon public aid to meet their needs.³⁵ Despite fears that private citizens cannot withstand increased insurance expenses in a

²⁹ AUTISM SPEAKS, *supra* note 1, at 15.

³⁰ Marty Wyngaarden Kraus et al., *Access to Specialty Medical Care for Children with Mental Retardation, Autism, and Other Special Health Care Needs*, 41 MENTAL RETARDATION 329, 333 (2003).

³¹ *Id.* at 334.

³² BORTFELD, *supra* note 18, at 25 (clarifying that it is the state in which the policy is written and funded whose laws govern the insurance).

³³ See generally Autism Treatment Acceleration Act of 2008, 110th Cong. (2d Sess. 2008), available at <http://www.autismvotes.org/atf/cf/%7B2A179B73-96E2-44C3-8816-1B1C0BE5334B%7D/Obama%20federal%20autism%20reform.pdf>.

³⁴ See Telephone Interview with Lee Jorwig, *supra* note 11.

³⁵ *Id.*

challenging economy, spending additional money today makes more sense than further stressing an already strained public aid system in the future. Ultimately, a federal mandate likely would reduce the monetary burden on the public aid system if these children learn to function independently at a young age without the need for lifelong support.

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Vaccinations and Public Health: For the Greater Good

*Sherri DeVito**

I. INTRODUCTION

Americans are, among other things, a decidedly independent group of individuals inhabiting the same vast land. Citizens of this country take pride in their ability to choose, whether it be where they work, where they live, who they marry, their future aspirations, all justified by the simple phrase “it’s a free country.” No decision, big or small, is taken lightly or overlooked, and impositions of government mandates, no matter how beneficial, are often viewed as an imposition on an American’s freedom. Such is the case for vaccinations. For example, most people accept the government’s immunization requirements, but there is a small and growing group of citizens displeased with the large number of childhood vaccines and their uncertain safety records.¹ These groups bemoan the ‘one size fits all’ vaccination schedule, and argue instead for the ability to ‘pick and choose’ their own schedule which contradicts the Centers for Disease Control and Prevention’s (CDC) recommendations.² However, this individual-centric attitude ignores the utilitarian purpose of vaccines: greater good of the group, not the individual, is the paramount concern.

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¹ See generally GenerationRescue.org, <http://generationrescue.org/index.html> (last visited Apr. 13, 2009).

² See GenerationRescue.org, Vaccine Safety, <http://generationrescue.org/vaccines.html> (last visited Apr. 13, 2009).

While vaccines are imperfect and perceived as dangerous by a limited few, the standards in place should not necessarily be changed. Rather, the public needs a workable standard, such as that in place in Illinois, which is not subject to change and flux based upon the misplaced fears of various groups.

II. VACCINE DEVELOPMENT AND IMPACT ON COMMUNICABLE DISEASES

Edward Jenner first developed vaccines in 1796³ after hearing that dairymaids who contracted cowpox were naturally protected against smallpox.⁴ In May of 1796, Jenner took material from cowpox lesions and inoculated an eight-year old boy with it.⁵ The boy initially developed a fever, discomfort, loss of appetite and coldness.⁶ After the boy felt better, Jenner then inoculated the boy again, but this time with material from a smallpox lesion, and no disease developed.⁷ From this experiment, modern vaccines developed and smallpox was eventually eradicated in 1977.⁸

Although the vaccination process today is different than that developed by Edward Jenner, the result is the same. For instance, while vaccinations no longer involve taking matter directly from an ill person and introducing it to a healthy person, vaccination still involves the introduction of a virus. Currently, there are two types of vaccinations: “live attenuated” and “inactivated.”⁹ Live attenuated viruses are made by modifying a “wild” virus or bacterium in a laboratory.¹⁰ The modified virus reproduces and provides immunity from the disease rather than causing illness.¹¹ The resulting immunity is identical to that produced by a

³ Stefan Riedel, *Edward Jenner and the History of Smallpox and Vaccination*, 18 BUMC PROC. 21, 24 (2005).

⁴ *Id.* at 24.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.* at 25.

⁹ CTRS. FOR DISEASE CONTROL & PREVENTION, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES 4 (2008), <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/prinvac-508.pdf> [hereinafter EPIDEMIOLOGY].

¹⁰ *Id.* at 4.

¹¹ *Id.*

natural infection.¹² However, adverse reactions to live attenuated vaccines sometimes occur, and while the disease produced is usually milder than the natural one, the immune response is identical to that produced by a natural infection.¹³ Inactivated vaccines are bacteria or viruses grown in a culture and inactivated with heat and/or chemicals.¹⁴ Unlike live attenuated vaccines, inactivated vaccines are not alive, cannot replicate, and cannot cause infection even in an immunodeficient person.¹⁵ Additionally, inactivated vaccines require multiple doses, whereas live attenuated vaccines are usually effective with one dose.¹⁶

The success of vaccines is irrefutable. A recent *Journal of the American Medical Association* article analyzed morbidity and mortality rates before and after widespread implementation of national vaccine recommendations for thirteen vaccine-preventable diseases.¹⁷ The authors concluded that since the introduction of national vaccine recommendations in 1980, the number of cases of most vaccine-preventable diseases and deaths related to these diseases has decreased strikingly.¹⁸ Specifically, the study showed a greater than ninety-nine percent decline in the number of cases for diphtheria, measles, paralytic poliomyelitis, rubella, congenital rubella syndrome, and smallpox.¹⁹ Thus, vaccines have substantially decreased the incidence of morbidity and mortality related to several life-threatening diseases.

III. VILIFICATION IN THE FACE OF SUCCESS: MISPLACED FEARS ABOUT VACCINATIONS

¹² *Id.* at 5.

¹³ *Id.*

¹⁴ *Id.* at 6.

¹⁵ EPIDEMIOLOGY, *supra* note 9, at 6.

¹⁶ *Id.* at 5-6.

¹⁷ Sandra W. Roush & Trudy V. Murphy, *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 JAMA 2155, 2155 (2007). The study analyzed the following diseases: diphtheria, pertussis, tetanus, poliomyelitis, measles, mumps, rubella, *haemophilus influenzae* type b, acute hepatitis B, hepatitis A, varicella, *streptococcus pneumoniae*, and smallpox.

¹⁸ *Id.* at 2160.

¹⁹ *Id.*

Despite the success of vaccines in eliminating deadly diseases such as smallpox and polio, vaccines are not lauded by all. Some parents argue that the recommended vaccine schedule for children causes vaccine overload and results in overwhelming or weakening a child's immune system.²⁰ However, no scientific evidence indicates combined vaccines overload a child's immune system.²¹

Why, then, in the face of scientific evidence, do people shun that which has saved so many? Perhaps it is because over the past decade, the focus on individual health, emphasizing exercise, diet, and natural living, has increased. Along with the greater focus on what goes in one's body has come increased attention on vaccines and increased public distrust even though vaccines are proven methods of health preservation. Further, heart disease, which kills the greatest number of Americans,²² is not caused by or related to vaccinations.²³ Given the absence of scientific proof of danger or evidence of ineffectiveness, the main reason for this misguided focus on vaccines is fear.

IV. AUTISM AND VACCINATIONS: IS THERE A CONNECTION?

No anti-vaccine group has been more successful at engendering fear than a small faction of those in the autistic community. Parent-run websites such as GenerationRescue.org are staunchly critical of the current recommended vaccination schedule, the substances in some vaccinations, and the supposed lack of evidence to support the claimed safety of vaccines.²⁴ Indeed, sometimes

²⁰ Shona Hilton et al., 'Combined Vaccines Are Like a Sudden Onslaught to the Body's Immune System': Parental Concerns About Vaccine 'Overload' and "Immune-Vulnerability," 24 VACCINE 4321, 4324 (2006).

²¹ *Id.* at 4322.

²² HSIANG-CHING KUNG ET AL., DEATHS: FINAL DATA FOR 2005, 56 NAT'L VITAL STAT. REP. 1, 7-8. As of the date of publishing of this article, the most recent year with complete and final data was 2005.

²³ See generally Mayo Clinic, Heart Disease: Causes, <http://www.mayoclinic.com/health/heart-disease/DS01120/DSECTION=causes> (last visited Apr. 13, 2009).

²⁴ See generally GenerationRescue.org, Vaccine Safety, <http://generationrescue.org/vaccines.html> (last visited Apr. 13, 2009).

vaccines do harm people.²⁵ In those instances, injured persons can file claims with the National Vaccine Injury Compensation Program (VICP), a federal program.²⁶ The VICP is a no-fault system for resolving claims, and claims are adjudicated before the United States Court of Federal Claims.²⁷ The Vaccine Injury Compensation Trust Fund funds the VICP through a \$0.75 excise tax on each dose of vaccine purchased.²⁸ ²⁹

Since 2001, over 5,000 claims filed with the VICP have alleged autism resulted from the Measles-Mumps-Rubella (MMR) vaccine and/or the thimerosal ingredient in certain other vaccines.³⁰ Indeed, autism prevalence has increased since the 1980s.³¹ For example, in Olmsted County, MN, autism prevalence increased from four to ten per 10,000 children in the 1980s and early 1990s to thirty to fifty per 10,000 children in 2005.³² The increase spiked after 1987, coinciding with the publication of the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition* (DSM-III-R), which introduced a broader autism spectrum and provided formal diagnostic criteria.³³ The fourth edition of that publication further broadened the autism diagnostic criteria in 1994.³⁴ Before the dissemination of such criteria, children with autism may have been less precisely

²⁵ See National Childhood Vaccine Injury Act, Vaccine Injury Table, Health Resources and Services Administration, <ftp://ftp.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf> (last visited Apr. 13, 2009).

²⁶ See National Vaccine Injury Compensation Program, <http://www.hrsa.gov/vaccinecompensation/> (last visited Apr. 13, 2009) [hereinafter VICP]. Currently, the VICP is limited to the following vaccines: diphtheria, tetanus, pertussis (commonly known as DTP, DTaP, Tdap, DT, Td, or TT), *haemophilus influenzae* type b, hepatitis A, hepatitis B, human papillomavirus (HPV), influenza, measles, mumps, rubella (MMR), meningococcal. *See also* Vaccine Injury Table, *supra* note 25, at 1.

²⁷ *Id.*

²⁸ See Vaccine Injury Compensation Trust Fund, http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm (last visited Apr. 13, 2009) [hereinafter Trust Fund].

²⁹ Vaccine Injury Table, *supra* note 25, at 1.

³⁰ See Omnibus Autism Proceeding, Health Resources and Services Administration, <http://www.hrsa.gov/vaccinecompensation/omnibusproceeding.htm> (last visited Apr. 13, 2009).

³¹ William J. Barbaresi et al., *The Incidence of Autism in Olmsted County, Minnesota, 1976-1997*, 159 ARCH. PEDIATR. ADOLESC. MED. 37, 37 (2005).

³² *Id.*

³³ Barbaresi et al., *supra* note 31, at 38, 42.

³⁴ *Id.* at 42.

diagnosed, and classified as developmentally delayed or mentally retarded.³⁵ The Olmsted study ultimately concluded that the increase in the incidence of autism coincided with the publication of broader, less restrictive diagnostic criteria, increased availability of special education services, and increased awareness of autism.³⁶ Further, no link connected the MMR vaccine to the increase in autism, because MMR vaccine use began years before the spike in autism diagnoses.³⁷

In a landmark decision on February 12, 2009, the Court of Federal Claims held in three test cases that no scientific proof indicates vaccines cause autism.³⁸ Therefore, those persons who filed a claim with the VICP alleging autism as a result of vaccination will not receive compensation. The decision is being appealed.

V. WHERE DO WE GO FROM HERE?

Although loathed by many and injurious to some, vaccines have worked for over two centuries, saved innumerable lives from previously deadly diseases, and have contributed to longer life expectancies. If left up to each individual, there is no guarantee that society will continue this protection. One argument against further vaccination is that because so many people are already vaccinated, “herd immunity” exists and therefore it is not necessary that everyone immunize. Herd immunity occurs where there are a sufficient number of immunized individuals to prevent disease transmission to the non-immunized.³⁹ Therefore, some non-vaccinated individuals have immunity to certain diseases by virtue of their presence in a mostly-vaccinated community.⁴⁰ However, as more people

³⁵ *Id.* at 38.

³⁶ *Id.* at 42.

³⁷ *Id.*

³⁸ *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V (Fed. Cl. Feb. 12, 2009); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V (Fed. Cl. Feb. 12, 2009); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V (Fed. Cl. Feb. 12, 2009).

³⁹ Emma S. McBryde, Letter to the Editor, *Network Structure Can Play a Role in Vaccination Thresholds and Herd Immunity: A Simulation Using a Network Mathematical Model*, 48 CLIN. INFECT. DIS. 685, 685 (2009).

⁴⁰ *Id.*

refuse vaccination and attempt to “freeload” off of the rest of the community, fewer remain in the vaccinated “herd,” thereby increasing the risk of infection both among the unvaccinated and vaccinated.⁴¹ Thus, claiming herd immunity should not exempt an individual from the requirements imposed upon all.

Vaccinations have proven to be a challenging issue, and for that reason, the public needs a clear and workable standard to deal with the long standing conflict. The Illinois model meets this standard and provides vaccination exemptions for those with conflicting religious beliefs or where the child’s physician believes the vaccination is medically contraindicated for the child.⁴² Parents who believe vaccinating is morally or philosophically wrong or possibly dangerous are not exempted.⁴³ This standard ensures each community has maximum immunity to infectious diseases while still allowing exemptions to a select few. Also, this standard avoids increased incidences of vaccine-preventable diseases which have been documented in other states where parents can easily obtain non-medical exemptions from vaccinations.⁴⁴ In addition, this standard provides guidance to doctors, who at times find themselves in the difficult situation of balancing legal vaccination requirements, the patient’s best interests, and reconciling those two things with parental fears and wishes.

Conversely, the federal government already has vaccine recommendations and guidelines that could be implemented nationwide.⁴⁵ Under the CDC’s guidelines, exemptions exist for medical reasons, but no exemptions exist for religious, moral, or philosophical reasons.⁴⁶ Currently, states are responsible for

⁴¹ Daniel S. Rubin & Sophie Kasimow, *The Problem of Vaccination Noncompliance: Public Health Goals and the Limitations of Tort Law*, 107 MICH. L. REV. FIRST IMPRESSIONS 114, 115 (2009). <http://www.michiganlawreview.org/firstimpressions/vol107/rubinkasimow.pdf>.

⁴² ILL. ADMIN. CODE tit. 77, § 695.30 (2008).

⁴³ VaccineSafety.edu, Vaccine Exemption Issues, <http://www.vaccinesafety.edu/cc-exem.htm> (last visited Apr. 13, 2009). Currently, 21 states allow personal belief exemptions to vaccinations.

⁴⁴ Saaed B. Omer et al., *Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence*, 296 JAMA 1757, 1761 (2006).

⁴⁵ CTRS. FOR DISEASE CONTROL & PREVENTION, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES APP. A (Atkinson W, Hamborsky J, McIntyre L, Wolfe S, eds., 10th ed. 2008.), available at <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/applications/A/age-interval-table.pdf>.

⁴⁶ VaccineSafety.edu, *supra* note 43.

the development and enforcement of vaccination laws, and there is great divergence between states as to vaccination requirements.⁴⁷ Guidelines of universal application, such as the CDC's, are a preferable alternative because they can better protect the general population.

VI. CONCLUSION

While in rare instances vaccines may cause deleterious effects, most people's fears and misgivings about vaccinations are misguided and unsupported by the research. Vaccines successfully eliminated smallpox, and decreased the morbidity rates associated with seven other diseases by nearly 100%.⁴⁸ Universal acceptance and application of vaccine guidelines could perhaps make today's common illnesses—such as influenza—a disease of the past, much like smallpox. While some individuals are injured as a result of vaccines, the reality of vaccines is such that some must suffer so many may survive. Although vaccines are an imperfect answer to a serious problem, they are paramount to the continued health of society, and for that reason the standards in place should be strengthened.

⁴⁷ FOOD & DRUG ADMIN., VACCINE FREQUENTLY ASKED QUESTIONS, <http://www.fda.gov/CBER/faq/vacfaq.htm> (last visited Apr. 13, 2009).

⁴⁸ CTR. FOR DISEASE CONTROL & PREVENTION, IMPACT OF VACCINES UNIVERSALLY RECOMMENDED FOR CHILDREN, 48 MORBIDITY & MORTALITY WKLY. REP. 243, 245-6 (1999). As a result of vaccine use, the morbidity rates associated with diphtheria, polio, measles, mumps, rubella, congenital rubella syndrome, and *haemophilus influenza type b* have decreased by nearly 100%.

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Ethnic Disparities in Influenza Immunization Rates

*Susie Shin**

I. INTRODUCTION

Influenza causes 36,000 deaths and more than 200,000 hospitalizations per year in the United States.¹ Ninety percent of these deaths include individuals aged sixty-five and older who are especially susceptible to influenza.² If these individuals had received the influenza vaccine, mortality and morbidity rates would be reduced, especially among elderly individuals with diabetes, asthma, and other conditions.³ Additionally, vaccinations would reduce the costs of hospitalization and health care in general.⁴

Although influenza is vaccine-preventable, only 40% of individuals aged sixty-five and older are vaccinated in the United States.⁵ Currently, the Advisory Community on Immunization Practices (ACIP) recommends yearly influenza

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¹ Lynda Flowers et al., *Racial and Ethnic Disparities in Influenza and Pneumococcal Immunization Rates Among Medicare Beneficiaries*, AARP Pub. Pol'y Inst. 1, Oct. 2008, available at http://assets.aarp.org/rgcenter/health/i12_flu.pdf.

² *Id.*

³ Leonard E. Egede & Deyi Zheng, *Racial/Ethnic Differences in Influenza Vaccination Coverage in High-Risk Adults*, 93(12) AM. J. PUB. HEALTH 2074, 2074 (2003).

⁴ *Id.* at 2074; K.L. Nichol et al., *The Efficacy and Cost Effectiveness of Vaccination Against Influenza Among Elderly Persons Living in the Community*, 331(12) NEW ENG. J. MED. 778, 783 (1994) (among individuals aged sixty-four years and older, annual influenza vaccination savings averaged \$117 per person vaccinated with cumulative savings of almost \$5 million).

⁵ Lawson et al., *Standing Orders for Influenza Vaccination Increased Vaccination Rates in Inpatient Settings Compared with Community Rates*, 55A(9) J. GERONTOLOGY: MED. SCI., M522, M522 (2000).

vaccinations for adults aged 50 and older.⁶ Medicare also encourages beneficiaries to be vaccinated by paying for vaccines with participating providers.⁷

Despite these efforts, disparities in influenza vaccination rates between races still persist.⁸ In 2006, among Medicare beneficiaries aged sixty-five years and older, 67% of Caucasians received the influenza vaccine, while only 47% of African Americans and 45% of Hispanics received it.⁹ These variations exist even among individuals that are most likely to be vaccinated, such as highly educated individuals.¹⁰ If the percentage of minority citizens who are vaccinated increased or surpassed the current level of vaccinations amongst Caucasian citizens, the benefits of influenza vaccinations, including the prevention of hospitalizations, deaths, and financial losses, would be significant.¹¹ Specifically, 1,880 minority deaths could be prevented annually if African Americans and Hispanics were immunized at the same rate as Caucasians.¹²

Although these discrepancies are extensively documented, the reasons they exist are poorly understood.¹³ There are several possibilities why different ethnicities may not receive the influenza vaccine, including the lack of knowledge about the vaccine,¹⁴ the inability to afford the vaccine,¹⁵ or the inaccessibility of

⁶ Flowers, *supra* note 1 at 1 (“The ACIP is an expert panel selected by the U.S. Department of Health and Human Services to advise the nation on how to reduce vaccine-preventable diseases”); ANTHONY E. FIORE ET AL., PREVENTION AND CONTROL OF INFLUENZA: RECOMMENDATIONS OF THE ADVISORY COMMUNITY ON IMMUNIZATION PRACTICES (ACIP) (2008), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5707a1.htm>.

⁷ CENTERS FOR MEDICARE & MEDICAID SERVICES, IMMUNIZERS’ QUESTION & ANSWER GUIDE TO MEDICARE COVERAGE OF INFLUENZA AND PNEUMOCOCCAL VACCINATIONS 13 (2006), <http://www.cms.hhs.gov/AdultImmunizations/Downloads/fluguide0607rev.pdf> [hereinafter Q&A].

⁸ Michael W. Link et al., *Racial and Ethnic Disparities in Influenza Vaccination Coverage Among Adults During the 2004-2005 Season*, 163(6) AM. J. EPIDEMIOLOGY 571, 571 (2006).

⁹ Flowers, *supra* note 1, at 2.

¹⁰ *Id.*

¹¹ Egede, *supra* note 3, at 2074.

¹² Kevin Fiscella et al., *Impact of Influenza Vaccination Disparities on Elderly Mortality in the United States*, 45 PREVENTIVE MED. 83, 84 (2007).

¹³ Carla A. Winston et al., *Factors Associated with Vaccination of Medicare Beneficiaries in Five U.S. Communities: Results from the Racial and Ethnic Adult Disparities in Immunization Initiative Survey, 2003*, 54(2) J. AM. GERIATRICS SOC’Y 303, 303 (2006).

¹⁴ Winston, *supra* note 12, at 303.

providers to administer the vaccine.¹⁶ With a better understanding of why they are present, laws and policies could be implemented to relieve ethnic disparities in influenza vaccination rates.

II. CAUSES OF VARIATIONS IN VACCINATION RATES

One major reason for the ethnic disparity in influenza vaccination rates is health insurance coverage.¹⁷ Compared to Caucasians, African Americans are almost twice as likely, and Hispanics are three times as likely, to be uninsured.¹⁸ These uninsured individuals are unlikely to visit a healthcare provider for a routine checkup where vaccines are primarily administered.

A lack of health insurance may also be linked to an individual's lack of understanding about the influenza vaccination and general healthcare system.¹⁹ Without insurance, minorities may not know healthcare providers or how to access them.²⁰ In particular, they may not know about the preventive benefits available to them, such as an influenza vaccination.²¹

Minority beneficiaries could learn about preventive benefits through a healthcare professional. However, in areas where large numbers of minorities live, there is a lack of providers which could hinder influenza vaccination.²² In addition to an already low number of available providers, minorities tend to seek out healthcare providers of the same ethnic group.²³ In particular, those with

¹⁵ Timothy Stoltzfus Jost, *Disentangling Fact From Fiction: The Realities of Unequal Health Care Treatment: Article: Racial And Ethnic Disparities in Medicare: What the Department Of Health and Human Services and the Centers for Medicare and Medicaid Services Can, and Should, Do*, 9 DEPAUL J. HEALTH CARE L. 667, 675 (2005).

¹⁶ *Id.* at 677.

¹⁷ *Id.* at 675.

¹⁸ *Id.*

¹⁹ *Id.* at 680.

²⁰ *Id.*

²¹ *Id.*; Paul L. Hebert et al., *The Causes of Racial and Ethnic Differences in Influenza Vaccination Rates Among Elderly Medicare Beneficiaries*, 40(2) HEALTH SERV. RES. 517, 520 (2005) (Twenty one percent of Caucasians stated that they did not receive an influenza vaccine because they did not know it was needed. In contrast, 33% of Hispanics and 25% of African Americans were unaware of a need for influenza vaccination).

²² Jost, *supra* note 16, at 677.

²³ *Id.*

limited English proficiency prefer a provider with their same ethnicity.²⁴ Therefore, the lack of providers that minorities feel comfortable with can deter minorities from receiving influenza vaccinations.

III. LAWS AND POLICIES TO INCREASE IMMUNIZATION RATES

A. Existing Laws and Policies

Since 1993, Medicare has provided financial coverage for the influenza vaccine.²⁵ In 2002, the Centers for Disease Control and Prevention (CDC) collaborated with federal agencies to start the Racial and Ethnic Adult Disparities in Immunization Initiative project to address lower vaccination rates among African American and Hispanic Medicare beneficiaries.²⁶ The project was set up in five areas: Chicago, Illinois; Rochester, New York; San Antonio, Texas; Milwaukee, Wisconsin; and several counties in the Mississippi delta region.²⁷ As part of the project, each area created strategies to reach out to African American and Hispanic individuals aged sixty-five and older.²⁸ The results showed that the most successful strategy was targeting providers to encourage them to contact their patients to visit their offices for an influenza vaccination.²⁹

In 2005, the Centers for Medicare and Medicaid Services (CMS) also issued federal rules requiring long-term care facilities housing Medicare and Medicaid beneficiaries to offer influenza vaccines.³⁰ Although this regulation did not specifically target minority groups, African Americans and Hispanics living in long-term care facilities benefited.³¹

²⁴ See *id.* at 678.

²⁵ Q&A, *supra* note 7, at 4.

²⁶ Flowers, *supra* note 1, at 3.

²⁷ *Id.*

²⁸ CENTERS FOR DISEASE CONTROL AND PREVENTION, HIGHLIGHTS IN MINORITY HEALTH & HEALTH DISPARITIES (2006), available at <http://www.cdc.gov/omhd/Highlights/2006/HAug06.htm#PROGRAMS>.

²⁹ Flowers, *supra* note 1, at 3.

³⁰ *Id.* at 4.

³¹ *Id.*

Individual states also have implemented influenza vaccination initiatives. In 2007, the Chicago Department of Public Health in Illinois provided vaccine clinics and promoted vaccination in high-risk communities targeting the elderly during the flu season.³² In 2008, 70% of long-term care facility residents in Illinois had received the influenza vaccine.³³ Moreover, in Montana, letters were sent to Medicare beneficiaries that promoted influenza vaccination.³⁴ As a result, influenza vaccination rates increased 9% with personal letters and 7% with form letters.³⁵ Similarly, in Wyoming, influenza vaccination rates increased by 19% with personal letters and 20% with form letters.³⁶

B. Possible Future Laws and Policies

A range of laws and policies should be implemented to reach a large amount of minorities aged sixty-five and older. Past studies and research have shown effective strategies, including sending influenza vaccination reminders directly to individuals,³⁷ encouraging healthcare providers promote influenza vaccination,³⁸ executing standing order programs,³⁹ providing interpreter services,⁴⁰ and incentivizing physicians to work in minority areas.⁴¹

Hospitals and providers should educate minorities about vaccinations.⁴² A small amount of Caucasians (8%) who did not have a medically documented resistance to vaccination remained unvaccinated despite being seen in providers' offices during the influenza vaccination period, whereas 14% of African

³² *Id.*

³³ *Id.*

³⁴ DM Berwick, *Flu Mailings Boost Vaccination Rates Among Medicare Enrollees*, J. WATCH GEN MED., Oct. 31, 1995, available at <http://general-medicine.jwatch.org/cgi/content/full/1995/1031/1>.

³⁵ *Id.*

³⁶ *Id.*

³⁷ Flowers, *supra* note 1, at 3.

³⁸ See Dale W. Bratzler et al., *Failure to Vaccinate Medicare Inpatients*, 162 ARCHIVES INTERNAL MED. 2349, 2352 (2002).

³⁹ Charles M. Helms, et al., *Strengthening the Nation's Influenza Vaccination System: An NVAC Assessment*, 29 AM. J. PREVENTIVE MED. 221, 223 (2005).

⁴⁰ Jost, *supra* note 16, at 702.

⁴¹ *Id.* at 691.

⁴² See Bratzler, *supra* note 39, at 2352.

Americans and 17% of Hispanics remained unvaccinated under similar conditions.⁴³ These figures indicate that healthcare professionals are missing vaccination opportunities.⁴⁴ Because studies have shown that patients respond well to providers' recommendations,⁴⁵ more patients may be encouraged to receive the influenza vaccine if healthcare professionals actively promoted it.⁴⁶ In addition, most adults seek healthcare providers when they have an acute or chronic illness, not for a preventive service like a vaccination.⁴⁷ Therefore, if minority patients go to a provider for non-vaccination purposes during the influenza vaccination period, providers should take advantage of this opportunity to educate patients.

On an institutional level, hospitals could execute standing order programs. Some hospitals require a physician's written order before a hospital can vaccinate a patient.⁴⁸ This administrative step hinders access to vaccines.⁴⁹ A standing order program can increase access by allowing vaccines to be administered without a written order from a physician.⁵⁰ For example, a hospital without a standing order policy had about 33% of its patients vaccinated, while a hospital with a standing order program in place had over 90% of its patients vaccinated.⁵¹

Standing order programs at non-traditional healthcare centers, such as pharmacies and grocery stores, also can increase vaccination access.⁵² For example, states in which pharmacists were allowed to administer influenza vaccines to individuals aged sixty-five and older had significantly higher influenza vaccination rates than in states without standing order programs.⁵³ Non-traditional healthcare centers could be helpful in areas with physician shortages.

⁴³ Hebert, *supra* note 22, at 529.

⁴⁴ *Id.* at 532.

⁴⁵ Flowers, *supra* note 1, at 3.

⁴⁶ David S. Fedson, *Clinical Practice and Public Policy for Influenza and Pneumococcal Vaccination of the Elderly*, 8(1) CLINICS IN GERIATRIC MED. 183, 190 (1992).

⁴⁷ Helms, *supra* note 40, at 223.

⁴⁸ Lawson, *supra* note 5, at M522.

⁴⁹ *Id.*

⁵⁰ *Id.* at M525.

⁵¹ *Id.* at M524.

⁵² Helms, *supra* note 40, at 223.

⁵³ Flowers, *supra* note 1 at 6.

They also could lessen financial barriers since influenza vaccines are less expensive at a local pharmacy than at a physician's office,⁵⁴ which would help uninsured minorities. A standing order program could break down language barriers since patients could be vaccinated at a local grocery store or pharmacy where the healthcare professional and patient may speak the same language.

One strategy that could be put in place nationally is based on the finding that the strongest predictor of future immunization is whether an individual has received the influenza vaccination previously.⁵⁵ If the Social Security Administration (SSA) included information about influenza vaccinations in social security check envelopes, never-vaccinated seniors would be reminded to obtain vaccination. In turn, these individuals may seek another vaccination the following year. Additionally, these reminders could be written in different languages depending on the recipient's primary language.

To further minimize challenges associated with language differences, Congress could require all Medicare providers to provide interpreter services. Individual states and the Department of Health and Human Services (HHS) should help supplement the costs.⁵⁶ At least ten state Medicaid programs are already paying for interpreters.⁵⁷ Further, interpreter services are low in cost.⁵⁸ The United States Office of Management and Budget estimate that the average cost for interpreter services is only \$4.04 per visit.⁵⁹

Other government agencies, such as CMS, should incentivize physicians to serve in minority communities.⁶⁰ Currently, in order to increase physician access in rural areas, the government provides bonuses to physicians who work in such areas.⁶¹ Similarly, the government could offer bonuses to physicians who

⁵⁴ *Id.*

⁵⁵ Berwick, *supra* note 35. The study found that the strongest predictor of immunization in Montana and Wyoming in the 1994 season was prior immunization in 1993. *Id.*

⁵⁶ Jost, *supra* note 16, at 701.

⁵⁷ *Id.*

⁵⁸ *Id.* at 702.

⁵⁹ *Id.*

⁶⁰ *Id.* at 691.

⁶¹ *Id.* at 669.

serve minority beneficiaries or work in understaffed areas largely populated by minorities.⁶² The Medicare Modernization Act currently provides health care professionals a 10% incentive payment for working in government-designated health professional shortage areas and a 5% incentive payment in physician scarcity areas.⁶³ However, these areas do not include minority populations.⁶⁴ CMS should modify the provisions to expressly include minority areas.⁶⁵

IV. CONCLUSION

Ethnic disparities in influenza vaccination rates contribute considerably to minority mortality in those aged sixty-five years and older.⁶⁶ Although the government is promoting influenza vaccination at the state and federal levels, vaccination disparities still exist.⁶⁷ As a result, efforts need to be made to specifically target minorities. Effective strategies can be promulgated by hospitals and healthcare providers who can educate and vaccinate minorities directly. In addition, laws requiring standing order programs can be utilized. Strategies also can be through government agencies, such as the SSA, CMS, or HHS. By applying effective laws and policies, ethnic disparities can be decreased significantly, minimizing economical losses and more importantly, preventable fatalities.

⁶² *Id.*

⁶³ *Id.* at 691.

⁶⁴ *Id.* CMS interprets the 5% incentive as applying at the county level and excluding urban areas where minorities live.

⁶⁵ *Id.*

⁶⁶ Fiscella, *supra* note 11, at 85.

⁶⁷ Flowers, *supra* note 1, at 1.

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Good Importer Practices: Can the FDA Afford to Rely on the Importer for Food Safety?

*Christy O’Berry**

I. INTRODUCTION

The Food and Drug Administration (FDA) is responsible for protecting the public health by inspecting and maintaining the United States' food supply.¹ The FDA is responsible for inspecting approximately eighty percent of the U.S. food supply, including both domestic and imported food, whereas the United States Department of Agriculture (USDA) is responsible for the remaining twenty percent of the food supply.²

Recent outbreaks of E. coli in spinach, salmonella in peanut butter, and melamine contamination in pet food prompted the FDA to formulate the *Food Protection Plan* to address the oversight of food safety³ and led to the *Draft Guidance for Industry on Good Importer Practices* (GIP).⁴ Upon finalization, the

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¹ FDA, FDA’s MISSION STATEMENT, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Mar. 29, 2009).

² U.S. GOV’T ACCOUNTABILITY OFF., GAO-08-435T, FEDERAL OVERSIGHT OF FOOD SAFETY: FDA’S FOOD PROTECTION PLAN PROPOSES POSITIVE FIRST STEPS, BUT CAPACITY TO CARRY THEM OUT IS CRITICAL 1, 4 (2008) [hereinafter FOOD PROTECTION PLAN] (testimony of Lisa Shames, Director Natural Resources and Environment); see Eric M. Goldstein, *Inspecting the Hands that Feed Us: Requiring U.S. Quality for all Imported Foods*, 7 Wash. U. Global Stud. L. Rev. 137, 139 (2008).

³ FOOD PROTECTION PLAN, *supra* note 2, at 1.

⁴ Notice for Draft Guidance for Industry on Good Importer Practices, 74 Fed. Reg. 1692, 1692 (proposed Jan. 13, 2009).

GIP will not create legally enforceable rights or responsibilities but rather, will establish the current position of the United States on food safety.⁵ With promulgation of the GIP, the FDA will rely on importers, and the food safety and inspection laws of other countries to meet the standards set forth in the GIP. An importer “initiates or causes the entry or attempted entry of foreign-sourced products into the U.S. or the reimportation of U.S.-made products (American Goods Returned) for commercial purposes or distribution.”⁶ The FDA lacks many of the resources, such as personnel and funding to inspect all importers, which may be to blame for its inability to inspect all imported foods and to order mandatory recalls when contaminated food is discovered.⁷ This article examines the effectiveness of the GIP.

II. BACKGROUND

A. *The FDA*

The mission statement of the FDA is, in part, to protect the safety of the U.S. food supply through enforcement of the Federal Food, Drug, and Cosmetic Act (FD&C), which includes both imported and domestic food lines.⁸ The enforcement division of the FDA, the Office of Regulatory Affairs (ORA), has the mission to “safeguard the public health and to ensure honesty and fair dealing between the regulated industry and consumers,”⁹ as well as to conduct inspections on foreign imports.¹⁰ Imported foods must meet the same standards as domestic

⁵ FDA, FDA-2009-D-0675, DRAFT GUIDANCE FOR INDUSTRY ON GOOD IMPORTER PRACTICES 3 (2009) [hereinafter FDA, DRAFT GUIDANCE].

⁶ *Id.*

⁷ See Noam N. Levey, *Food Safety Reform Sits on Back Burner: Obama Appears to Back a Long-Sought Overhaul of the FDA, but More Urgent Issues May Push it Aside*, L.A. TIMES, Dec. 26, 2008, at A17.

⁸ OFF. OF REG. AFF., FDA IMPORT PROGRAM SYSTEM INFORMATION, http://www.fda.gov/ora/import/ora_import_system.html (last visited Mar. 29, 2009).

⁹ FDA, IMPORTS AND INSPECTIONS: INTERNATIONAL REGULATORY ACTIVITIES, <http://www.fda.gov/oha/impinsp.htm> (last visited Mar. 29, 2009).

¹⁰ *Id.*

food.¹¹ Practically, this means that they must be safe to eat and produced under sanitary conditions.¹²

However, inadequate financial resources, inadequate personnel, new responsibilities imposed by Congress, and increased food safety demands have prevented the FDA from fulfilling its mission.¹³ The FDA accounted for only twenty-four percent of the federal food safety budget but is responsible for approximately eighty percent of the nation's food supply.¹⁴ Additionally, the FDA lacks the authority it needs to appropriately regulate the food industry.¹⁵ For instance, the FDA lacks the authority to implement mandatory recalls and the ability to set binding standards for the safe production of fruits and vegetables.¹⁶

B. Food Borne Illnesses

The Centers for Disease Control and Prevention (CDC) "estimates that approximately 76 million cases of food borne illness occur in the United States each year, resulting in 325,000 hospitalizations and 5,000 deaths annually."¹⁷ Domestic and imported food has been linked to these outbreaks of food borne illnesses.¹⁸ In fact, some of the most serious outbreaks over the past twenty years have been associated with imported foods that are under the jurisdiction of the FDA.¹⁹ For instance, in July 2008, salmonella-tainted jalapeños imported from Mexico sickened more than 1,200 people in forty-three states, the District of Columbia, and Canada.²⁰ In 2007, melamine, an ingredient used to make plastics and tanning leather, was found as an additive in pet food imported from China

¹¹ OFF. OF REG. AFF., *supra* note 8.

¹² *Id.*

¹³ FOOD PROTECTION PLAN, *supra* note 2; see Richard Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 432 (2008).

¹⁴ FOOD PROTECTION PLAN, *supra* note 2, at 4.

¹⁵ Levey, *supra* note 7.

¹⁶ *Id.*

¹⁷ Goldstein, *supra* note 2, at 158.

¹⁸ U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-1047, FOOD SAFETY: IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE 1 (2008).

¹⁹ Goldstein, *supra* note 2, at 137.

²⁰ Annys Shin, *Salmonella-Tainted Jalapeño Found in Texas*, WASH. POST, July 22, 2008, at A1.

and caused thousands of animal fatalities in the United States.²¹ Melamine was also added to milk powder in China, killing at least three children and causing illness to over 1,300 more.²² As the United States becomes more reliant on imported foods, the food supply will become more vulnerable to contamination.²³

C. Inspections

With respect to imported food, the FDA relies on inspections at ports of entry to prevent contaminated food from entering the U.S. food supply.²⁴ The FDA electronically screens all shipments when they arrive at the U.S. border using data supplied by the shipper's themselves.²⁵ Since only about one percent of imported food is tested at the U.S. border,²⁶ most shippers are aware that it is unlikely that the food they are importing will be inspected.²⁷ Therefore, adulterated or contaminated food is more likely to enter the U.S.' food supply.²⁸

Furthermore, many of the contaminants that enter the food at the processor's facility are undetectable at port of entry inspections even if the food is laboratory tested.²⁹ To address this issue, the FDA is attempting to implement a system of preemptive testing, in which the FDA will test the foreign food producer's facility for contaminants that may be introduced at the facility.³⁰ For example, the FDA has an inspection office in China.³¹ However, the office in China is staffed with only eight inspectors and will have little impact on a country

²¹ Lee Spears & Helen Yuan, *China Widens Probe into Milk Scandal as Recalls Rise (Update 2)*, BLOOMBERG.COM, <http://www.bloomberg.com/apps/news?pid=20601080&sid=a01qefqeLN1o&refer=asia#> (last visited Mar. 29, 2009).

²² *Id.*

²³ Goldstein, *supra* note 2, at 137, 138.

²⁴ David Plunkett & Caroline Smith DeWaal, *Who is Responsible for the Safety of Food in a Global Market? Government Certification v. Importer Accountability as Models for Assuring the Safety of Internationally Traded Foods*, 63 Food & Drug L.J. 657, 657 (2008).

²⁵ Goldstein, *supra* note 2, at 145, 150.

²⁶ Plunkett & DeWaal, *supra* note 24, at 657-658.

²⁷ See Goldstein, *supra* note 2, at 151.

²⁸ *Id.* at 146.

²⁹ *Id.* at 150.

³⁰ *Id.*

³¹ Steve Brozak, *Caution – FDA Could be Hazardous to Your Health*, UPDATE, Jan./Feb. 2009, at 30, 31.

as large as China.³² The United States also plans to open offices in India, Europe, and Latin America so that they can conduct inspections in countries that have a growing number of imports into the United States.³³ Although the ideal situation would be to inspect all 189,000 foreign food facilities,³⁴ doing so would cost over three billion dollars when the FDA's proposed food safety budget is less than one billion dollars.³⁵

III. GOOD IMPORTER PRACTICE DRAFT GUIDELINES

The GIP is intended to help importers ensure their products meet U.S. health and safety requirements.³⁶ The GIP sets forth recommendations designed to mitigate safety hazards that might be present in a foreign-sourced product's life cycle and offers preventative controls that facilities can implement.³⁷ The product's life cycle consists of growing, manufacturing, processing, and transportation.³⁸

The principles of the GIP are set out under four guidelines: (1) "Establishing a Product Safety Management Program;" (2) "Knowing the Product and Applicable U.S. Requirements;" (3) "Verifying Product and Firm Compliance with U.S. Requirements throughout the Supply Chain;" and (4) "Taking Corrective and Preventative Action When the Product or Firm is Not Compliant with U.S. Requirements."³⁹

The first principle suggests that importers should develop a clearly defined organizational structure to implement the recommendations in the guidelines and to foster corporate accountability.⁴⁰ The second principle suggests that the

³² *Id.*

³³ *Id.*

³⁴ See Gardiner Harris, *Report Faults F.D.A. Action for Safe Food*, N.Y. TIMES, June 12, 2008, at A22.

³⁵ *Id.*

³⁶ FDA, DRAFT GUIDANCE, *supra* note 5, at 2.

³⁷ *Id.* at 4.

³⁸ *Id.* at 2.

³⁹ *Id.* at 6.

⁴⁰ *Id.*

importers should have a good understanding of where the product originates, its intended use, and any vulnerabilities and risks associated with the product.⁴¹ In addition, the importer should be aware of which import regulations or requirements apply to the product throughout its life cycle and the product's compliance history.⁴² The third principle states that once importers know the regulatory requirements that apply to their product and the producer, the importer should ensure that they meet these requirements.⁴³ Importers must take several steps to ensure product compliance before, during, and after entry into the United States.⁴⁴ Finally, the fourth principle suggests that in order to minimize the potential of importing a hazardous product, the importer should develop a plan that implements corrective and preventative action if a non-compliant product is discovered.⁴⁵

IV. EFFECT OF THE GOOD IMPORTER PRACTICE GUIDELINES

The GIP puts the burden of inspecting the food supply on the importer and relies on the regulatory scheme of the country where the importer is located.⁴⁶ However, relying on the regulatory scheme of other countries and the importer to police the food supply is unlikely to have a positive effect, especially in countries where the adequacy of government oversight and regulatory structure has been questionable.⁴⁷ For instance, China, the second largest source of imported goods into the United States, has been the subject of numerous food health and safety concerns.⁴⁸ The imports of concern include toothpaste, pet foods, seafood, and more recently, milk products.⁴⁹

⁴¹ *Id.* at 7.

⁴² FDA, DRAFT GUIDANCE, *supra* note 5, at 7.

⁴³ *Id.* at 9.

⁴⁴ *Id.* at 9-10.

⁴⁵ *Id.* at 14.

⁴⁶ See *Id.*

⁴⁷ WAYNE M. MORRISON, CONG. RESEARCH SERV., HEALTH AND SAFETY CONCERN OVER U.S. IMPORTS OF CHINESE PRODUCTS: AN OVERVIEW, CRS REPORT RS22713, 1 (Aug. 28, 2007).

⁴⁸ *Id.* at 2.

⁴⁹ *Id.* at 1; see THE OFF. OF REG. AFF., FDA IMPORT ALERT 99-30 (Jan. 15, 2009), http://www.fda.gov/ora/fiars/ora_import_ia9930.html.

Agreements between the United States and China to boost protection of the public health would be difficult due to China's vast geography and rudimentary system of national oversight and inspection; thus, it would be unwise to rely on the Chinese importer for food safety.⁵⁰ This issue is further compounded by the Chinese central government's lack of control over some remote provinces⁵¹ and its inability to create and enforce food safety regulations.⁵² With similar bureaucratic problems found in other importing countries, the result of reliance on the importer through the GIP is unlikely to improve food safety.⁵³

Even though these guidelines do not have any legally enforceable rights, they may prove more effective than anticipated because U.S. product liability law holds parties in the food supply chain accountable for the defects found in their products.⁵⁴ However, recovery for damages from the importers of contaminated products is not guaranteed.⁵⁵

V. CONCLUSION

In light of the economic downturn, the FDA is unlikely to see any necessary reforms and will have to rely on the GIP to encourage accountability with foreign importers and other countries to assure food safety for imported products.⁵⁶ Furthermore, with the passage of more unfunded congressional mandates, Congress will be putting the U.S. food supply at risk due to the FDA's financial inability to meet its expanding responsibilities.⁵⁷ Along with the FDA's expanding financial woes, public fears and distrust with the FDA's inability to quickly identify the source of food contamination have intensified.⁵⁸ The FDA's

⁵⁰ See Brozak, *supra* note 31, at 31.

⁵¹ *Id.*

⁵² Michael Lelyveld, *China's Bureaucracy Stymies Food Safety*, RADIO FREE ASIA, Nov. 4, 2008, http://www.rfa.org/english/energy_watch/food-safety-11042008154540.html.

⁵³ *See Id.*

⁵⁴ Plunkett & DeWaal, *supra* note 24, at 660.

⁵⁵ *Id.* at 661.

⁵⁶ See Levey, *supra* note 7.

⁵⁷ Hutt, *supra* note 13, at 432.

⁵⁸ Levey, *supra* note 7.

inability to find the source of food contamination is linked to their lack of technology that would allow them to analyze historical data and assess the risks to the food supply.⁵⁹ Considering these basic infrastructure problems surrounding the FDA, it is an illusion to believe that reliance on the importer is going to improve the safety of imported food.

⁵⁹ *Id.*

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Patent Pools for Orphan Diseases

*Jeffrey D. Shelley**

Each year, millions of people living in low and middle-income countries die from treatable and preventable diseases.¹ However, many deaths are the result of inadequate and improper drugs being administered to people in these countries.² For example, the most commonly used drug to treat African sleeping sickness, Melarsoprol, is arsenic-based.³ Melarsoprol kills between three to ten percent of people treated with the drug.⁴ Nevertheless, drug companies have little incentive to develop drugs for these “orphan diseases,” such as African sleeping sickness, because the profitability of the market is very small.⁵ In fact, drug companies based in the United States only generate five to seven percent of their profits from low to middle-income countries.⁶

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¹ Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1032 (2005).

² *Id.*

³ *Id.* at 1037-38. See World Health Organization [WHO], African Trypanosomiasis (Sleeping Sickness), <http://www.who.int/mediacentre/factsheets/fs259/en/> (last visited Mar. 22, 2009) (“Melarsoprol: discovered in 1949, it is used in both forms of [Human African Trypanosomiasis]. It derives from arsenic and has many undesired side effects. The most dramatic being a reactive encephalopathy (encephalopathic syndrome) which can be fatal (3% to 10%).”).

⁴ WHO, *supra* note 3.

⁵ Kapczynski, *supra* 1, at 1038. See Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371, 375 (2007) (“[Orphan diseases] ... affect[] only one in 25,000 births [in the U.S.], so pharmaceutical companies [are] reluctant to invest in research because of the small revenues anticipated from any results.”).

⁶ *Id.*

Many people believe market-based incentives for patents inhibit research and development related to orphan diseases.⁷ However, a properly constructed patent pool could stimulate orphan disease research and development and improve global public health through access to these drugs.

I. WHAT IS A PATENT POOL?

Patent pools are not novel, having been widely used since the late 19th century.⁸ “Today, patent pools are frequently utilized in technology fields that require common standards, such as radio, DVD-video, DVD-ROM and MPEG_2 compression technology.”⁹ The United States Patent and Trademark Office describes a “patent pool” as:

[A]n agreement between two or more patent owners to license one or more of their patents to one another or third parties. Alternatively, a patent pool may also be defined as “the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool.”¹⁰

In addition, “a [patent] pool may involve simple cross-licensing among two or more competitors, in order to share a handful of patents necessary for the manufacture and sale of a particular product, or it may involve a large, industry-

⁷ *Id.*

⁸ Knowledge Ecology International, *IGWG Submission on Collective Management of Intellectual Property – The Use of Patent Pools to Expand Access to Needed Medical Technologies* (Sept. 30, 2007), http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_ManonRess-PatentPool.pdf, at 1.

⁹ *Id.* at 2.

¹⁰ Jeanne Clark et al., Patent Pools: A Solution to the Problem of Access in Biotechnology Patents? (Dec. 5, 2000), www.uspto.gov/web/offices/pac/dapp/ola/patentpool.pdf, at 4 (quoting Joel I. Klein, AN ADDRESS TO THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, ON THE SUBJECT OF CROSS-LICENSING AND ANTITRUST LAW (May 2, 1997), available at <http://www.usdoj.gov/atr/public/speeches/1118.htm>).

wide [patent] pool open to anyone, encompassing hundreds of manufacturers and thousands of patents.”¹¹

Although there are no formal requirements for patent pools, patent pools generally enable its members to license patents in the patent pool based on standard licensing fees or royalties determined by a pre-set formula or procedure.¹² Additionally, a portion of the licensing fees or royalties is usually allocated to patent owners, who are also members of the patent pool.¹³

II. PROPOSED FRAMEWORK FOR AN ORPHAN DISEASE PATENT POOL

A. *The Goal of the Orphan Disease Patent Pool*

The goal of the orphan disease patent pool would be to enhance global public health by enabling the development of cost effective drugs for orphan diseases. Admittedly, an industry-wide orphan disease patent pool would be elaborate.¹⁴ Moreover, it would require extensive cooperation among international drug companies and federal governments.¹⁵ Nevertheless, the pursuit of patent pools is recommended for the development of treatments for orphan diseases that take the lives of millions of people each year.¹⁶

B. *The Participants for the Orphan Disease Patent Pool*

The development of an orphan disease patent pool can begin with establishing participants. An orphan disease patent pool can require the

¹¹ Knowledge Ecology International, *supra* note 8, at 1.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* (“A pool may involve … large, industry-wide pool open to anyone, encompassing hundreds of manufacturers and thousands of patents, as well as other intellectual property.”).

¹⁵ *Id.* at 6 (“The Pool [to expand access to needed medical technologies] would simultaneously negotiate agreements with patent holders and national governments. The pool would execute Memoranda of Understanding (MOU) with governments, purchasing agencies and donors in order to generate support for the patent pool model as well as to facilitate cooperation between the numerous interested parties.”).

¹⁶ See Kapczynski, *supra* note 1, at 1032 (“Each year, millions of people in low- and middle-income (LMI) countries die from preventable and treatable diseases.”).

participation of federal governments and drug companies.¹⁷ Federal governments' contributions would include providing incentives to drug companies to participate.¹⁸ Initially, drug companies might be reluctant to participate because patents "provide a competitive advantage in a highly competitive and lucrative environment" such as the drug industry.¹⁹ Moreover, drug companies focus research and development resources on inventions that promise lucrative financial rewards.²⁰ Accordingly, drug companies typically do not develop drugs for orphan diseases that primarily affect low and middle-income countries because the market is not lucrative.²¹ Finding the ideal incentive package to ensure that drug company patent holders participate will be vital to the initial success of an orphan disease patent pool.

C. Incentives Needed to Ensure Participation of Drug Companies

An economic committee would need to determine the ideal incentive package to ensure drug company patent holders participate. Therefore, detailed incentive packages will not be discussed. However, there are two laws codified by the United States government that will be used to illustrate how patent-related incentives may be leveraged.

First, the Bayh-Dole Act allows universities, faculty inventors, and private industry that receive federal funding to obtain ownership of patent rights from

¹⁷ Knowledge Ecology International, *supra* note 8, at 6 (For example, Memoranda of Understanding (MOU) with governments, purchasing agencies and donors would have to be executed.).

¹⁸ Consumer Project on Technology, The Bayh-Dole Act, <http://www.cptech.org/ip/health/bd/> (last visited Mar. 22, 2009) (The Bayh-Dole Act provides one example of how a government may provide incentives. The Bayh-Dole Act "allows for the transfer of exclusive control over many government funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialization.").

¹⁹ Intellectual Asset Management, Building a Strong Patent Portfolio, <http://www.iam-magazine.com/issues/Article.ashx?g=fd9a3044-e7a4-4787-b108-8f85c2906b44> (last visited Mar. 22, 2009).

²⁰ Consumers International, Drugs, Doctors and Dinners: How Drug Companies Influence Health in the Developing World, (Oct. 2007), http://www.marketingoverdose.org/documents/ci_pharma_2007.pdf, at 10.

²¹ *Id.*

inventions stemming from federal dollars.²² It also allows these parties the ability to license the inventions to other parties for economic gain.²³ However, the federal government reserves “march-in” rights, whereby under limited circumstances the government may license the invention to third parties without the consent of the patent holder or the original licensee.²⁴

Second, the Orphan Drug Act of 1983 provides marketing exclusivity, tax incentives, and research grants for companies engaging in research on orphan diseases.²⁵ The Act provides, “[a seven]-year marketing exclusivity to sponsors of approved orphan products, a tax credit of [fifty] percent of the cost of conducting human clinical testing, and research grants for clinical testing of new therapies to treat orphan diseases.”²⁶ Exclusive marketing rights prevent other companies from marketing the same version of the drug.²⁷ Currently, the Orphan Drug Act is limited in scope to orphan diseases that affect the American population.²⁸

As will be discussed, the orphan disease patent pool may benefit from some of the features of these Acts already codified by the United States government.

D. An Example of an Orphan Disease Patent Pool

The following example outlines one possible framework of an orphan disease patent pool, which incorporates features of the Bayh-Dole Act and the Orphan Drug Act of 1983.

²² Kapczynski, *supra* note 1, at 1063; see Bayh-Dole Act, 35 U.S.C. §§ 200-12 (2006).

²³ *Id.*

²⁴ Consumer Project on Technology, *supra* note 18.

²⁵ Colleen Chien, *Cheap Drugs at what Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 866 (2003); see Orphan Drug Act of 1983, 21 U.S.C. § 360ee (2006).

²⁶ Department of Health and Human Services, Office of Inspector General, *The Orphan Drug Act Implementation and Impact*, May 2001, <http://www.oig.hhs.gov/oei/reports/oei-09-00-00380.pdf>, at 1.

²⁷ *Id.*

²⁸ *Id.*

The orphan disease patent pool initially may be populated with relevant patents owned by member drug companies.²⁹ Members would be granted nonexclusive license rights to these patents for the sole purpose of advancing the goal of developing and producing cost effective drugs for orphan diseases that affect low to middle-income countries.³⁰ Of course, the members would pay a reasonable licensing fee designated by the patent pool.³¹ In addition, as with the Orphan Drug Act of 1983, governments could provide marketing exclusivity, tax incentives, and research grants to incentivize drug companies to participate.³² However, similar to the Bayh-Dole Act, governments that provide these incentives to members could reserve march-in rights under pre-defined circumstances.³³

Additionally, similar to the government's role in the Bayh-Dole Act, a patent pool governing body, elected by member drug companies, could prioritize orphan drug research and development and direct funds to member drug companies to conduct the research and development on priority orphan drugs.³⁴ However, in contrast to the Bayh-Dole Act, members of the patent pool would not have the ability to obtain exclusive licenses.³⁵ Rather, the patents generated from patent pool funding would further populate the patent pool.

As the orphan disease patent pool progresses, members would begin producing drugs for orphan diseases. Members' profits directly related to licensing would be split in two proportions designated by the patent pool: the first part of the profits would compensate the patent owner for its ingenuity, and the second part of the profits would be returned to the patent pool for the benefit of all members to fund future efforts. Over time, the patent pool would increasingly become self-sufficient by funding itself through patent pool profits. In addition,

²⁹ Knowledge Ecology International, *supra* note 8, at 6.

³⁰ *Id.*

³¹ *Id.*

³² See Chien, *supra* note 25, at 866.

³³ Consumer Project on Technology, *supra* note 18.

³⁴ See Kapczynski, *supra* note 1, at 1063.

³⁵ See *Id.*

the patent pool could allow member drug companies to use their patents without licensing fees.

III. BENEFITS AND A CRITIQUE OF THE ORPHAN DISEASE PATENT POOL

The orphan disease patent pool offers a number of benefits that could enhance global public health by enabling the development of cost effective drugs for orphan diseases.³⁶ The following are the three primary benefits of the orphan disease patent pool, followed by a common critical response.

A. *The Orphan Disease Patent Pool Eliminates the Problems Caused by “Blocking” Patents*

Patent pools eliminate “blocking” patents.³⁷ Companies that hold patents on an industry’s core technology may prevent, or “block,” others from using that core technology to bring other products to market.³⁸ By including blocking patents in the orphan diseases patent pool, member drug companies may efficiently license all patents in the patent pool, including blocking patents, necessary to produce a particular orphan drug.³⁹

B. *The Orphan Disease Patent Pool Reduces Licensing Transaction Costs*

Patent pools may reduce licensing transaction costs.⁴⁰ For example, members of the orphan disease patent pool can reduce or eliminate the need for litigation over patent rights, because the members will be able to settle, or even avoid, litigation through the creation of the patent pool.⁴¹ In addition, members will be able to efficiently obtain the licenses for technology encompassed by the

³⁶ See Clark, *supra* note 10, at 8.

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

orphan diseases patent pool.⁴² In essence, the patent pool creates one-stop licensing, because a member will be able to obtain one license for all patents in the patent pool.⁴³ As a result, licensing becomes more efficient and streamlined.⁴⁴

C. The Orphan Disease Patent Pool Distributes Risks

Patent pools distribute the financial risk and cost associated with research and development of new drugs.⁴⁵ Depending on how the patent pool is setup, all members could receive a set income based upon a percentage of the patent pool's royalties.⁴⁶ In addition, a portion of the profits associated with a drug could be returned to the patent pool to fund future research. Therefore, the success of one member of the patent pool could result in research funding for all members.

D. Critique of the Orphan Disease Patent Pool

Critics primarily argue that patent pools may be susceptible to anticompetitive effects.⁴⁷ In particular, critics argue that there are “dangers that the [patent] pool group might possess market power in the industry, artificially inflating prices, or that other patents might shield invalid patents, since they are sold as a package.”⁴⁸ In response, the Justice Department set guidelines to help patent pools avoid anticompetitive effects.⁴⁹ The Justice Department’s guidelines specify: “(1) the patents in the pool must be valid and not expired, (2) no aggregation of competitive technologies and setting a single price for them, (3) an independent expert should be used to determine whether a patent is essential to complement technologies in the pool, (4) the pool agreement must not disadvantage competitors in downstream product markets, and (5) the pool

⁴² Clark, *supra* note 10, at 9.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ May Mowzoon, *Access Versus Incentive: Balancing Policies in Genetic Patents*, 35 ARIZ. ST. L.J. 1077, 1101 (2003).

⁴⁸ *Id.* at 1102.

⁴⁹ *Id.*

participants must not collude on prices outside the scope of the pool.”⁵⁰ Accordingly, the orphan disease patent pool should follow the Justice Department’s guidelines to avoid anticompetitive effects.

IV. CONCLUSION

Patent pools could stimulate research and development on orphan disease drugs and enhance global access to resulting drugs. In order to ensure participation, federal governments would have to help administer the orphan disease patent pool and provide adequate incentives to encourage private drug companies to participate. The incentives, in addition to details of the patent pool, would have to be thoroughly studied before an effective orphan disease patent pool could be established. In addition, the orphan disease patent pool would have to ensure no anticompetitive effects, on a country-by-country basis. Nevertheless, the social and economic benefits stemming from orphan disease research and development, and global access to related drugs, outweigh for-profit interests and is well worth the endeavor.

⁵⁰ Clark, *supra* note 10, at 7.

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Access to Mental Health Services for Juvenile Detainees

*Colleen Burns**

Approximately twelve percent of American children, age nine through seventeen, have a diagnosable psychiatric disorder; yet up to two-thirds of these children have never been treated for their illnesses.¹ Rates of mental disorders among youth in detention facilities are estimated to be as high as sixty or seventy percent, or two to three times higher than in the general population.² With mental illness being so prevalent in juvenile detainees, adequate mental health services are necessary to ensure detainees are receiving proper treatment and to ultimately decrease recidivism rates.

I. MENTAL ILLNESSES AMONGST DETAINEES

The Surgeon General defines “mental illness” collectively, as all diagnosable mental disorders.³ In the case of juvenile detainees, mental illness can refer to serious cognitive impairments like schizophrenia or depression, or it can refer to anxiety disorders such as attention-deficit and disruptive behavior

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¹ Elizabeth S. Boison, *Mental Health Parity for Children and Adolescents: How Private Insurance Discrimination and ERISA Have Kept American Youth from Getting the Treatment They Need*, 13 AM. U. J. GENDER SOC. POL’Y & L. 187, 191 (2005).

² Barbara Kahn et al., *Making the Connection: Legal Advocacy and Mental Health Services*, 45 FAM. CT. REV. 486, 487 (2007).

³ U.S. DEP’T OF HEALTH & HUMAN SERVS., MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 5 (1999), available at <http://www.surgeongeneral.gov/library/mentalhealth/pdfs/c1.pdf>.

disorders, autism, or eating disorders.⁴ Diagnosis is usually based on the judgment and experience of the clinician who, in making his or her diagnosis, may also rely on the patient's self-description of the nature of the symptoms, the clinician's own observations of the patient's behavior, and a mental status examination.⁵

A 2003 Senate Committee Report on Governmental Affairs reported that approximately 15,000 children with mental illnesses were improperly incarcerated in detention centers because of a lack of necessary mental health treatment.⁶ The Democratic staff of the House Committee on Government Reform conducted a study in 2004 that included a survey of juvenile detention centers and how mentally ill detainees are treated.⁷ The study found that due to a lack of mental health services, children as young as seven were unnecessarily incarcerated.⁸ More than 340 detention centers, two-thirds of those that responded to the survey, indicated that juveniles with mental disorders remained incarcerated while awaiting treatment because there was nowhere else for them to go.⁹ Of the centers that responded, seventy-one said they were holding mentally ill juveniles even though no charges had been filed against them.¹⁰

Few juvenile detainees are screened for mental illnesses and, in many cases, juveniles are released from detention facilities only to find themselves back in prison due to the lack of proper mental health treatment.¹¹ Mental illnesses frequently go undiagnosed in youths because the symptoms they exhibit tend to have an aggressive factor and this often leads the juvenile to be perceived as

⁴ Kasey Corbit, *Inadequate and Inappropriate Mental Health Treatment and Minority Overrepresentation in the Juvenile Justice System*, 3 HASTINGS RACE & POVERTY L.J. 75, 79 (2005), U.S. DEP'T OF HEALTH & HUMAN SERVS., MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 5 (1999), available at <http://www.surgeongeneral.gov/library/mentalhealth/pdfs/c1.pdf>.

⁵ *Id.*

⁶ Robert Pear, *Many Youths Reported Held Awaiting Mental Help*, N.Y. TIMES, July 8, 2004, at A18.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ David L. Harvey III, *Theories of Therapeutic Evolution for Juvenile Drug Courts in the Face of the Onset of the Co-Occurrence of Mental Health Issues and Substance/Alcohol Abuse*, 19 J.L. HEALTH 177, 191 (2004-2005).

threatening instead of potentially afflicted by an undiagnosed and untreated mental illness.¹² Furthermore, Post-Traumatic Stress Disorder (PTSD) is a common mental disorder among juvenile detainees.¹³ Juveniles with PTSD often have trouble with impulse control and aggression, something that can be volatile in the prison environment.¹⁴ Detection and treatment is especially important in juveniles because symptoms of their mental illness can increase with age.¹⁵

Additionally, the prevalence undiagnosed or untreated mental illness in juvenile offenders raises serious concerns about competency to stand trial.¹⁶ Often, juvenile offenders are simply presumed by the juvenile justice to be competent to stand trial.¹⁷ A recent study by the MacArthur Foundation stated, “[t]his study confronts policymakers and courts with an uncomfortable reality. Under well-accepted constitutional restrictions on the state’s authority to adjudicate those charged with crimes, many young offenders – particularly among those under 14 – may not be appropriate participants for criminal adjudication.”¹⁸ Developmental immaturity, something very common among juvenile detainees, is often not seen as a traditional mental illness, yet, it can seriously impact a juvenile’s competency to stand trial.

The MacArthur Study involved over 1,400 juveniles from four different communities, and data was collected from 1997 to 2002.¹⁹ The study found that it was likely that “about one-third of 11- to 13-year-olds and one-fifth of 14- to 15-year-olds probably are not competent to stand trial.”²⁰ Juvenile courts must look at competency issues when they screen youth for potential mental illness or

¹² Corbit, *supra* note 4, at 83.

¹³ Thomas L. Hafemeister, *Parameters and Implementation of a Right to Mental Health Treatment for Juvenile Offenders*, 12 VA. J. SOC. POL’Y & L. 61, 69 (2004).

¹⁴ *Id.*

¹⁵ Harvey, *supra* note 11, at 191.

¹⁶ David R. Katner, *The Mental Health Paradigm and the MacArthur Study: Emerging Issues Challenging the Competence of Juveniles in Delinquency Systems*, 32 AM. J.L. & MED. 503, 503 (2006).

¹⁷ *Id.*

¹⁸ Thomas Grisso et al., *Juveniles’ Competence to Stand Trial: A Comparison of Adolescents’ and Adults’ Capacities as Trial Defendants*, 27 LAW & HUM. BEHAV. 333, 358 (2003).

¹⁹ *Id.*

²⁰ Laurence Steinberg, *Juveniles on Trial: MacArthur Foundation Study Calls Competency into Question*, CRIM. JUST. 20, 23 (2003).

disorders. Since most juvenile facilities do not provide direct mental health services,²¹ if there is an indication of a mental illness, steps should be taken to decide what treatment is warranted and where to make referrals within the community.

II. POTENTIAL SOLUTIONS

The Surgeon General has warned that, “the system for delivering mental health services to children and their families is complex, sometimes to the point of inscrutability - a patchwork of providers, interventions, and payers.”²² Mental health services do exist, but there are coordination problem. Who is going to make a patchwork system of community-based care accessible to the Court, but also to the juvenile? And where should the system intervene?

The first step is to screen all incoming juveniles for mental illness, before they appear in court. The Cook County Juvenile Court Clinic aims to provide the link between the courts, the community, and mental health access.²³ Cook County began placing trained staff, known as clinical coordinators, in each courtroom whose job was to provide judges, attorneys, and probation officers with information and consultation regarding potentially necessary clinical information.²⁴ The goal was to provide detailed, relevant, and culturally sensitive information to the Court of Cook County for use in its proceedings.²⁵ Research indicated that Juvenile Court personnel lacked the knowledge and training necessary to identify the mental health needs of juveniles.²⁶ There was a disconnect between the court itself and clinicians (such as psychiatrists and social

²¹ See MINORITY STAFF, SPECIAL INVESTIGATIONS DIVISION OF HOUSE COMM. ON GOVERNMENT REFORM, INCARCERATION OF YOUTH WHO ARE WAITING FOR COMMUNITY MENTAL HEALTH SERVICES IN THE UNITED STATES i-ii, 9-10 (July 2004).

²² U.S. DEP’T OF HEALTH & HUMAN SERVS., MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 179 (1999), available at <http://www.surgeongeneral.gov/library/mentalhealth/pdfs/c3.pdf>.

²³ Kahn, *supra* note 2, at 489-90

²⁴ *Id.*

²⁵ *Id.* at 490-91.

²⁶ *Id.* at 489.

workers).²⁷ The clinical coordinators help the court determine what services are necessary to address the juvenile's mental health needs.²⁸ They also developed a comprehensive list of community mental health and social service agencies that is frequently updated.²⁹ The coordinators are intimately acquainted with community providers and can therefore determine the best placement for screened youth.³⁰ The Cook County Juvenile Court Clinic has been nationally recognized as both innovative and effective in its programs.³¹

Another important goal for any placement of a juvenile in secured detention should be preparation for the juvenile's rehabilitation and subsequent return to the community.³² The ultimate goal of the juvenile justice system is rehabilitation. Thus, the focus should be on giving the juvenile tools to live responsibly within his or her community. Any model that is implemented should include a written plan for services needed after release as well as the juvenile's own goals for education, housing, and employment.

A. Mental Health Courts

Mental health courts are another potential remedy for the lack of adequate mental health treatment for juvenile offenders. Mental health courts have largely been modeled after drug treatment courts started in 1989.³³ Mental health courts were developed to address the mental health needs of adults who entered the criminal justice system.³⁴ These courts maintain a separate docket and have trained judges and lawyers who are capable of dealing with adults who are suffering from mental illnesses.³⁵ Mental Health America states that, "mental

²⁷ *Id.*

²⁸ *Id.* at 490.

²⁹ Kahn, *supra* note 2, at 491.

³⁰ *Id.*

³¹ *Id.* at 489.

³² Hafemeister, *supra* note 13, at 116.

³³ Patrick Geary, *Juvenile Mental Health Courts and Therapeutic Jurisprudence: Facing the Challenges Posed by Youth With Mental Disabilities in the Juvenile Justice System*, YALE J. HEALTH POL'Y, L. & ETHICS 671, 682 (2005).

³⁴ *Id.* at 683.

³⁵ *Id.* at 684.

health courts play a role in convening criminal justice, mental health, substance abuse and other relevant social service agencies to facilitate diversion from the criminal justice system.”³⁶ Mental Health America further advocates that the courts should neither coerce nor compel treatment, and that should focus on recovery, and include “mental and physical healthcare, case management, housing, supportive education, substance abuse treatment, and psychosocial services in the least restrictive environment possible.”³⁷

Implementing a separate mental health court system like the one used for adults would pose particular challenges in the context of juvenile offenders. Those challenges are highlighted by those faced by drug courts set up to handle juvenile cases. The juvenile drug courts face several problems including immature offenders and family environments that can contribute to substance abuse.³⁸ If juvenile mental health courts are created, they must tailor the programs to individual needs and remain flexible in addressing the unique mental health issues that juveniles face.³⁹ In addition, if juvenile mental health courts are in fact started on a much larger scale, the fundamental emphasis on treatment and rehabilitation must remain.

Mental health courts, however, have not proven to be the best solution for the mental health needs of juveniles within the criminal justice system.⁴⁰ These courts would have to be implemented on an enormous scale to have a significant impact on the large population of juvenile offenders with mental health issues.⁴¹ The juvenile justice system has already implemented many of the policies that mental health courts emphasize.⁴² Still, there is a lot that can be learned from mental health courts, including encouraging “juvenile courts to function as child-

³⁶ Mental Health America, Position Statement 53: Mental Health Courts, <http://www.mentalhealthamerica.net/go/position-statements/53> (last visited Mar. 31, 2007).

³⁷ *Id.*

³⁸ Geary, *supra*, note 33, at 687.

³⁹ *Id.*

⁴⁰ *Id.* at 691.

⁴¹ *Id.*

⁴² *Id.* at 692.

centered, family-focused, community-based, and culturally competent institutions.”⁴³

B. Therapeutic Jurisprudence

Starting in the late 1980’s and early 1990’s, the juvenile justice system began to shift to a “therapeutic justice system.”⁴⁴ This model seeks to get judges, attorneys, and probation officers to work as a team to emphasize treatment of the juvenile rather than “distributing punishment to the juvenile offenders that enter its system.”⁴⁵ Therapeutic jurisprudence is defined as “the use of social science to study the extent to which a legal rule or practice promotes the psychological or physical wellbeing of the people it affects.”⁴⁶ The legal system, its rules, procedures, and actors are seen as “social forces that, whether intended or not, often produce therapeutic or antitherapeutic consequences.”⁴⁷ One essential element of therapeutic jurisprudence is that it contemplates using knowledge gained from the mental health field to create better legislation.⁴⁸ Lawyers and other legal professionals are called to examine their roles in the system and how they can adjust those roles to serve clients in a manner that is therapeutically beneficial.⁴⁹ Therapeutic jurisprudence recognizes that legal professionals play an important role in addressing the mental health needs of their clients.⁵⁰

Why is this especially important for juveniles with mental health? Juveniles with mental illnesses need a distinct model of care from regular

⁴³ *Id.* at 693.

⁴⁴ David L. Harvey III, *Theories of Therapeutic Evolution for Juvenile Drug Courts in the Face of the Onset of the Co-Occurrence of Mental Health Issues and Substance/Alcohol Abuse*, 19 J.L. & HEALTH 177, 178 (2004-2005).

⁴⁵ *Id.*

⁴⁶ David B. Wexler, *Reflections on the Scope of Therapeutic Jurisprudence*, 1 PSYCHOL. PUB. POL'Y & L. 220, 223-24 (1995) (quoting Christopher Slobogin, *Therapeutic Jurisprudence: Five Dilemmas to Ponder*, 1 PSYCHOL. PUB. POL'Y & L. 193, 196 (1995)).

⁴⁷ Bruce J. Winick, *The Jurisprudence of Therapeutic Jurisprudence*, 3 PSYCHOL. PUB. POL'Y & L. 184, 185 (1997).

⁴⁸ Gene Griffin & Michael J. Jenuwine, *Using Therapeutic Jurisprudence to Bridge the Juvenile Justice and Mental Health Systems*, 71 U. CIN. L. REV. 65, 66 (2002).

⁴⁹ *Id.*

⁵⁰ *Id.*

detainees.⁵¹ Many juvenile institutions use the positive peer culture method, a system of rewards and punishments for rehabilitation.⁵² It puts the juvenile in charge of his own progress, using group feedback, group confrontation, and group physical discipline.⁵³ One can imagine how hard some of these methods might be on a juvenile with a mental illness. These traditional methods (which can work well with adult detainees) can seriously endanger juveniles with mental illness, not only exacerbating their symptoms, but putting them at an increased risk for repeat offenses.⁵⁴ In addition, “[c]hildren who are in the juvenile justice system because of their mental health issues tend to stay up to twice as long as the general population of juvenile detainees, often because there is nowhere to place them upon discharge.”⁵⁵

III. CONCLUSION

It would be unrealistic to suggest that the law can help address all the mental health needs of juvenile detainees. However, a partnership must be formed between the law, the juvenile, the juvenile’s family, mental health professionals, and social service providers. Essentially, assessing a juvenile’s potential mental health needs, determining the best course of treatment (preferably community-based treatment), and continuously monitoring their mental health needs are the best ways to ensure that juvenile delinquents receive necessary mental health treatment. A failure to attend to the mental health needs of juvenile detainees can have long-term negative consequences. Delivering necessary mental health services to these delinquents will help decrease

⁵¹ *Id.* at 67.

⁵² Leslie Calhoun, *Rethinking Juvenile Rehabilitation Techniques: How Failure to Modify Positive Peer Culture for Mentally Ill Youths Violates Title II of the ADA*, 50 WAYNE L. REV. 201, 202, 207 (2004).

⁵³ *Id.* at 207.

⁵⁴ *Id.* at 209.

⁵⁵ Corbit, *supra* note 4, at 82.

recidivism⁵⁶, and ensure that these youths can return to their communities with as much guidance as possible.

⁵⁶ Kahn, *supra* note 2, at 487.

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Altria Group, Inc. v. Good: A Battle over the Preemption Argument

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Over forty-five million Americans smoke cigarettes.¹ In the 1950's, cigarette manufacturers introduced filtered cigarettes and began what they called the "Tar Derby" in response to smoking-related health concerns.² Cigarette manufacturers sought to encourage health conscious smokers to use these so-called "healthier" and "less dangerous" cigarettes.³ As a result, many smokers switched to "light" cigarettes.⁴ Today, nearly eighty-five percent of all American smokers buy "light" cigarettes that are advertised as having lower tar and nicotine content than regular cigarettes because they believe that these cigarettes are less dangerous.⁵ However, medical studies have demonstrated that this belief is incorrect.⁶ While tests conducted using machines show that light cigarettes emit less tar when burned, actual smokers

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¹ David G. Savage, *Suits Over 'Light' Cigarettes Get Supreme Court Airing; Tobacco Firms Tell the Justices They're Shielded by the Federal Warning Label Law*, L.A. TIMES, Oct. 7, 2008, at A12.

² L. T. Kozlowski & R. J. O'Connor, *Cigarette Filter Ventilation is a Defective Design Because of Misleading Taste, Bigger Puffs, and Blocked Vents*, 11 TOBACCO CONTROL i40, i40 (2002), available at http://tobaccocontrol.bmjjournals.org/cgi/reprint/11/suppl_1/i40.

³ *Id.*

⁴ *Good v. Altria Group, Inc.*, 501 F.3d 29, 31 (1st Cir. 2007).

⁵ Savage, *supra* note 1, at A12.

⁶ Lynn T. Kozlowski et al., *Smokers' Misperceptions of Light and Ultra-Light Cigarettes May Keep Them Smoking*, 15 AM. J. PREV. MED. 9, 9 (1998).

inhale about the same amount of tar because they tend to take larger and more frequent puffs when smoking light cigarettes.⁷

Smokers and ex-smokers who believe they were mislead by light and low-tar cigarette advertisements are currently involved in more than thirty class action lawsuits against tobacco manufacturers.⁸ In December 2008, consumers celebrated a major win when the United States Supreme Court issued its 5-4 opinion in *Altria Group, Inc. v. Good*.⁹ In that case, the Supreme Court ruled that the Federal Cigarette Labeling and Advertising Act (Labeling Act) did not preempt a false advertising claim brought under the state consumer protection law.¹⁰

Under the Labeling Act “[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.”¹¹ Since Congress decided that no additional warning statement is needed to attain the goal of informing the public of the health consequences of smoking,¹² states may not intrude on federal regulation by imposing stronger restrictions.¹³

In *Altria Group*, a group of Maine residents sued Richmond, Virginia-based Altria Group, Inc., the parent company of Philip Morris USA, alleging that Altria Group violated the Maine Unfair Trade Practices Act (MUTPA) by fraudulently advertising that their “light” cigarettes delivered less tar and nicotine than regular brands.¹⁴ The District Court granted summary judgment for Altria Group, finding that the state law claim was pre-empted by the

⁷ *Id.*; Stephen S. Hecht et al., *Similar Uptake of Lung Carcinogens by Smokers of Regular, Light, and Ultralight Cigarettes*, CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 693, 693 (2005).

⁸ Savage, *supra* note 1, at A12.

⁹ *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 541 (U.S. 2008).

¹⁰ *Id.*

¹¹ 15 U.S.C. § 1334(b) (2009).

¹² 15 U.S.C. § 1334(a).

¹³ *Altria Group*, 129 S. Ct. at 544.

¹⁴ *Id.* at 541, 542.

Labeling Act.¹⁵ The Court of Appeals for the First Circuit reversed that decision, holding that the Labeling Act neither expressly nor impliedly pre-empted respondents' fraud claim.¹⁶ Thereafter, Altria Group appealed to the U.S. Supreme Court, which granted certiorari in order to resolve this conflict.¹⁷

Justice Stevens delivered the opinion of the Court with which Justices Kennedy, Souter, Ginsburg, and Breyer joined.¹⁸ The Supreme Court reasoned that the phrase "based on smoking and health" in the Labeling Act did not preempt the state fraud rule because the state law merely codified a common law duty not to deceive.¹⁹ Justice Stevens relied on the Court's 1992 ruling in *Cipollone v. Liggett Group Inc.*,²⁰ where the petitioner alleged that the cigarette manufacturers were liable for his mother's death because they fraudulently misrepresented the hazards of smoking.²¹ In its plurality opinion, the *Cipollone* Court held that the plaintiff's claim that cigarette manufacturers had fraudulently misrepresented and concealed a material fact was not pre-empted.²² Similarly, the *Altria Group* Court found that claim of Maine smokers was not preempted.²³ The Supreme Court held that the duty codified in MUTPA, like the manufacturers' duty not to deceive imposed by the state common law rule in *Cipollone*, had nothing to do with "smoking and health."²⁴ Furthermore, Justice Stevens rejected Altria's argument that the respondents' claim was impliedly pre-empted.²⁵

Justice Thomas wrote a dissenting opinion with which Chief Justice Roberts, Justice Scalia, and Justice Alito joined.²⁶ Justice Thomas criticized the majority opinion for adopting the methodology of the *Cipollone* plurality as

¹⁵ *Id.* at 542.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.* at 540.

¹⁹ *Altria Group*, 129 S. Ct. at 545.

²⁰ *Id.*

²¹ *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 508-09 (1992) (plurality opinion).

²² *Id.* at 521.

²³ *Altria Group*, 129 S. Ct. at 545.

²⁴ *Id.*

²⁵ *Id.* at 551.

²⁶ *Id.* (Thomas, J., dissenting).

governing law.²⁷ He concluded that the majority erroneously held that state law liability for deceiving consumers about the health effects of smoking light cigarettes was not a “requirement or prohibition based on smoking and health” under the Labeling Act.²⁸ Justice Thomas emphasized that the majority’s ruling defeated an “express congressional purpose, opening the door to an untold number of deceptive-practices lawsuits across the country.”²⁹

The *Altria Group* decision has not become an automatic win for plaintiffs, as they still would need to prevail on the underlying merits of the case in state court.³⁰ However, after *Altria Group*, companies whose products or advertisements are allegedly fraudulent can no longer depend solely on the preemption argument. The *Altria Group* decision presents a great challenge for the lawyers who represent business groups and companies in product liability lawsuits because it takes away the preemption argument-- a formerly powerful weapon for the dismissal of these types of claims.³¹ Whether this decision will cause a flood of litigation is uncertain at this point.³² However, it is apparent that the court’s decision may encourage plaintiffs to file consumer fraud complaints in cases that might otherwise be product liability actions.

²⁷ *Id.* at 552.

²⁸ *Id.*

²⁹ *Id.* at 561.

³⁰ *Altria Group*, 129 S. Ct. at 551 (majority opinion) (“Respondents still must prove that petitioners’ use of ‘light’ and ‘lowered tar’ descriptors in fact violated the state deceptive practices statute, but neither the Labeling Act’s pre-emption provision nor the FTC’s actions in this field prevent a jury from considering that claim.”).

³¹ See Jess Bravin, *Altria Case Deals Blow to Efforts Reining in Lawsuits*, WALL ST. J., Dec. 16, 2008, at A1 (“Robin Conrad, executive vice president of the chamber’s litigation arm, said the decision ‘doesn’t provide the kind of predictability that the business community has been looking for.’”); see also Adam Liptak, *Top Court Lets Smokers Sue for Fraud*, N.Y. TIMES, Dec. 16, 2008, at B1 (“Alan E. Untereiner, the author of a book on the pre-emption defense and a lawyer who often represents business groups and companies arguing for pre-emption, said Monday’s decision was ‘a step backward in the recent trend of making pre-emption law more coherent.’”).

³² Mark A. Hofmann, *State Fraud Law Survives Pre-emption Challenge; Supreme Court Ruling in ‘Light’ Cigarette Case May Have Wider Effect*, BUS. INS., Dec. 22, 2008, at 3.

The *Altria Group* decision is a threat, not only to the tobacco industry, but also to other federally regulated industries.³³ Cases where advertising and testing are permitted by federal authorities, but are deemed misleading under state law, are especially susceptible to this threat.³⁴ Indeed, the *Altria Group* decision “may open the door for similar claims against other companies, such as pharmaceutical companies, which had previously assumed their compliance with federal regulations established by the Food and Drug Administration would preempt state personal injury laws.”³⁵

The absence of uniformity in regulation of cigarette advertising is potentially one of the most undesirable consequences of the *Altria Group* decision. Since *Altria Group*, states can impose additional restrictions on cigarette advertising, conflicting situations may arise where “light” cigarettes sold in some states might be considered “full-flavor” cigarettes in other states.³⁶ As a result, smokers from one state may become confused by product naming conventions in other states, leading to unintended purchases of cigarettes with higher or lower tar and nicotine content than the smoker desires.³⁷

Finally, the *Altria Group* decision could create incentives for tobacco companies to change their advertising to avoid fraud claims under various state laws.³⁸ Consequently, the companies will warn consumers that their “light” cigarettes might be just as unhealthy and dangerous as the “full-flavor”

³³ See Brief for Chamber of Commerce of the United States of America as Amicus Curiae Supporting Petitioners at 7–8, *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008) (No. 07-562), 2008 U.S. LEXIS 9127 [hereinafter Brief Supporting Petitioners].

³⁴ *Id.*

³⁵ Isabel Cowles, *Supreme Court Rules That “Light” Cigarette Lawsuit Is Not Preempted by Federal Law*, FINDINGDULCINEA.COM, Dec. 16, 2008, <http://www.findingdulcinea.com/news/Americas/2008/December/Supreme-Court-Rules-Against-Big-Tobacco-in--Light--Cigarette-Lawsuit.html>.

³⁶ See Brief Supporting Petitioners, *supra* note 33, at 20.

³⁷ *Id.* (“The important interests of avoiding consumer confusion and ensuring national uniformity are ill-served by giving the exact same products different names based on the happenstance of location. That is no less true for cigarettes than for any other product that regularly travels in interstate commerce.”).

³⁸ See Liptak, *supra* note 31, at B1 (“It would be appropriate for the tobacco companies to take a very hard look at how they market their products, because they have for decades been making deceptive claims about their products.”).

cigarettes.³⁹ Although the change in advertising will hardly cause a decrease in the number of smokers, at the very least, these consumers would be made fully aware of the gravity of their choice. While it is hard to predict the full effect of the *Altria Group* decision, there is a great possibility that it will influence cigarette advertising and litigation strategies for both consumers and tobacco companies.

³⁹ *Id.*

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Chronicling Past and Prospective Efforts in Illinois to Establish Legal Protections for Medical Marijuana Users

*Kevin Lichtenberg**

Justice Louis Brandeis' state-government "laborator[ies]"¹ are hard at work. During the 2007 and 2008 legislative sessions, fifty-two medical marijuana related bills were proposed on twenty-seven different state legislature floors.² Michigan, through a November 2008 ballot initiative, became the thirteenth state in the United States³ to legalize marijuana for medicinal purposes.⁴ On the federal level, Representative Barney Frank sent shockwaves throughout Capitol Hill on April 17, 2008 when he introduced H.R. 5842: the Medical Marijuana Patient Protection Act.⁵

The movement toward establishing legal safeguards for severely ill individuals to use medical marijuana is gaining momentum in state legislatures

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¹ *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932). In his famous dissent, Justice Louis Brandeis penned the idea that state experimentation in public policy not only avoids exposing the entire nation to risk, but may lead to the most innovative of public policy.

² MARIJUANA POLICY PROJECT, STATE-BY-STATE MEDICAL MARIJUANA LAWS: HOW TO REMOVE THE THREAT OF ARREST L-1 - L-9 (2008), available at http://www.mpp.org/assets/pdfs/download-materials/SBSR_NOV2008.pdf.

³ Amy Lane & Jay Greene, *All Sides Await Administrative Rules for Medical Marijuana Law*, CRAIN'S BUS. DETROIT, Nov. 9, 2008, available at <http://www.crainsdetroit.com/apps/pbcs.dll/article?AID=/20081109/SUB01/811070285>.

⁴ Michigan Medical Marihuana Act, MICH. COMP. LAWS SERV. § 333.26424 (2008). The measure passed 62.6% to 37.4%. Election Results 2008 – Michigan, N.Y. TIMES, Dec. 9, 2008, available at <http://elections.nytimes.com/2008/results/states/michigan.html>.

⁵ Medical Marijuana Patient Protection Act, H.R. 5842, 110th Cong. (2008); see generally *K Street in Brief*, THE HILL, June 18, 2008, at 14 (noting the existence of a battlefield between medical marijuana advocates and opponents).

across the United States. This article will discuss three facets of how this movement may affect Illinois. First, this article will review current Illinois law and state court decisions related to medical marijuana. Second, this article will chronicle recent medical marijuana legislative efforts in Illinois. Third, this article will proffer a prediction as to whether Illinoisans should expect a medical marijuana bill to be passed.

I. MEDICAL MARIJUANA & ILLINOIS LAW

The only current Illinois law related to medical marijuana is the therapeutic research program (TRP).⁶ The TRP is carved out of Illinois' Cannabis Control Act.⁷ The TRP provision permits the Illinois Department of Human Services (DHS) to authorize the possession, production, manufacture, and delivery of products containing marijuana⁸ by persons engaged in research if the persons meet two conditions.⁹ First, the research must be necessary for the treatment of glaucoma, the treatment of side effects from chemotherapy or radiation therapy in cancer patients, or the treatment for other procedures certified to be medically necessary.¹⁰ Second, a licensed physician must request the authorization from DHS.¹¹ Only then would the person seeking to use the marijuana, under color of the TRP, be exempt from criminal prosecution in Illinois.¹²

Illinois' TRP is largely ineffective. The law requires that the person using the marijuana register with the Federal government.¹³ However, Illinois is not one of the seven states that has obtained all of the necessary federal permissions

⁶ Cannabis Control Act, 720 ILL. COMP. STAT. 550/11 (2009); *see also* ILL. ADMIN. CODE tit. 77, § 2085-2085.65 (2009) (implementing section 11 of the Cannabis Control Act).

⁷ Cannabis Control Act, *supra* note 6, at 720 ILCS 550/11.

⁸ Under Illinois statutes, the term "cannabis" is exclusively used. *Id.* For purposes of clarity, this article will use the term "marijuana," which has been widely adopted in health law academic circles.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ Cannabis Control Act, *supra* note 6, at 720 ILCS 550/11.

to receive marijuana distributions.¹⁴ As a result, Illinois' DHS has not received any marijuana from the federal government (the exclusive supplier).¹⁵ Therefore, not a single person in Illinois has received marijuana for research purposes under Illinois' TRP.¹⁶

Despite being ineffective, Illinois' TRP statute generated a highly publicized¹⁷ case in the Appellate Court of Illinois in 2004.¹⁸ *People v. Kratovil* stemmed from the arrest (and subsequent conviction) of a woman who grew more than two dozen marijuana plants in her backyard to treat her glaucoma.¹⁹ The Appellate Court addressed whether Defendant Kratovil fell within the "narrow exception for cannabis possession by a medical research patient as provided for"²⁰ under Illinois' TRP law. The court found that Kratovil did not fit within the exception because her physician did not certify her use of marijuana to treat glaucoma and because her physician had not obtained authorization from DHS.²¹ Lastly, the Appellate Court held that an affirmative defense for medical use of marijuana did not exist in the state of Illinois, absent the legislature enacting such a defense.²²

II. RECENT LEGISLATIVE EFFORTS

Unlike Michigan, Illinois law does not provide a statutory initiative process, so public questions such as legalization of medical marijuana cannot be

¹⁴ MARIJUANA POLICY PROJECT, *supra* note 2, at J-1. Illinois joins eighteen other states that also enacted TRP laws and similarly did not obtain necessary federal permissions. *Id.*

¹⁵ See *id.*; see also Marc Kaufman, *Federal Marijuana Monopoly Challenged*, WASH. POST, Dec. 12, 2005, at A02, available at http://www.washingtonpost.com/wp-dyn/content/article/2005/12/11/AR2005121100825_pf.html (explaining that the federal government is the nation's only legal producer of marijuana).

¹⁶ See MARIJUANA POLICY PROJECT, *supra* note 2, at J-1.

¹⁷ See Susan Kuczka, *Woman Convicted of Growing Marijuana*, CHI. TRIB., June 24, 2003, at N1; see also Eric Zorn, *Drug Laws Look Extreme Through Woman's Eyes*, CHI. TRIB., June 19, 2003, at C1.

¹⁸ *People v. Kratovil*, 815 N.E.2d 78, 90 (Ill. App. 2d 2004).

¹⁹ Kuczka, *supra* note 17, at N1.

²⁰ *Kratovil*, 815 N.E.2d at 91.

²¹ *Id.*

²² *Id.* at 92.

placed on the ballot.²³ Therefore, any medical marijuana provision must emanate from the Illinois General Assembly. Throughout the history of the Illinois General Assembly, three non-binding medical marijuana resolutions have passed²⁴ while eight medical marijuana bills have failed.²⁵

Early in 2004, the “Medical Cannabis Act” (House Bill 4868) became the first medical marijuana bill ever proposed in the General Assembly.²⁶ That bill would have allowed any person “who has been diagnosed by a physician as having a debilitating medical condition”²⁷ and who has received a valid registry card from the state, to possess and use up to one ounce of cannabis and six marijuana plants.²⁸ That bill was sent to a subcommittee but never reached a vote.²⁹

Three years later, in February 2007, State Senator John Cullerton introduced a medical marijuana bill to amend Illinois’ Cannabis Control Act (Senate Bill 650).³⁰ The bill provided that when a person has been diagnosed by a physician as having a debilitating medical condition, the Department of Public Health may issue registry identification cards to the person or his or her caregiver to permit those persons to legally possess no more than twelve marijuana plants and 2.5 ounces of usable marijuana that must be grown in an indoor and locked facility.³¹ The bill was narrowly defeated by a 22-29 vote.³² Less than half of all

²³ Initiative & Referendum Institute at the University of S. Cal., State-by-State List of Initiative & Referendum Provisions, http://www.iandrinstitute.org/statewide_i&r.htm (last visited Apr. 1, 2009).

²⁴ H.R.J. Res. 57, 94th Leg. (Ill. 2005); H.R. Res. 398, 94th Leg. (Ill. 2005); S. Res. 256, 94th Leg. (Ill. 2005). The General Assembly sent all three resolutions to the Director of Public Health in 2005. Ill. H.R.J. Res. 57; Ill. H.R. Res. 398; Ill. S. Res. 256.

²⁵ H.R. 4868, 93d Leg. (Ill. 2004); S. 2440, 93d Leg. (Ill. 2004); H.R. 407, 94th Leg. (Ill. 2005); S. 2568, 94th Leg. (Ill. 2006); S. 650, 95th Leg. (Ill. 2007); H.R. 5499, 95th Leg. (Ill. 2008); S. 2865, 95th Leg. (Ill. 2008); H.R. 5938, 95th Leg. (Ill. 2008).

²⁶ Ill. H.R. 4868.

²⁷ *Id.*

²⁸ *Id.*

²⁹ Bill Status of H.R. 4868, 93rd Ill. Gen. Assem., <http://www.ilga.gov/legislation/BillStatus.asp?DocNum=4868&GAID=3&DocTypeID=HB&LegID=9532&SessionID=3&SpecSess=&Session=&GA=93#actions> (last visited Apr. 1, 2009).

³⁰ Ill. S. 650.

³¹ *Id.*

³² S. Doc. No. 15, 95th Leg. (Ill. 2007).

the fifty-nine state senators voted against the bill, indicating that if Senator Cullerton could have garnered support from the remaining eight senators, who either voted present or abstained, the bill would likely have passed.³³

A year later, in February 2008, Senator Cullerton introduced another medical marijuana bill: The Alternative Treatment for Serious Diseases Causing Chronic Pain and Debilitating Conditions Act (Senate Bill 2865).³⁴ The bill provided that: (1) the Department of Public Health shall issue registry identification cards to qualifying patients, (2) the patient may not possess more than twelve marijuana plants and 2.5 ounces of usable marijuana, and (3) the TRP provision of the Cannabis Control Act be repealed.³⁵ This bill picked up four more sponsors than its predecessor and was making its way through the state senate, only to fall short a vote on the floor before the legislative session ended on January 13, 2009.³⁶

III. CONDITIONS IN ILLINOIS: FAVORABLE TO MEDICAL MARIJUANA?

In Illinois, the prospects for adopting medical marijuana provisions received a boost when State Senator John Cullerton assumed his post as Illinois State Senate President.³⁷ In the 96th Legislative session, on February 11, 2009, State Senator William Haine introduced a bill similar to the one Senator Cullerton introduced in the previous session.³⁸ Senator Haine's bill would create the Compassionate Use of Medical Cannabis Pilot Program Act (Senate Bill 1381).³⁹ The bill provides that when a person has been diagnosed by a physician as having

³³ *Id.*; see Marijuana Policy Project, *Illinois Medical Marijuana Bill Narrowly Defeated in Senate 22-29*, <http://www.mpp.org/states/illinois/alerts/illinois-medical-marijuana-bill-narrowly-defeated-in-senate-22-2.html> (last visited Apr. 1, 2009).

³⁴ S. 2865, 95th Leg. (Ill. 2008).

³⁵ *Id.*

³⁶ Bill Status of S.B. 2865, 95th Ill. Gen. Assem., <http://www.ilga.gov/legislation/billstatus.asp?DocNum=2865&GAID=9&GA=95&DocTypeID=S&B&LegID=37610&SessionID=51> (last visited Apr. 1, 2009).

³⁷ Marijuana Policy Project, *Patients Look Forward to 2009 Session for Relief*, <http://www.mpp.org/states/illinois/overviews/patients-look-forward-001-1.html> (last visited Apr. 1, 2009).

³⁸ S. 1381, 96th Leg. (Ill. 2009).

³⁹ *Id.*

a debilitating medical condition, the person and his or her primary caregiver may be issued a registry identification card by the Department of Public Health, and these persons may legally possess no more than seven dried cannabis plants and two ounces of dried, usable cannabis.⁴⁰

In fact, Senator Haine's bill adopts many of the amendments made to Senator Cullerton's bill (Senate Bill 2865) after Senator Cullerton sat down with law enforcement agencies to listen to their concerns.⁴¹ Since its introduction, Senator Haine's bill has picked up two chief Co-Sponsors, passed the Senate Public Health Subcommittee on Special Issues, and currently awaits a vote on the floor.⁴² Furthermore, while Senate President Cullerton's office cannot release any opinion regarding whether Senator Haine's bill will pass⁴³, the potential support of the Senate President would be significant.

Public opinion in Illinois seems to compliment more favorable conditions in the state legislature. A public opinion poll, conducted by Mason-Dixon Polling in February 2008 of 625 registered voters in Illinois, revealed that 68% of those voters are in support of allowing seriously and terminally ill patients to use and grow medical marijuana for personal use if the patient's doctor recommends doing so.⁴⁴

IV. CONCLUSION

Certainly, the prospects for legalized medical marijuana in Illinois are not as "grim" as Andrew J. Boyd assessed them to be in 2004.⁴⁵ While medical

⁴⁰ *Id.*

⁴¹ Marijuana Policy Project, *Medical Marijuana Bill in Illinois Updated*, <http://www.mpp.org/states/illinois/ChangesToSB2865.html> (last visited Apr. 1, 2009).

⁴² Bill Status of SB 1381, 96th Ill. Gen. Assem., <http://www.ilga.gov/legislation/billstatus.asp?DocNum=1381&GAID=10&GA=96&DocTypeID=SB&LegID=42617&SessionID=76> (last visited Apr. 9, 2009).

⁴³ E-mail from Justine Miele, District Director, Illinois State Senator John Cullerton, to Kevin Lichtenberg, ANNALS HEALTH L. Member, Loyola University Chicago School of Law (Feb. 13, 2009, 15:02 CST) (on file with author).

⁴⁴ MARIJUANA POLICY PROJECT, *supra* note 2, at D-4.

⁴⁵ Andrew J. Boyd, *Medical Marijuana and Personal Autonomy*, 37 J. MARSHALL L. REV. 1253, 1269 (2004).

marijuana bills have had a troubled history in the Illinois General Assembly, numerous forces are at work to make an Illinois medical marijuana law reality. Illinois policymakers should look to the thirteen other states already providing legal protection for seriously ill individuals who use medical marijuana for helpful templates. In that way, *when* the Illinois General Assembly passes such a law, it will be administered efficiently and effectively.

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Should We Tax the Fat out of America? The Trouble of Selling the Fat Tax to the Public

*Robert O. Lynch**

I. INTRODUCTION

In January of 2009 the New York State Assembly introduced legislation that, if passed, will impose an 18% tax on sugary sodas and juice drinks.¹ The bill states:

[T]here are hereby imposed and there shall be paid additional sales and compensating use taxes, at the rate of eighteen percent, on (i) fruit drinks that contain less than seventy percent of natural fruit juice and (ii) soft drinks, sodas, and beverages such as are ordinarily dispensed at soda fountains or in connection therewith . . .²

Proponents of this bill argue that this legislation will reduce the prevalence of obesity while raising more than \$400 million per year for health programs.³ Others, including the American Beverage Association, argue that the bill's purpose is generating revenue for the state rather than protecting the health of the population and express doubt that singling out one industry will significantly affect obesity levels.⁴

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¹ A. 160/S. 60, 2009 Assem., Reg. Sess. § 1105-D (N.Y. 2009).

² *Id.*

³ Sewell Chan, *A Tax on Many Soft Drinks Sets Off a Spirited Debate*, N.Y. TIMES, Dec. 17, 2008, at A36, available at <http://www.nytimes.com/2008/12/17/nyregion/17sugartax.html>.

⁴ *Id.*

Obesity is one of America's fastest-growing health concerns.⁵ Nationally, nearly one third of adult Americans are obese.⁶ Obesity has been defined by the Centers for Disease Control and Prevention to be a label "for ranges of weight that are greater than what is generally considered healthy for a given height."⁷ Obesity levels are determined by using a person's height and weight to calculate their body mass index (BMI).⁸ In most cases, one's BMI correlates with one's amount of body fat.⁹ In New York, one out of every four people is classified as obese, an alarming increase from the 14% of New Yorkers that were classified as obese in 1995.¹⁰

Obesity increases the risk of health problems, including coronary heart disease, type two diabetes, cancer, stroke, liver disease, sleep apnea, respiratory problems, and hypertension.¹¹ Obesity and related illnesses have cost the nation billions of dollars in health care costs, especially from federally funded Medicaid and Medicare.¹²

II. THE HISTORICAL TAXING OF TOBACCO AS A GUIDE TO "FAT TAXES"

Taxing foods and drinks that are linked to obesity in an effort to lower the prevalence of obesity in America may appear to be a novel idea, but it is hardly unique. There have been many occasions when taxes were used to promote public health by discouraging consumption of an unhealthy product, most

⁵ CTRS. FOR DISEASE CONTROL & PREVENTION, OVERWEIGHT AND OBESITY: U.S. OBESITY TRENDS 1985–2007, <http://www.cdc.gov/nccdphp/dnpa/obesity/trend/maps/index.htm> (last visited Mar. 29, 2009).

⁶ US DEPT. OF HEALTH & HUMAN SERVICES, STATISTICS RELATED TO OVERWEIGHT AND OBESITY 4 (2007), available at <http://win.niddk.nih.gov/publications/PDFs/stat904z.pdf>.

⁷ CTRS. FOR DISEASE CONTROL & PREVENTION, OVERWEIGHT AND OBESITY: DEFINING OVERWEIGHT AND OBESITY, <http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm> (last visited Mar. 29, 2009).

⁸ *Id.*

⁹ *Id.*

¹⁰ Chan, *supra* note 3.

¹¹ CTRS. FOR DISEASE CONTROL & PREVENTION, OBESITY AND OVERWEIGHT: INTRODUCTION, <http://www.cdc.gov/nccdphp/dnpa/obesity/index.htm> (last visited Mar. 29, 2009).

¹² Sayward Byrd, *Civil Rights and the "Twinkie" Tax: The 900-Pound Gorilla in the War on Obesity*, 65 LA. L. REV. 303, 323 (2004) ("In 1998, Medicaid spending related to obesity totaled 14.1 billion dollars, while Medicare spending totaled 23.5 billion dollars mitigating, treating, or attempting to treat the effects of obesity.").

famously, tobacco. Federal and state excise taxes on tobacco have raised billions of dollars in revenue since they were introduced, and have also contributed to a decline in total consumption of cigarettes.¹³ Statistics show that as states have raised excise taxes on cigarettes, total consumption has significantly declined.¹⁴ For example, when North Carolina raised its cigarette tax from \$0.05 to \$0.35, cigarette sales fell 18%.¹⁵ Likewise, in the five years after Connecticut increased its tax to \$1.51 per pack from \$0.50 per pack, the per capita consumption of cigarettes fell 37%.¹⁶ In South Carolina, the state with the lowest cigarette tax in the nation (\$0.07), consumption fell only 5% between 2000 and 2007.¹⁷

Recently, President Obama signed the Children's Health Insurance Bill. A portion of the programs created by the bill are funded by increasing the federal excise tax on tobacco.¹⁸ Under this act, the federal tax on a pack of cigarettes will increase from \$0.39 to \$1.00.¹⁹ Economists suggest that this raise in the cigarette tax will reduce smoking rates by 6%.²⁰ Furthermore, this estimate is reinforced by research studies that concluded that a 40% increase in the federal tax on cigarettes will drop smoking prevalence from 21.1% to 15.2% over a twenty-year period.²¹ It is estimated that this tax increase will decrease smoking-related medical care costs by an estimated \$317 billion over the next twenty years.²²

The underlying public health problems stemming from smoking are similar to the health issues and costs associated with the obesity epidemic that is

¹³ Dennis Cauchon, *Smoking Declines as Taxes Increase*, USA TODAY, Aug. 9, 2007, available at http://www.usatoday.com/news/health/2007-08-09-1Aerde_N.htm.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Robert Pear, *Obama Signs Children's Health Insurance Bill*, N.Y. TIMES, Feb. 4, 2009, available at <http://www.nytimes.com/2009/02/05/us/politics/05health.html>.

¹⁹ See Children's Health Insurance Program Reauthorization Act of 2009, Pub. L. No. 111-3, §701, 123 Stat. 8, 106 (2009).

²⁰ Cauchon, *supra* note 13.

²¹ Sajjad Ahmad & Gregor A. Franz, *Raising Taxes to Reduce Smoking Prevalence in the US: A Simulation of Anticipated Health and Economic Impacts*, 122 PUB. HEALTH 3, 7 (2008).

²² *Id.* at 8.

plaguing American today, prompting both proponents and critics of governmental intervention to cite smoking when discussing obesity.²³

III. THE JUNK FOOD TAX VERSUS THE FAT TAX

Most taxes imposed on unhealthy foods can be categorized into two groups: smaller “junk food taxes” and more aggressive “fat taxes.” Many of the existing junk food taxes pre-dated the obesity epidemic and were enacted when there was much less concern about the health impact of such foods.²⁴ Advocates now propose extending these existing taxes, and using the large revenues they generate, to fund public health initiatives.²⁵ These junk food taxes are relatively small, generally less than 5%, but over time they generate significant revenue.²⁶ Polls suggest that the public approves of these small taxes, something that cannot be said about tobacco taxes or the more aggressive fat taxes.²⁷ Furthermore, these junk food taxes appear to be a viable way to raise revenue that can be allocated to promote healthy eating habits without affecting consumer access to these foods.²⁸ Individually, these relatively small junk food taxes are unlikely to substantially influence consumer diet quality or health since the taxes themselves are unlikely to significantly affect the price or accessibility of the foods and drinks.²⁹ Therefore, if these small junk food taxes are employed, there is an added importance and responsibility of allocating the revenue collected to programs that either promote healthy alternatives or subsidize healthy food.

²³ See David Paterson, *Commentary: Why We Need an Obesity Tax*, CNN, Dec. 18, 2008, <http://www.cnn.com/2008/HEALTH/12/18/paterson.obesity/>.

²⁴ Jeff Strnad, *Conceptualizing the “Fat Tax”: The Role of Food Taxes in Developed Economies*, 78 S. CAL. L. REV. 1221, 1224-25 (2005).

²⁵ *Id.* at 1225.

²⁶ See Michael F. Jacobson & Kelly D. Brownell, *Small Taxes on Soft Drinks and Snack Foods to Promote Health*, 90 AM. J. PUB. HEALTH 854 (2000).

²⁷ *Id.* at 856 (explaining that a national poll found that 45% of adults surveyed would support a one cent tax per pound of soft drinks, chips, and butter, with revenues used to fund health education programs).

²⁸ See *Id.* at 854.

²⁹ Fred Kuchler et al., U.S. Dept. of Agric., *Taxing Snack Foods: What to Expect for Diet and Tax Revenues*, Aug. 2004, at 1, 10, available at <http://www.ers.usda.gov/Publications/aib747/aib74708.pdf>.

Since small taxes are relatively ineffective in directly affecting consumption, state legislatures and local governments have proposed more aggressive fat taxes that call for the taxing of unhealthy food with the explicit goal of influencing consumer behavior to meet public health goals.³⁰ Critics of these fat taxes argue that they disproportionately affect the poor because smaller incomes create a financial burden when coupled with the lack of access to affordable, healthier alternatives.³¹

Once a state makes the decision to implement a small junk food or an aggressive fat tax, it must ultimately decide what foods and drinks will be subject to the tax. One method that experts recommend is to tax foods based on their content of standard or trans fat rather than taxing categories of foods.³² However most legislators, like those in New York, choose to create overly broad categories, such as “sugary drinks.”³³

IV. DEFENDING NEW YORK’S OBESITY TAX

New York’s obesity tax falls into the category of a fat tax because the stated goal is to reduce the consumption of high calorie drinks.³⁴ New York Governor David Patterson, who has championed the bill, believes this tax will help reduce the prevalence of obesity, much in the same way that cigarette taxes have been used to reduce the number of smokers.³⁵ While Governor Patterson also acknowledges that the tax itself may be unpopular, he cites a reduction in smoking following an increase in the state’s cigarette tax as being evidence of the potential public health benefits the obesity tax will foster.³⁶

New York’s fat tax is likely to face strong resistance, not just from the beverage industry, but also from the public. The state legislature needs only to

³⁰ Strnad, *supra* note 24 at 1226.

³¹ Byrd, *supra* note 12, at 329.

³² Jacobson & Brownell, *supra* note 26 at 854.

³³ *Id.*

³⁴ Paterson, *supra* note 23.

³⁵ *Id.*

³⁶ *Id.*

look at some recently enacted and proposed legislation from around the country to anticipate the public reaction to the tax. In Maine, voters overturned an April 2008 state law that added new taxes on sodas and the sugary syrups used to make them.³⁷ Similarly, a proposal from the mayor of San Francisco to charge stores a fee when they sell sugary drinks has not advanced since being introduced over a year ago.³⁸ It appears that the New York legislature will likely fight an uphill battle in convincing the public that this obesity tax will aid in the reduction of the prevalence of obesity in the state.

V. NEW YORK'S OBESITY TAX IS UNLIKELY TO SUCCEED

Given the history of aggressive fat taxes it is unlikely that New York's obesity tax on sodas and sugary drinks will pass into law because of broad opposition. Although aggressive taxing has appeared to work in lowering the prevalence of smoking, the same tactics will run into several roadblocks when applied to foods and drinks linked to obesity. New York may have more success raising revenues through employing smaller junk food taxes on sodas and sugary drinks. However, this will not raise nearly the same level of revenue, nor will it be as effective in lowering the prevalence of obesity. Until the public is more receptive to these fat taxes, state and local governments attempting to fight obesity will need to be content with employing smaller junk food taxes and promoting healthy alternatives.

³⁷ Chan, *supra* note 3.

³⁸ *Id.*; see also Jesse McKinley, *San Francisco's Mayor Proposes Fee on Sales of Sugary Soft Drinks*, N.Y. TIMES, Dec. 18, 2007, available at <http://www.nytimes.com/2007/12/18/us/18soda.html>.

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Lyme Disease: A Biting Conflict

*Christine Becer**

I. INTRODUCTION

Lyme disease, the most common tick-borne illness, is a serious public health problem.¹ Lyme disease has existed in the United States since the 1940s.² It takes its name from the town Lyme in Connecticut, where it was recognized as a cluster of cases in the mid 1970s.³ From 1992 to 2006, a total of 248,074 Lyme disease cases were reported to the Centers for Disease Control and Prevention.⁴ The overall trend indicates a steady increase in the number of reported cases each year.⁵ Ecological changes are one of the direct causes of the spread of Lyme disease.⁶ Avoidance of exposure to the deer tick, the primary source of Lyme disease in the United States, is a fundamental solution.⁷

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¹ Henry M. Feder, Jr. et al., *A Critical Appraisal of "Chronic Lyme Disease,"* 357 NEW ENG. J. MED. 1422, 1422 (2007).

² Alfred DeMaria, Jr., *Globalization of Infectious Diseases: Questions Posed by the Behavioral, Social, Economic and Environmental Context of Emerging Infections,* 11 NEW ENG. J. INT'L & COMP. L. 37, 43 (2004).

³ See *id.*

⁴ Rendi Murphree Bacon, Kiersten J. Kugeler & Paul S. Mead, MORBIDITY & MORTALITY WKLY. REP. SURVEILLANCE SUMMARIES (Ctrs. for Disease Control & Prevention, Atlanta, Ga.), Oct. 3, 2008, at 1, 1, available at <http://www.cdc.gov/mmwr/PDF/ss/ss5710.pdf>.

⁵ *Id.* ("During 1992-2006, the number of reported cases more than doubled.")

⁶ DeMaria, *supra* note 2, at 44.

⁷ See CTRS. for Disease Control & Prevention, Learn About Lyme Disease, <http://www.cdc.gov/ncidod/dvbid/lyme> (last visited Mar. 28, 2009).

Lyme disease presents itself with diverse clinical signs and symptoms and with several variations in the progression of the unmitigated disease course.⁸ This uncertain progression led to contrasting opinions in the medical community about the existence and treatment of long-term symptoms of the disease.⁹ In 2006, the Infectious Diseases Society of America (IDSA) released guidelines recommending that patients infected with Lyme disease should receive only one treatment of antibiotics, but the International Lyme and Associated Diseases Society (ILADS) called for a retraction of these guidelines.¹⁰ Additionally, in 2007, both the Senate and the House of Representatives presented bills designed to combat Lyme disease, but neither has been implemented.¹¹

This article will first discuss the signs and symptoms of Lyme disease. This article will then discuss the implications of the conflicting points of view surrounding chronic Lyme disease and how they affect the clinical care of patients stricken with Lyme disease. Finally, this article will briefly explore Lyme disease legislation.

II. SIGNS AND SYMPTOMS OF LYME DISEASE

Lyme disease is transmitted by a deer tick infected with borrelia, highly invasive bacteria that can localize in selected tissues.¹² A complete presentation of the untreated disease is a very unusual observation; a tick bite leading to a skin lesion, followed by involvement of the heart and nervous system, and then arthritis.¹³ The only physical sign that enables a reliable clinical diagnosis in everyday medical practice is a typical skin lesion called erythema migrans.¹⁴ At

⁸ Feder et al., *supra* note 1, at 1422.

⁹ *Id.*

¹⁰ Press Release, Int'l Lyme & Associated Diseases Soc'y, Lyme Wars: Lyme Disease Expert Critical of New Treatment Guidelines (Nov. 27, 2006), available at http://www.ilads.org/publications Cameron_11_2006.pdf [hereinafter Lyme Wars].

¹¹ Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007, H.R. 741, 110th Cong. (1st Sess. 2007); S. 1708, 110th Cong. (1st Sess. 2007).

¹² Gerold Stanek & Franc Strle, *Lyme Borreliosis*, 362 LANCET 1639, 1640 (2003).

¹³ Feder et al., *supra* note 1, at 1422.

¹⁴ *Id.* Laboratory tests can also confirm the presence of the bacteria early in the illness. Allen C. Steere, *Lyme Disease*, 345 NEW ENG. J. MED. 115, 116, 120 (2001).

this first sign, conventional antibiotics, such as doxycycline and amoxicillin, are normally prescribed.¹⁵ Most other signs and symptoms are of low or even no diagnostic value because they can be attributed to other causes.¹⁶

Erythema migrans, commonly referred to as a bulls-eye rash, is the most valuable clinical sign of Lyme disease.¹⁷ After being bitten by an infected tick, “a small red macula or papule appears on the skin, usually at the site of the bite.”¹⁸ A ring-like lesion becomes visible as the red patch slowly enlarges and the middle of the lesion begins to clear.¹⁹ If left untreated, the lesion will persist and expand.²⁰ The lesion’s diameter may range from a few centimeters to more than a meter and can often go undetected depending on what area of the body the lesion is located.²¹ In adult patients, the lesion is more often located on the lower half of the body; in children, the upper part of the body is more frequently affected.²² Symptoms accompanying the bite include mild itching, burning, or pain.²³ A smaller proportion of people have systemic flu-like symptoms such as fatigue and malaise, headache, and muscle or joint pain.²⁴ Without treatment, the disease can affect the nervous system, heart, and the joints.²⁵ These symptoms are intermittent and differ in intensity and position.²⁶ Antibiotic therapy is effective

¹⁵ Steere, *supra* note 14, at 121.

¹⁶ See JONATHAN A. EDLOW, TICK-BORNE DISEASES, LYME, EMEDICINE, Dec. 12, 2008, <http://emedicine.medscape.com/article/786767-overview> (last visited Mar. 28, 2009); see also Feder et al., *supra* note 1, at 1422.

¹⁷ Stanek & Strle, *supra* note 12, at 1640.

¹⁸ *Id.*; see American Lyme Disease Foundation, Pictures of Erythema Migrans, <http://www.aldf.com/EMPoster.shtml> (last visited Mar. 28, 2009) (showing pictures of the ring-like lesion).

¹⁹ Stanek & Strle, *supra* note 12, at 1640.

²⁰ *Id.*

²¹ *Id.*

²² *Id.* Children and adults have similar manifestations of Lyme disease. Kristina A. Bryant & Gary S. Marshall, *Clinical Manifestations of Tick-Borne Infections in Children*, 7 CLINICAL & DIAGNOSTIC LABORATORY IMMUNOLOGY, 523, 523 (2000).

²³ Stanek & Strle, *supra* note 12, at 1640.

²⁴ *Id.*

²⁵ Steere, *supra* note 14, at 117-18.

²⁶ *Id.*

for patients with objective manifestations of Lyme disease, especially when given early in the course of the illness.²⁷

III. THE MEDICAL CONFLICT SURROUNDING CHRONIC LYME DISEASE

A minority of patients progress to a chronic course of Lyme disease, where patients continue to have “fatigue, musculoskeletal pain, difficulties with concentration or short-term memory, or all of these symptoms” even after antibiotic treatment and resolution of the objective signs of Lyme disease.²⁸ The diagnosis of chronic Lyme disease is based on clinical judgment and surveillance rather than clinical criteria or laboratory studies.²⁹ As such, the progressed disease often remains unchecked and undiagnosed.

A medical conflict arises for patients who suffer from a chronic state of Lyme disease. In 2006, the IDSA released guidelines stating that Lyme disease must be diagnosed by a visible rash and common blood tests and should be treated with a standard course of antibiotics for ten to twenty-one days.³⁰ While the IDSA questions the existence of chronic Lyme disease,³¹ ILADS recognizes chronic Lyme disease and the ILADS guidelines call for long-term antibiotic treatment for persistent Lyme disease or infection complications.³²

The IDSA uses the term “chronic Lyme disease” to refer to patients who have well-documented Lyme disease and remain symptomatic for months to years after receipt of appropriate antibiotics.³³ Often these patients complain only of

²⁷ *Id.* at 121.

²⁸ Feder et al. *supra* note 1, at 1422.

²⁹ *Id.* at 1423.

³⁰ Gary P. Wormser, et al., *The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America*, 43 CLINICAL INFECTION DISEASES 1089, 1089-90, 1091 (2006).

³¹ *Id.* at 1094.

³² Int'l Lyme & Associated Diseases Soc'y, *Evidence-Based Guidelines for the Management of Lyme Disease*, 2 EXPERT REV. ANTI-INFECTIVE THERAPY S1, at S9 (2004) [hereinafter ILADS] (responding to the 2000 IDSA guidelines that also denied the existence of chronic Lyme disease).

³³ Wormser et al., *supra* note 30, at 1116.

subjective symptoms such as musculoskeletal pain, cognitive issues, and fatigue.³⁴ The IDSA claims that the unoriginality of these complaints is suspect because many people without Lyme disease also report having these symptoms.³⁵ Citing two controlled treatment studies, the IDSA concluded that there is no convincing evidence for the existence of symptomatic chronic Lyme disease infection among patients after receiving appropriate treatment.³⁶ They concluded that antibiotic therapy has not proven successful and is not recommended for patients who experience more than six months of subjective symptoms after receiving the recommended treatment for Lyme disease.³⁷ The IDSA also stated that there are inherent risks from long-term antibiotic treatment such as infection at intravenous sites and the creation of antibiotic resistant bacteria.³⁸

Alternatively, ILADS claims that IDSA's symptomatic approaches to Lyme disease are limited and exclude many individuals with persisting clinical and laboratory evidence of active Lyme infection.³⁹ In addition, physicians treating patients with Lyme disease recognize the need for new treatment protocols to better serve the population.⁴⁰ ILADS recognizes that some patients respond poorly to the initial antibiotic treatment and may need further interventions.⁴¹ The organization criticized the accuracy of the studies embraced by IDSA for enrolling patients with chronic Lyme disease who were sick for an average of about five years despite three courses of antibiotics, and for relying only on one treatment protocol.⁴² In view of this unreliable research, ILADS recommends that physicians base their treatment on the patient's clinical response

³⁴ *Id.*

³⁵ *Id.* at 1115.

³⁶ *Id.* at 1119-21.

³⁷ *Id.* at 1121.

³⁸ Ronni Berke, *10-Year Battle with Pain Highlights Lyme Disease Debate*, CNN, <http://www.cnn.com/2008/HEALTH/conditions/07/06/lymedisease.treatment/index.html> (last visited Mar. 28, 2009).

³⁹ ILADS, *supra* note 32, at S4.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.* at S6.

and notes that several months of antibiotic therapy may be required to accomplish noticeable improvement.⁴³

IV. REPERCUSSIONS FOR PATIENTS

The medical community and insurers generally respect guidelines published by medical organizations.⁴⁴ However, there is a real contradiction between two Lyme disease societies about chronic Lyme disease.⁴⁵ Patients who believe they suffer from chronic Lyme disease want antibiotic treatment, and the IDSA guidelines potentially deny them access to that treatment.⁴⁶ The attorney general's office in Connecticut, the state with the country's highest incidence of Lyme disease, launched an anti-trust investigation into the IDSA panel.⁴⁷ Connecticut Attorney General Richard Blumenthal inquired into whether IDSA ignored any studies supporting long-term antibiotic treatment and if there were any conflicts of interests.⁴⁸ There was a concern that insurance companies might use these new guidelines to deny payment for Lyme treatment.⁴⁹ Blumenthal also claimed that some members of the IDSA panel who wrote the guidelines consulted for insurance companies and one member had a patent for a Lyme disease treatment.⁵⁰ Both issues represent conflicts of interest that could arguably lead to unfair guidelines in respect to chronic Lyme disease.

On April 30, 2008, the IDSA reached a settlement with Blumenthal; the IDSA was required to implement a plan in which a review panel will determine whether the 2006 guidelines should be revised or updated.⁵¹ This review panel

⁴³ *Id.* at S6, S9.

⁴⁴ Lyme Wars, *supra* note 10.

⁴⁵ E.g., Mary Carmichael, *The Great Lyme Debate*, NEWSWEEK, Aug. 6, 2007, at 42, available at <http://www.newsweek.com/id/32657>.

⁴⁶ See Lyme Wars, *supra* note 10.

⁴⁷ Berke, *supra* note 38; Bacon, Kugeler & Mead, *supra* note 4, at 4.

⁴⁸ Berke, *supra* note 38.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Agreement Between Conn. Att'y Gen. & Infectious Diseases Soc'y of Am. 1, 5 (April 30, 2008), available at <http://www.ct.gov/ag/lib/ag/health/idsaagreement.pdf>.

was selected on January 26, 2009.⁵² On February 2, 2009, the panel initiated a sixty day input period to allow the public to submit information to ensure that all points of view are taken into consideration.⁵³ The outcomes of the investigation by the review panel remain to be seen.

V. CONCLUSION

The prevalence of Lyme disease is on the rise in the United States.⁵⁴ With the possibility that Lyme disease can be a chronic infection and that early treatment is most effective, prevention of this disease is essential. In response to this concern, on January 31, 2007, Rep. Christopher Smith from New Jersey introduced the Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007.⁵⁵ This bill would “provide for the expansion of Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme [disease].”⁵⁶ The bill also called for the establishment of a Tick-Borne Diseases Advisory Committee.⁵⁷ Unfortunately, the bill was referred to the Subcommittee on Health.⁵⁸ The authors of the bill recognized that Lyme disease can lead to serious problems, and patients reporting persistent symptoms without reliable testing make treatment more difficult.⁵⁹ The fact that the efficacy and treatment of chronic Lyme disease remains in dispute complicates the dilemma and clinical treatment of patients.

⁵² Statement from IDSA on Selection of Panelists for Review, <http://www.idsociety.org/PrintFriendly.aspx?id=13310> (last visited Mar. 28, 2009).

⁵³ IDSA Lyme Disease Review Panel Announces Public Input Period and Hearing Date, <http://www.idsociety.org/PrintFriendly.aspx?id=13352> (last visited Feb. 15, 2009).

⁵⁴ See Bacon, Kugeler & Mead, *supra* note 4 (“During 1992-2006, the number of cases more than doubled.”).

⁵⁵ See Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007, H.R. 741, 110th Cong. (2007). The Senate version of the bill was introduced by Sen. Christopher Dodd on June 27, 2007. S. 1708, 110th Cong. (2007). It was read twice and then referred to the Committee on Health, Education, Labor, and Pensions. 153 CONG. REC. S8610 (2007).

⁵⁶ H.R. 741.

⁵⁷ *Id.* § 3.

⁵⁸ Library of Congress, THOMAS, <http://thomas.loc.gov/cgi-bin/bdquery/z?d110:h.r.00741>: (last visited Mar. 28, 2009).

⁵⁹ H.R. 741 § 2.

Although the IDSA does not currently recognize chronic Lyme disease, many physicians agree that there are a large number of patients who have chronic symptoms of Lyme disease.⁶⁰ Both the IDSA and ILADS provide guidelines for clinicians in deciding the appropriate treatment of Lyme disease.⁶¹ These societies should be cautious to rule out long-term treatments for Lyme disease without thorough research, especially due to the fact that insurers rely on these guidelines and are looking for means to avoid costs in these times of coverage crisis. In the case of Lyme disease, anything less than expert medical analysis of effective treatment does a disservice to those stricken with the disease.

⁶⁰ See Carmichael, *supra* note 45. However, “the doctors who made the new IDSA guidelines on treatment say there’s no such thing as chronic Lyme.” *Id.*

⁶¹ See *supra* Part III.

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Conscience and its Consequences: Reconciling Practitioner and Patient Rights

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On December 19, 2008, the Bush administration issued last-minute regulations to strengthen existing federal “conscience clauses.”¹ A conscience clause is a statutory provision that permits medical practitioners and institutions to refuse to provide medical procedures on the basis of religious or moral beliefs.² Several federal conscience clause laws exist which protect those in the healthcare field from taking part in abortion or sterilization procedures.³ But arguably the broadest conscience clause statute already in existence provides that “[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services” if doing so “would be contrary to his religious beliefs or moral convictions.”⁴ This statute potentially applies to all health service programs and research activities.

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¹ Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory

Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072 (Dec. 19, 2008) (to be codified at 45 C.F.R. pt. 88).

² Ascension Health, Healthcare Ethics, Conscience Clause, http://www.ascensionhealth.org/ethics/public/issues/conscience_clause.asp (last visited Apr. 16, 2009).

³ See, e.g., 42 U.S.C. § 300a-7(b)-(d) (2006).

⁴ 42 U.S.C. § 300a-7(d) (2006).

Although these conscience clause regulations merely reinforce already-existing protections,⁵ there is speculation that the Bush administration strengthened the rule because the Obama administration has pledged support for the Freedom of Choice Act, which would make it illegal for federally-funded health institutions to deny an abortion prior to fetal viability.⁶ On January 15, 2009, a bill was proposed in the House of Representatives that would effectively repeal the Bush regulations.⁷ On February 27, 2009, the Obama administration stated its intent to rescind the last-minute Bush regulations.⁸ This flurry of legislative activity and the recent change in executive opinion make conscience clauses a timely issue worth examining in search of a compromise.

I. PRACTITIONER RIGHTS: SUPPORT FOR CONSCIENCE CLAUSES

Many health care practitioners hold moral or religious beliefs which may conflict with certain medical procedures or practices. In citing the nationwide shortage of healthcare practitioners, the last-minute Bush regulations from the Department of Health and Human Services note that the agency is “concerned about the development of an environment in sectors of the health care field that is intolerant of individual objections to abortion or other individual religious beliefs or moral convictions.”⁹ Such an environment could potentially discourage

⁵ Brian Montopoli, *Abortion Foes Warn of Hospital Closures*, CBSNEWS.COM, Jan. 28, 2009, <http://www.cbsnews.com/stories/2009/01/27/politics/main4757890.shtml> (discussing opposition to the Freedom of Choice Act proposed in Congress).

⁶ Diana Sroka, *Hospitals Avoiding National Controversy*, NORTHWEST HERALD, Jan. 21, 2009, available at <http://www.nwherald.com/articles/2009/01/21/09105338/index.xml>; S. 1173, 110th Cong., § 1 (2007).

⁷ Protecting Patients and Health Care Act of 2009, H.R. 570, 111th Cong. § 1 (2009), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h570ih.txt.pdf.

⁸ Saundra Young, *White House Set to Reverse Health Care Conscience Clause*, CNN.COM, Feb. 27, 2009, <http://www.cnn.com/2009/POLITICS/02/27/conscience.rollback/index.html>.

⁹ Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,073 (Dec. 19, 2008) (to be codified at 45 C.F.R. pt. 88).

persons with objections to certain medical procedures from pursuing careers in health care.¹⁰

The tenets of the Catholic faith, coupled with the religion's strong ties to medical care, serve as an illustrative example of the dilemma presented to certain healthcare practitioners. Catholicism's stances on "many crucial issues are distinctly and unapologetically ethically counter-cultural," and some of their positions are shared by other religious groups.¹¹ Despite the fact that the Catholic position on certain health issues often differs from mainstream opinion, one out of every six patients hospitalized in the United States receives care at a Catholic hospital.¹² Although administered by religious institutions, such hospitals "operate in the public sphere and they do so largely with public funding."¹³ Catholics are implored by their religious leaders to conscientiously object to medical practices which contradict their faith.¹⁴ Consequently, a practitioner is, in certain circumstances, essentially forced to choose between the tenets of her faith and the realities of her profession.¹⁵ Conscience clauses serve to limit such pressures on health care practitioners, yet, as a result, the burden inevitably shifts to the patient.

II. THE EFFECTS OF CONSCIENCE CLAUSES ON PATIENTS' RIGHTS

Practitioners' religious beliefs "often conflict with accepted standards of medical practice and patients' right to self-determination."¹⁶ Conscience clauses have the potential to place significant burdens on patients by creating obstacles to

¹⁰ See *id.*

¹¹ Edmund D. Pellegrino, *The Physician's Conscience, Conscience Clauses, and Religious Belief: A Catholic Perspective*, 30 FORDHAM URB. L.J. 221, 225 (2002).

¹² Ben Arnoldy, *Catholic Groups Fear Abortion Rights Bill*, CHRISTIAN SCI. MONITOR, Dec. 5, 2008, at 3, available at <http://www.csmonitor.com/2008/1205/p03s03-ussc.html>.

¹³ Susan Berke Fogel & Lourdes A. Rivera, *Saving Roe Is Not Enough: When Religion Controls Healthcare*, 31 FORDHAM URB. L.J. 725, 742 (2003-2004).

¹⁴ See, e.g., Pope John Paul II, Address to International Congress of Catholic Obstetricians and Gynecologists (June 18, 2001), available at http://www.lifeissues.net/writers/doc/doc_13_obstetandgynec.html.

¹⁵ See *id.*

¹⁶ Fogel & Rivera, *supra* note 14, at 727.

certain health care decisions and options.¹⁷ Rural or medically underserved regions of the country may be especially affected by conscience clauses.¹⁸ Many medical services, such as the prescription of emergency contraception, must be administered in a timely manner to ensure effectiveness.¹⁹ A patient's ability to travel might be a determining factor in her outcome if the health care practitioner she visits first will not perform the requested procedure.²⁰ But low-income patients with limited mobility are not the only ones at the mercy of practitioners. In 2006, for example, a married lawyer and writer in Washington, D.C. contacted her doctor for a prescription for emergency contraception,²¹ was refused by two providers and could not get an appointment with a third; the 72-hour period of effectiveness was about to expire, so she decided to take her chances and became pregnant.²² The woman eventually underwent an abortion as a direct result of being refused emergency contraception.²³

Patients, like the one in the previous example, do not usually consider their practitioner's beliefs before seeking care. In fact, the common perception among patients is that even if they seek care at a religious institution, they will be able to receive their requested treatment, even if it goes against the institution's religious teachings.²⁴ Even if a willing provider can be found, the patient is

¹⁷ See *id.*

¹⁸ See *id.* at 729.

¹⁹ See, e.g., Plan B®: Frequently Asked Questions, <http://www.go2planb.com/plan-b-faq.aspx> (instructing the user that if the drug is taken within 72 hours of unprotected sex, it can significantly decrease the chance of pregnancy).

²⁰ See Fogel & Rivera, *supra* note 14, at 733.

²¹ Emergency contraception has since been made available on an over-the-counter basis for persons 18 years of age and older. See Press Release, FDA, FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older Prescription Remains Required for Those 17 and Under (Aug. 24, 2006) (on file with author), available at <http://www.fda.gov/bbs/topics/news/2006/new01436.html>. However, the dispensation of emergency contraception is still an issue at doctors' offices (for minors) and at hospitals. See Reena Singh, *New Barriers to Emergency Contraceptive Access for Rape Victims: A Report from Connecticut*, WOMEN'S HEALTH ADVOC. (Nat'l Women's Health Network, Wash., D.C.), May 1, 2007, http://www.nwhn.org/newsletter/article1.cfm?newsletterarticles_id=135.

For example, rape victims in the emergency room may have no other access to emergency contraception. See *id.*

²² Dana L., *What Happens When There Is No Plan B?*, WASH. POST, June 4, 2006, at B1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/06/02/AR2006060201405.html>.

²³ *Id.*

²⁴ See Fogel & Rivera, *supra* note 14, at 740-41.

presumably forced to pay, whether out-of-pocket or with insurance, for the first visit to the refusing practitioner as well as the second visit where the procedure was performed. In such a scenario, the practitioner's moral burden becomes a financial burden to the patient.

III. BRIDGING THE GAP BETWEEN PRACTITIONERS AND PATIENTS

Although it is unknown whether existing conscience clause rules will remain intact or whether they will be limited by the Obama administration, patient rights can still be expanded within current conscience clause provisions. Perhaps most importantly, disclosure to patients is crucial. The Bush regulations, while strengthening the practitioner's right of refusal, stress that there should be "open communication between [practitioner and patient] so patients can be confident that the care they seek and receive is endorsed by their health care provider."²⁵ Even Catholic scholars who favor conscience clauses have suggested that "physicians must make their positions publicly known," so that patients will have advance knowledge and an opportunity to find another practitioner.²⁶ For example, if all of the health care practitioner's objections are disclosed when a patient schedules an appointment, the patient has early notice and, if necessary, can look elsewhere for care without spending money on a wasted visit.

Yet, the reality is that advance knowledge of a practitioner's beliefs is often impossible to attain. Therefore, another way to protect both practitioners and patients is to require that institutions have a non-objecting practitioner available on the premises at all times.²⁷ However, in practice, this compromise would be particularly complex when it comes to hospitals affiliated with the

²⁵ See Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,073 (Dec. 19, 2008) (to be codified at 45 C.F.R. pt. 88).

²⁶ Pellegrino, *supra* note 12, at 243-44.

²⁷ See AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, COMM. ON ETHICS, COMMITTEE OPINION NO. 385, THE LIMITS OF CONSCIENTIOUS OBJECTION IN REPRODUCTIVE MEDICINE 5 (2007), available at http://www.acog.org/from_home/publications/ethics/co385.pdf [hereinafter ACOG Opinion].

Catholic church, which limit medical services that conflict with Catholic teachings.²⁸ Specifically, the individual practitioners at the hospitals do not necessarily have any discretion in the matter.²⁹

Some critics of conscience clauses take a stricter stance. The Committee on Ethics of the American College of Obstetricians and Gynecologists published an advisory opinion in 2007, stating that in an emergency, a professional has a duty to provide a service, even if he or she objects, when no other provider is available and the patient's physical or mental health is at risk.³⁰ Others believe that instead of going so far as to require the practitioner to perform the requested service, the practitioner should instead be required to counsel the patient and ensure that the patient receives a referral to a willing practitioner.³¹ Consequently, such a duty would effectively guarantee that the patient receives the service anyway. It is not difficult to imagine that some objecting practitioners would not be satisfied with this compromise.

IV. CONCLUSION

The Hippocratic Oath implicitly and famously tells physicians to do no harm when treating patients, and the modern version of the Oath instructs physicians to not "play at God."³² Yet, today's society has created numerous circumstances in which the practitioner and patient have different perspectives on what constitutes "harm" and what "play[ing] at God" really means. Healthcare practitioners undeniably serve a valuable and necessary role in our society, and conscience clauses serve as effective tools in shielding practitioners from retribution for their beliefs. However, individual medical care is also a deeply personal matter for patients, and the law should not unreasonably hinder patients from getting the care they desire. Compromises will be necessary, especially in

²⁸ See Fogel & Rivera, *supra* note 14, at 732.

²⁹ See *id.*

³⁰ ACOG Opinion, *supra* note 28, at 5.

³¹ Fogel & Rivera, *supra* note 14, at 747-48.

³² Louis Lasagna, The Hippocratic Oath - Modern Version (1964), available at http://www.pbs.org/wgbh/nova/doctors/oath_modern.html.

the case of federally-funded religious healthcare institutions, in order for the rights of patients to be adequately protected.