# BAD MEDICINE: PRESCRIPTION DRUGS, PREEMPTION, AND THE POTENTIAL FOR A NO-FAULT FIX

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ABSTRACT

For decades, federal regulation of pharmaceutical drugs and medical devices has worked hand in hand with state tort claims to protect the health and safety of the American public. Now, a new trend toward preemption endangers this scheme. In recent years, the Supreme Court has given increasing deference to agency assertions about their preemptive authority and has found preemption in an increasing number of cases. In the process, the Supreme Court has preempted claims for medical device injuries and left claims for pharmaceutical harms in a precarious position. The elimination of common law claims for drug and device harms will leave holes in the FDA's regulatory scheme, endangering the health and safety of Americans. It will also prevent ordinary Americans from seeking compensation for their injuries—even those injuries caused by manufacturer malfeasance. This Article proposes that Congress create a no-fault compensation scheme for drugs and medical devices to close these gaps. Such a scheme could be both practical and politically possible, satisfying manufacturers, tort reformers, patients, and plaintiffs' lawyers alike.



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## I.
## INTRODUCTION

Carol met Robert Ernst in 1997. According to Carol, Robert changed her life. They volunteered for Habitat for Humanity. They camped in a tent for ten days at the Albuquerque International Balloon Fiesta. In May 2000, they married. In November 2000, Robert began taking Vioxx, a painkiller manufactured by Merck, for pain in his hands. On May 6, 2001, Robert took Carol to the Olive Garden where they had gone for their first date. That night, Robert—a marathon runner and triathlete—died in his

bed of a heart attack. "Bob was Merck's collateral damage," Mrs. Ernst told the *New York Times*. "They knew there were going to be Bobs, but they didn't care."[1]

Robert Ernst was one of the millions of Americans who tried Vioxx. Many of them requested the drug from their doctors after seeing television advertisements paid for by Merck.[2] As many as 55,000 patients like Robert may have died from heart attacks and strokes induced by the drug.[3] As early as February 2001, the Food and Drug Administration (FDA) was aware of studies showing that patients taking Vioxx had four times the risk of heart attacks as patients taking another pain reliever.[4] Yet the drug continued to be used until September 2004, when Merck voluntarily withdrew Vioxx from the market after a later study showed that the drug doubled the risk of heart attack and stroke.[5] Nevertheless, in February 2005, a panel of experts convened by the FDA to evaluate Vioxx and other drugs voted seventeen to fifteen against banning the drug.[6] Ten of the thirty-two members of that panel had previously consulted for the drugs' makers; without the votes of these members, the panel would have voted fourteen to eight that Vioxx should not return to the market.[7]

The actions and inaction of the FDA are intimately connected to the lives of all Americans. The Food, Drugs, and Cosmetics Act (FDCA) grants the FDA sole responsibility for evaluating the safety and efficacy of all human drugs, vaccines, and medical devices before they enter the market; the FDA issues nearly one hundred new approvals each year.[8] The

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1. Alex Berenson, *In First of Many Vioxx Cases, a Texas Widow Prepares to Take the Stand*, N.Y. TIMES, July 13, 2005, at C1, *available at* http://www.nytimes.com/2005/07/13/business/13vioxx.html?pagewanted=1.

2. Melody Petersen, *Doubts Are Raised on the Safety of 2 Popular Arthritis Drugs*, N.Y. TIMES, May 22, 2001, at C1, *available at* http://www.nytimes.com/2001/05/22/business/doubts-are-raised-on-the-safety-of-2-popular-arthritis-drugs.html.

3. Gardiner Harris, *F.D.A. Official Admits 'Lapses' on Vioxx*, N.Y. TIMES, Mar. 2, 2005, at A15, *available at* http://www.nytimes.com/2005/03/02/politics/02fda.html.

4. Petersen, *supra* note 2.

5. Gardiner Harris, *F.D.A. Is Advised to Let Pain Pills Stay on Market,* N.Y. TIMES, Feb. 19, 2005, at A1, *available at* http://www.nytimes.com/2005/02/19/politics/19fda.html?pagewanted=1&fta=y.

6. *Id.*

7. Gardiner Harris and Alex Berenson, *10 Voters on Panel Backing Pain Pills Had Industry Ties*, N.Y. TIMES, Feb. 25, 2005, at A1, *available at* http://www.nytimes.com/2005/02/25/politics/25fda.html?pagewanted=1. According to the *Times*, the vote among these ten individuals was nine to one in favor of keeping the drug on the market. *Id.*

8. CTR. FOR DRUG EVALUATION AND RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., 2005 REP. TO THE NATION: IMPROVING PUB. HEALTH THROUGH HUMAN DRUGS 12, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/WhatWeDo/UCM078935.pdf (stating that the FDA approved seventy-eight new drugs and two new biologic products in 2005); Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER MAG. (Jan.–Feb. 2006),

FDA is also responsible for monitoring the safety of products that are already on the market: over 10,000 drugs, including both prescription and over-the-counter drugs.[9] Yet the agency is drastically underfunded and structurally unprepared to regulate these products effectively.[10] In some cases, these problems are further exacerbated by manufacturer malfeasance or agency officials' conflicts of interest, as may have happened with Vioxx. Even in the absence of these problems, while the FDA can remove drugs from the market to prevent future harm, the agency does not have the authority to compensate people like Robert Ernst and his family for their suffering.[11]

For decades, tort law has compensated for the failures of federal regulation of pharmaceutical drugs and medical devices. Tort cases uncover invaluable information about drug and device harms that were not discovered during the FDA approval process.[12] And, unlike the FDCA, tort law can require negligent manufacturers to compensate the victims of these harms.[13] By supplementing federal protections, state tort law has worked hand in hand with FDA regulation to protect the health and safety of the public.

However, this symbiotic balance of state and federal protections is in danger. Throughout the federal government, a trend toward preemption of state law has begun to erode private enforcement in favor of regulatory regimes managed by federal agencies.[14] At the same time, the Supreme Court has given increasing deference to the FDA's opinions about whether the agency's regulatory regime preempts state tort law.[15] In *Riegel v. Medtronic, Inc.*, the Court held that the FDCA preempted state tort claims for harm caused by FDA-approved medical devices.[16] While the Court so far has refused to hold that federal law preempts claims for injuries caused by pharmaceuticals, it has indicated that it may uphold future attempts by the FDA to preempt state tort law, leaving injured patients in a precarious position.[17] The Court's elimination of state common law tort claims for

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http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/default.htm.

9. Meredith Wadman, *Strong Medicine,* 11 NATURE MEDICINE 465, 465 (2005), *available at* http://www.nature.com/nm/journal/v11/n5/full/nm0505-465.html.

10. Lawrence O. Gostin, *The Deregulatory Effects of Preempting Tort Litigation: FDA Regulation of Medical Devices,* 299 JAMA 2313, 2314 (2008). *See also infra* Part II.B.

11. Gostin, *supra* note 10, at 2314. *See also infra* Part II.B.

12. *See infra* Part II.C.

13. *Id.*

14. Catherine Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 456 (2008) [hereinafter *Products Liability Preemption*].

15. *See infra* Part III.

16. Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

17. The year after *Riegel*, in *Wyeth v. Levine*, the Court held that a state failure-to-warn claim was not preempted by FDA regulation of prescription drugs, 129 S. Ct. 1187,

device harms both creates a compensation gap for victims and leaves holes in the FDA's regulatory scheme.[18] Given these developments, the future preemption of state tort claims by FDA regulation is not only possible, but likely.

As major changes in the balance of the Supreme Court seem unlikely, Congress must take swift action to protect patients' health and safety. Congress could amend the FDCA to clarify that the Act does not preempt tort claims for drug and device harms. Yet the strong opposition of powerful medical device companies, who are currently shielded from tort liability, may make such legislation politically infeasible. Attempts to reform the FDA—for example, by giving it more authority or more resources—may be derailed by similar political and practical difficulties.

A more feasible option would be to create a no-fault scheme for drug and device harms. No-fault schemes, such as workers' compensation and the National Vaccine Injury Compensation Program (NVICP), require that potentially harmful entities pay into a centralized fund, often through taxes.[19] These schemes then allow victims of certain harms to apply for compensation from the fund through a comparatively simple administrative process. A no-fault scheme for drug and device harms could both help people injured by pharmaceuticals and medical devices, and correct for the failures in the FDA regulatory process.[20] Importantly, such a solution may also be politically possible, as it may appeal to drug and device manufacturers, consumer advocates, and the plaintiffs' bar.

This Article discusses the factors that have led to this unique moment of interest-convergence[21] and describes what an effective no-fault scheme for drug and device harms might look like. Part II of this Article examines the obstacles to effective FDA regulation of drugs and devices and explains how tort law corrects for these failures. Part III examines the Supreme Court's recent jurisprudence on FDA preemption and the precarious fate of tort claims for drug and device harms. Part IV examines

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1204 (2009), but that the FDA had the authority to preempt these claims in the future if it engaged in a formal regulatory process, *id.* at 1200–1203.

18. *See infra* Part II.D.

19. *See infra* Part IV.

20. *See infra* Parts IV and V.

21. Professor Derrick Bell originated the principle of interest-convergence in the context of racial equality, arguing that "[t]he interest of blacks in achieving racial equality will only be accommodated when it converges with the interests of whites." Derrick Bell, Brown v. Board of Education *and the Interest-Convergence Dilemma,* 93 HARV. L. REV. 518, 523 (1980). The theory of interest-convergence can be applied more broadly to explain when and where courts and policymakers will take action that benefits less powerful groups—whether those groups are disfavored due to their race, gender, class, or sexual preference, or are simply comparatively poor and disorganized compared to their opponents. To paraphrase Professor Bell, these policies will be enacted if—and perhaps only if—they will secure, advance, or at least not harm societal interests deemed important by more socially, politically, and economically powerful groups. *Id.*

the viability of creating a no-fault compensation scheme for drugs and devices. It discusses several no-fault schemes currently in operation as well as the unique problems associated with creating a no-fault scheme for drugs and devices. Part V proposes a unique model for a no-fault scheme for drug and device harms that both ensures compensation for injured parties and attempts to replicate the information-gathering and educative effects of tort law.

## II.
## STATE TORT LAW COMPLEMENTS FDA REGULATION OF DRUGS AND DEVICES BY FILLING GAPS IN THE FDA'S REGULATORY SCHEME.

The FDA is responsible for "protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."[22] However, the FDA cannot accomplish this mission on its own. The agency is chronically underfunded, lacking the resources it needs to evaluate the costs and benefits of drugs and devices effectively.[23] Moreover, the FDA is structurally incapable of thoroughly evaluating these products, as the FDA's pre-market approval process does not uncover all of the potential harms of a drug or device before it enters the market. Nor does the FDA have adequate authority to monitor these products once they are in use by patients like Robert Ernst. Finally, manufacturers may hide information from the FDA, and regulators within the agency may have relationships with the manufacturers that prevent effective regulation (a problem often called "agency capture").[24] Tort law thus complements FDA regulation by compensating injured patients, identifying previously unknown harms, uncovering and deterring agency capture and manufacturer malfeasance, and educating the public about regulatory failure.

### *A. The FDCA Leaves Significant Gaps in the Regulation of Drug and Device Safety.*

#### *1. The FDA Does Not Have the Resources It Needs to Effectively Protect the Health and Safety of Americans.*

The FDA does not have sufficient resources to implement its

22. *What We Do*, FDA, http://www.fda.gov/aboutfda/whatwedo/default.htm (last visited June 22, 2011).

23. *See infra* Part II.A.1.

24. *See, e.g.*, Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039, 1060–67 (1997) (providing an overview of the theory of agency capture). *See also infra* Part II.A.4 (describing how the FDA's decision-making process can be hampered by agency capture).

regulatory scheme effectively. Like all agencies, the FDA must compete for a limited pool of tax revenue to fund its activities. Unfortunately, when Congress evaluates how much money to allocate to different interests and federal agencies, food and drug safety often loses out to more pressing or politically significant concerns. Congress has chronically starved the FDA of funds, even as the agency's functions have expanded and public concern for the safety of foods, drugs, and medical devices has increased.[25] Approximately 70 percent of FDA scientists believe that the FDA lacks sufficient resources to protect the public health, and two-thirds worry that the FDA is not adequately monitoring the safety of drugs once they are on the market.[26] The FDA's Science Board found that the agency needs "substantial and sustained additional appropriations" to properly fulfill its mission.[27]

### 2. *The FDA's Drug and Device Pre-Market Approval Processes Do Not Adequately or Accurately Assess Risk.*

Even if the FDA had sufficient resources to accomplish its mission, its approval process would not and could not uncover many of the potential harms and side effects caused by drugs and medical devices.[28] The FDA must approve new drugs, as well as many devices, before they enter the market. However, the FDA approval process does not, and does not intend to, ensure that those products are perfectly safe. Because "all drugs have serious potential side effects and all drugs are capable of serious harm if misused or abused," the safety of any drug is "relative."[29] The agency thus balances the "benefits and risks in advancing new and effective drug therapies."[30] Similarly, the Medical Device Amendments of

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25. Gostin, *supra* note 10, at 2314.

26. UNION OF CONCERNED SCIENTISTS, 2006 UCS AND PEER SURVEY OF U.S. FOOD AND DRUG ADMINISTRATION SCIENTISTS ¶ 1 (2006), *available at* http://ucsusa.wsm.ga3.org/scientific_integrity/interference/FDA-Survey-Questions-and-Results.html; OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., FDA'S REVIEW PROCESS FOR NEW DRUG APPLICATIONS: A MANAGEMENT REVIEW 12, 19 (2003), *available at* http://oig.hhs.gov/oei/reports/oei-01-01-00590.pdf (finding that significant numbers of FDA's own physicians and scientists reported pressure to recommend that drugs be approved even when they had reservations about safety or efficacy, and that two-thirds of the agency's drug reviewers lacked confidence that the agency "adequately monitors the safety of prescription drugs once they are on the market").

27. FDA SCIENCE BOARD, SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY 7 (2007).

28. *See* Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997) ("Even the most thorough regulation of a product . . . may fail to identify potential problems presented by the product.").

29. *See generally* SUBCOMM. ON SCI. RESEARCH AND TECH. OF THE H. COMM. ON SCI. AND TECH., 96TH CONG., THE FOOD AND DRUG ADMINISTRATION'S PROCESS FOR APPROVING NEW DRUGS 51 (Comm. Print 1980).

30. *Id.*

1976 (MDA),[31] a subset of the FDCA that governs medical devices, require the agency to "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use"[32] and "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives."[33]

This balancing unavoidably complicates doctors' and patients' decisions regarding treatment. In most cases, there are many ways to treat a given illness, including multiple drugs or devices and non-drug options. For example, patients suffering from arthritis, like Robert Ernst, are able to choose between several prescription drugs, such as Vioxx and Celebrex, and over-the-counter drugs, such as ibuprofen (the active ingredient in Advil) or naproxen sodium (the active ingredient in Aleve), to treat arthritis pain.[34] Because no drug or device is 100 percent safe for all people, doctors and patients cannot simply choose the "best" drug. Rather, they must weigh the risks and benefits of each option. In order to help patients make these decisions, doctors need both an accurate assessment of drug risks and an adequate method of learning about those risks in order to help patients make informed choices about their medical care. The information provided to patients and doctors, including the FDA's stamp of approval and the content and location of any warnings enclosed with a product, depends largely on the information provided by manufacturers during the pre-market approval process.

Before a new drug can reach the market, the manufacturer must follow the FDA's new drug approval (NDA) process to demonstrate the drug's safety and effectiveness with human subjects. In order to begin testing the drug on human subjects,[35] the manufacturer must first submit an investigational new drug application outlining the results of any pre-clinical research and describing how the manufacturer proposes to test the drug on humans.[36] The drug then goes through three phases of clinical

31. 21 U.S.C. § 360c *et seq.* (2002).

32. 21 U.S.C. § 360c(a)(2)(C) (2002).

33. Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008).

34. Mary Duenwald, *One Lesson from Vioxx: Approach New Drugs with Caution*, N.Y. TIMES, Oct. 5, 2004, at F5, *available at* http://www.nytimes.com/2004/10/05/health/05cons.html.

35. 21 C.F.R. § 314.126 (2002).

36. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (last visited Aug. 28, 2009) [hereinafter *The FDA's Drug Review Process*]. The Investigational New Drug (IND) application must include the names of parties responsible for the investigation, a statement of the investigational plan, a statement of the name of the drug to be tested and all its active ingredients, a summary of any previous human experience with the drug, a description of the overall plan for investigation, identification of phases of clinical investigation, a list of possible risks and side effects, a protocol for each planned study, and a summary of pharmacological and toxicological effects of the drug on animals. 21 C.F.R. § 312.23 (2000).

trials[37] in which the drug is tested on different populations with samples ranging from a few dozen to several thousand.

The FDA does not evaluate all medical *devices* with equal rigor. The MDA creates three categories of devices warranting different levels of oversight.[38] Only the most risky, Class III devices[39] undergo a pre-market approval process that parallels the rigorous approval process for prescription drugs. However, a Class III device that was on the market before the MDA went into effect[40] or that the FDA finds to be "substantially equivalent" to another device already on the market[41] is exempt from pre-market approval. Most new Class III devices enter the market through this second track without individualized pre-market

37. 21 C.F.R. § 312.21 (2000). In Phase 1, testing is usually conducted using 20 to 80 healthy volunteers, § 312.21(a), who are monitored to determine what the drug's most frequent side effects are and how the drug is metabolized and excreted, *The FDA's Drug Review Process*, *supra* note 36. According to media reports, many participants in these Phase 1 studies are drawn from a relatively small population of "professional research subjects" who frequently participate in clinical trials for financial gain. Carl Elliot, *Guinea-pigging; Healthy human subjects for drug-safety trials are in demand. But is it a living?*, THE NEW YORKER, Jan. 7, 2008, at 36. In Phase 2, from a few dozen to as many as 300 symptomatic patients (i.e., patients who have the condition the drug is intended to treat) participate in controlled trials that compare patients receiving the drug with similar patients receiving a different treatment—usually a placebo or a different drug. § 312.22(b) (2001); *The FDA's Drug Review Process*, *supra* note 36. In Phase 3, several hundred to about 3,000 people participate in studies that examine the effectiveness and safety of the drug in different populations, at different dosages, and in combination with other drugs. § 312.22(c); *The FDA's Drug Review Process*, *supra* note 36. At the close of Phase 3 testing, the manufacturer may submit the actual new drug application, which includes data collected and analyzed during experimentation, to the FDA. *See* 21 U.S.C. § 355(b) (2006).

38. The least risky Class I devices, which include devices such as elastic bandages and examination gloves, are only subject to "general controls," such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A) (2006). The more risky Class II devices, which include such devices as powered wheelchairs and surgical drapes, are subject to additional "special controls" such as performance standards and post-market surveillance measures. 21 U.S.C. § 360c(a)(1)(B).

39. In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii). Like the NDA process, a manufacturer applying for approval of a new device must submit a report to the FDA that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. 21 U.S.C. § 360e(c).

40. 21 U.S.C. § 360e(b)(1).

41. 21 U.S.C. § 360c(f)(1)(A)(ii).

approval.[42]

Despite these procedures, the FDA approval process routinely fails to uncover adverse effects caused by drugs and devices. As pharmaceuticals often have side effects that occur only in a narrow sub-sample of the population,[43] some side effects rarely emerge during the NDA process. One-half or more of a new drug's adverse reactions may not be discovered until after it is on the market and in widespread use.[44] Furthermore, some adverse effects take time to develop, and may not show up until patients have been using a product for months or even years.[45] The NDA process thus "virtually guarantees that the full risks and complete safety profile of these drugs will not be identified at the time of approval."[46]

The data collected through the FDA's pre-market approval process also may not be predictive of the risks and benefits of the drug for the average patient. Controlled experimental conditions do not duplicate physicians' day-to-day practices.[47] Nor does the NDA process account for

42. In 2005, for example, the FDA authorized the marketing of 3,148 devices that were "substantially similar" to other devices and granted pre-market approval to just 32 devices. PETER HUTT, RICHARD MERRILL, & LEWIS GROSSMAN, FOOD AND DRUG LAW 992 (3d ed. 2007).

43. Robert Rabin, *Regulatory Compliance as a Defense to Products Liability*, 88 GEO. L.J. 2049, 2077 (2000).

44. Bruce Kuhlik & Richard Kingham, *The Adverse Effects of Standardless Punitive Damage Awards on Pharmaceutical Development and Availability*, 45 FOOD DRUG COSM. L.J. 693, 696 (1990). According to one former FDA Deputy Commissioner for Policy, most clinical trials "can detect drug-related injuries that occur at a rate of between one in 500 and one in 1,000. Yet, if the drug is used by 200,000 people . . . a serious adverse event appearing in as few as one in 10,000 people is very significant, since it would occur 20 times. These rare reactions can be identified only after a drug has been widely used." William B. Schultz, *How To Improve Drug Safety*, WASH. POST, Dec. 2, 2004, at A35 (Mr. Schultz served as the FDA's Deputy Commissioner for Policy from 1994 to 1998). Many drugs are used by far more patients. Vioxx, for example, was used by an estimated 20 million patients. *See In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 779 (E.D. La. 2007).

45. Rabin, *supra* note 43, at 2077.

46. Catherine D. DeAngelis & Phil B. Fontanarosa, *Prescription Drugs, Tort Liability, and Preemption of Tort Litigation*, 300 JAMA 1939, 1939 (2008).

47. Kuhlik & Kingham, *supra* note 44, at 696 (*citing* ALFRED GILMAN, THEODORE RALL, ALAN NIES & PALMER TAYLOR, GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 64 (8th Ed. 1990) ("The results of clinical trials . . . may have severe limitations in terms of what can be expected of drugs when they are used in an office practice."). For example, researchers in a clinical trial have both knowledge of and control over most aspects of their subjects' lives, from when and whether they take their medication, to what and how much they eat, to what other activities they engage in. Ordinary doctors do not have such knowledge of or control over their patients' lives. Additionally, to the extent that Phase 1 testing relies on "professional research subjects," it may not be a representative sample of the population at large. For example, "professional research subjects," by definition, participate in multiple clinical trials. These subjects may be particularly resilient to drug and device harms compared to the average person, such that the medical costs of their participation are lower than the financial benefits. If these "professionals" suffered significant side effects during clinical trials, they would likely avoid future studies or would be screened out as potential subjects by the researchers themselves.

"off-label" use—i.e., the prescription of a drug for a use not approved by the FDA—even though the FDA and physicians endorse this practice.[48]

Because the data regarding adverse effects is necessarily incomplete at the time of approval, post-market action is often necessary to protect the health and safety of the public. An analysis of 174 biological products (e.g., antibodies, hormones, or enzymes) approved from January 1995 through June 2007 found that U.S. national and international drug regulatory agencies, including the FDA, took post-market safety-related regulatory actions against 23.6 percent of products.[49] A similar study of 548 new chemical entities found that 10.2 percent either acquired additional serious warnings or were withdrawn from the market entirely after problems arose in post-market use.[50]

### *3. The FDA Does Not Have an Effective System for Monitoring Drugs or Devices Following Approval.*

After a drug or device enters the market, the FDA has limited authority to mandate further data collection, either to identify adverse effects or to ensure compliance with labeling requirements such as the content and placement of warnings.[51] To identify emergent adverse effects, the FDA relies on the Adverse Effect Reporting System (AERS), which compiles information submitted by patients and doctors regarding perceived side effects, post-market studies conducted by manufacturers, and its own research using databases of patients' health records.[52]

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Elliot, *supra* note 37, at 36.

48. *See, e.g.*, 21 U.S.C. § 396 (2009) ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize."). In 1994, for example, 40 to 60 percent of all drugs were prescribed for off-label uses. *See* Fran Kritz, *FDA Seeks to Add Drugs' New Uses to Labels*, WASH. POST, Mar. 29, 1994, at Z11 (quoting a physician who was vice president of science and education for the American Medical Association).

49. DeAngelis & Fontanarosa, *supra* note 46, at 1939. Fourteen percent of the products analyzed had an initial safety-related regulatory action taken against them for the first time less than three years after approval; this number increased to 29 percent by ten years after approval. *Id.*

50. Karen E. Lasser, Paul D. Allen, Steffie J. Woolhandler, David U. Himmelstein, Sidney M. Wolfe & David H. Bor, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2215–20 (2002).

51. INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 156–57 (Alina Baciu, Kathleen Stratton & Sheila P. Burke eds., 2006) [hereinafter "IOM REPORT"].

52. If a manufacturer becomes aware of overdoses or any other reaction that is fatal, life-threatening, permanently disabling, or results in congenital anomaly or cancer through

However, because of the FDA's limited ability to force manufacturers to conduct further testing on their products and the limited effectiveness of its data mining efforts, the FDA's primary methods for post-market monitoring remain largely passive.

Currently, the FDA can only *require* post-market studies as a condition of approval in the rare cases when a new drug for a serious or life-threatening illness is given accelerated approval, or where pre-market testing on humans is considered unethical and testing is instead conducted on animals.[53] In the vast majority of cases, the FDA can only *request* that companies voluntarily perform post-marketing studies (so-called Phase 4 studies) for other drugs.[54] Yet the FDA has little leverage to ensure that these studies are carried out.[55] Less than one-quarter of the Phase 4 studies requested by the FDA have ever been completed, and many have never been started.[56] This abysmal completion rate may be explained by the voluntary nature of these studies, as the FDA has no recourse when drug manufacturers do not make progress or do not report on their commitments.[57] The Department of Health and Human Services has also reported "that postmarketing study commitments do not have a high

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new scientific literature, post-marketing studies, commercial marketing experience, consumers, or healthcare providers, it must report the event to the FDA within 15 days. 21 C.F.R. § 314.80(a), (c)(1) (2006); FDA, DRAFT GUIDANCE FOR INDUSTRY: POST-MARKETING SAFETY REPORTING FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS INCLUDING VACCINES (2001), *available at* http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074850.htm#WHATDOIREPORT. Less severe reactions must be reported every quarter for the first three years after approval and annually thereafter. § 314.80(c)(2). These annual reports must include any alterations in product manufacturing, labeling, or chemistry and any new clinical or animal test data available on a drug, whether or not the manufacturer created the test data. 21 C.F.R. § 314.81(b)(2) (2009) (specifying contents of mandatory annual post-market reports).

53. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 11 (2006) [hereinafter "GAO REPORT"]. A post-market study is similar to the large clinical trials that would ordinarily take place during Phase 3. Where these studies are required, the FDA may withdraw approval of these drugs if the studies fail to verify the drug's benefits or labeling or use restrictions that are inadequate to ensure safe use of the drug. *Id.*

54. *See* IOM REPORT, *supra* note 51, at 156 (describing a Department of Health and Human Services Report that found that "91 percent of postmarketing commitments between 1990 and 2004 were requested by the agency rather than being required by statute or regulation").

55. GAO REPORT, *supra* note 53, at 28; *see also* IOM REPORT, *supra* note 51, at 156 ("The 2005 Federal Register notice on sponsor progress in meeting post-marketing study commitments showed that 797 (65 percent) of New Drug Applications (NDAs) and abbreviated NDA-related postmarketing commitments are 'pending' (they are neither 'ongoing' nor 'delayed') and 47 percent of annual reports on studies that were due were not submitted to FDA.").

56. GAO REPORT, *supra* note 53, at 28.

57. IOM REPORT, *supra* note 51, at 156.

priority in the FDA, [and] the agency lacks a system for managing postmarketing study commitments."[58] At the same time, while the FDA has limited authority to subpoena private information and to require manufacturers to produce new information, the agency uses these powers conservatively because of the agency's limited resources and a fear of political backlash[59] from the Congressional allies of well-connected manufacturers who can use procedural and political tools, such as hearings, to delay the funding and operations of FDA activities.

While the Food and Drug Administration Amendments Act of 2007 (FDAAA) gave the FDA new resources to monitor the safety of drugs on the market,[60] it is unclear at the time of this writing how this will change the FDA's post-market monitoring process. The Act expanded the agency's power to require manufacturers to undertake Phase 4 studies,[61] permitting the FDA to do so if it recognizes a "known serious risk" or "signals of a serious risk" related to the drug, or if it seeks to "identify an unexpected serious risk" based on "new safety information."[62] The Act also requires manufacturers to set timetables for the completion of Phase 4 studies and file periodic status reports.[63]

The FDAAA also requires the agency to examine patient health records in existing electronic databases, including data from the Medicare program and private insurers, in order to identify patterns of patient injury that may indicate the existence of previously unknown side effects of drugs or combinations of drugs.[64] However, the efficacy of the FDA's data mining efforts is limited. The results of data mining are only as accurate as the databases analyzed and the algorithm used to identify correlations. Yet the government databases that the FDA is supposed to analyze contain limited information about patient safety. Moreover, these databases—particularly the Medicare database—are currently prohibited by law from being used to report adverse drug reactions and cannot be used for this purpose until existing statutes are amended.[65] It is therefore questionable whether this database surveillance technique will actually help the agency recognize emerging safety problems. Even if the FDA were to gain access

58. *Id.*

59. Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 699 (2007).

60. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.) [hereinafter FDA Amendments Act].

61. 21 U.S.C. § 355(o) (2006); FDA Amendments Act § 901(a)(o), 121 Stat. at 922–24.

62. 21 U.S.C. § 355(o)(3); FDA Amendments Act § 901(a)(o)(3), 121 Stat. at 923–24.

63. 21 U.S.C. § 355(o)(3)(E)(ii); FDA Amendments Act § 901(a)(o)(3)(E)(ii), 121 Stat. at 924.

64. David Kessler & David Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure to Warn Claims*, 96 GEO. L.J. 461, 472 n.46 (2008).

65. *Id.* at 472 n.47.

to this data, it is of limited utility from an epidemiological standpoint. Because the FDA lacks critical information about the population using a drug, such as how many patients there are and what their individual conditions are, the agency may have difficulty determining the incidence rate of a given adverse reaction—information necessary to formulate an informed response.[66]

In the absence of effective proactive monitoring tools, the FDA's primary resource in conducting post-market drug surveillance remains the Adverse Event Reporting System (AERS), which compiles information submitted by manufacturers, patients, and doctors regarding perceived side effects.[67] Once the FDA receives reports of adverse events, clinical reviewers at the agency evaluate the reports.[68] The MDA subjects medical devices to similar reporting requirements after approval.[69]

Unfortunately, AERS does not provide the FDA with sufficient information to make informed decisions about the existence of drug and device harms. The Department of Health and Human Services has found that many manufacturers' completed annual reports "lack useful information."[70] At the same time, because individual patients and healthcare providers are not required to report adverse events and many adverse events are not widely publicized, the FDA admits that it "does not receive all adverse event reports that occur with a product."[71] In fact, the FDA estimates that it hears about less than 1 percent of serious adverse reactions.[72] A report by the Institute of Medicine echoes this estimate, noting that although the FDA receives more than 400,000 reports each

66. *Id.* at 490.

67. *See supra* note 52.

68. *FDA Uses A Number Of Approaches To Assess Postmarketing Risk*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/Safety/SafetyofSpecificProducts/ucm180551.htm (last visited Sept. 4, 2011).

69. 21 U.S.C. § 360i (2006). Manufacturers are obligated to inform the FDA of any new clinical investigations or scientific studies concerning the device that the manufacturer knows or reasonably should know of. 21 C.F.R. § 814.84(b)(2). Manufacturers are also obligated to report incidents in which the device may have caused or contributed to death or serious injury or malfunctioned in a manner that would likely cause or contribute to death or serious injury if the malfunction recurred. § 803.50(a). Hospitals and nursing homes are also required to report deaths caused by medical devices to both the FDA and the manufacturer, and serious injuries to the manufacturer or to the FDA, if the manufacturer is unknown. *Reporting By Health Professionals*, FDA, http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm (last visited Mar. 14, 2010).

70. IOM REPORT, *supra* note 51, at 156.

71. *Adverse Events Reporting System (AERS)*, FDA, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm (last visited Mar. 14, 2010).

72. *Reauthorization of the Prescription Drug User Fee Act: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. 49 (2002) (statement of Rep. Henry A. Waxman).

year, this is only a "small fraction of all adverse effects of drugs."[73]

Given these limitations in the AERS data, it is difficult for the FDA to determine whether post-market action is necessary. For example, because it does not have information on how many patients are using any given drug, the FDA cannot calculate the frequency with which an adverse event occurs, making it difficult to identify the magnitude of the problem and to compare similar drugs.[74] Nor can the FDA easily identify a causal connection between a drug and an adverse event, particularly when the incidence rate of the adverse event in the user population is already high—for example, heart attacks among a user population of older adults.[75] Without such "new safety information," the FDA cannot exercise its powers under the FDAAA to require the manufacturer to undertake Phase 4 studies.

Even when the FDA is aware of dangerous side effects associated with drugs and devices, the agency's decision-making structure has proven unable to make efficient and accurate decisions about whether action, such as adding a warning or removing the drug from the market, is necessary. According to the Government Accountability Office (GAO), the FDA "lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket safety issues."[76] Two organizationally distinct FDA offices with different missions and different levels of responsibility are involved in post-market drug safety activities.[77] However, these offices often do not communicate with each other, and lines of responsibility about post-market decision-making are unclear.[78] The GAO found that these problems are exacerbated by "a lack of criteria for determining what safety actions to take and when to take them."[79] As such, the FDA cannot make effective post-market regulatory decisions.[80]

#### 4. *The FDA's Decision-Making Process Is Hampered by Manufacturer Malfeasance and Agency Capture.*

Manufacturers' influence over regulators and malfeasance impair the FDA's ability to make accurate and effective decisions. Agency capture can hinder effective regulatory decision-making by biasing the FDA

73. IOM REPORT, *supra* note 51, at 53. The low reporting rate from physicians and manufacturers is unsurprising. The system relies on the ability of busy medical professionals to draw correlations between a particular drug and adverse events and to use valuable time to report the problem rather than to simply stop using the drug and treat the symptoms.

74. GAO REPORT, *supra* note 53, at 24.

75. *Id.* at 25.

76. *Id.* at 5.

77. *Id.*

78. *Id.*

79. *Id.* at 18.

80. *Id.* at 5.

toward decisions that benefit drug and device manufacturers, such as by undervaluing the risks associated with a new drug or device. Manufacturer malfeasance, by contrast, limits or alters the field of information available to the FDA, preventing the agency from knowing of these risks at all.

Agency capture is neither a new concept nor a problem unique to the FDA.[81] However, the tension between the FDA's two missions—to "protect[] the public health by assuring the safety, efficacy and security of human and veterinary drugs . . . [and] medical devices" and to "advanc[e] the public health by helping to speed innovations that make medicines more effective, safer, and more affordable"[82]—make the agency vulnerable to manufacturer influence. In some cases, manufacturers' interests in getting their drugs and devices to the market as fast as possible and keeping those drugs and devices on the market may occasionally converge with the interests of a subset of the general public: for example, patients with serious or terminal illnesses and their families have long criticized the FDA for failing to approve new drug therapies fast enough, or for revoking approval after a drug proves to be unsafe for some patients.[83] At the same time, the FDA is at a particular disadvantage in trying to learn the general public's preferences for drug and device safety. As in other cases of agency capture, the regulated industry is "well-financed and well-organized, especially when compared to the general public and public interest groups," making them "better positioned to monitor agencies closely and to challenge any and all agency decisions that will negatively affect them."[84] In many cases, public interest organizations such as the American Civil Liberties Union or Natural Resourced Defense Council can act as a check to industry influence by lobbying on behalf of otherwise diffuse constituencies. There is no equivalent public interest organization

81. *See* Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1713 (1975) ("It has become widely accepted, not only by public interest lawyers, but by academic critics, legislators, judges, and even by some agency members, that the cooperative overrepresentation of regulated or client interests in the process of agency decision results in a persistent policy bias in favor if these interests.").

82. *What We Do*, FDA, http://www.fda.gov/aboutfda/whatwedo/default.htm (last visited Jan. 28, 2011).

83. *See, e.g.*, Lars Noah, *Pigeonholing Illness: Medical Diagnosis as a Legal Construct*, 540 HASTINGS L.J. 241, 291 (1999) ("More recently, most notably in the case of AIDS, patients have formed advocacy groups to lobby legislators and regulators to support research and accelerate the availability of potential treatments."); Andrew Pollack, *F.D.A. Plans to Revoke Approval for Breast Cancer Drug*, N.Y. TIMES (Dec. 16, 2010, 11:12 AM), http://prescriptions.blogs.nytimes.com/2010/12/16/f-d-a-revokes-approval-for-breast-cancer-drug/?scp=2&sq=fda%20AND%20%22drug%20manufacturer%22&st=cse (stating that, when an FDA advisory committee voted to revoke FDA approval for using the drug Avastin to treat breast cancer, "breast cancer patients and some patient advocacy groups have . . . urged the F.D.A. to keep the drug approved and not deny patients a chance at what they say could be a life-saving therapy").

84. Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Agency Institutional Design*, 89 TEX. L. REV. 15, 22 (2010).

to lobby on behalf of "the public's" optimal level of safety versus innovation. Instead, interest groups are often disease- or disorder-specific and may have internal disagreements about the optimal level of federal regulation.[85]

As the voting patterns of the FDA's Vioxx review panel demonstrate, manufacturer influence over the FDA is an ongoing problem.[86] The FDA has frequently conceived of itself as an ally of pharmaceutical and medical device manufacturers. As early as the 1970s, the FDA established a policy of cooperating with drug manufacturers, and sought to "block reviewing medical officers who followed a different philosophy."[87] In the Clinton Administration, FDA officials continued this policy, referring to the pharmaceutical industry as "our clients."[88]

The pro-manufacturer culture of the FDA has arguably affected agency decision-making. For example, FDA scientists have claimed that when they recommended approval of a drug, their analyses were rarely challenged by their superiors, but when they recommended not to approve a drug, their recommendations were not followed against the weight of evidence about safety.[89] These scientists felt pressure to favor the interests of manufacturers; in some cases, they even received requests directly from

85. *See, e.g.*, Pollack, *supra* note 83 (describing dispute among breast cancer advocacy groups over the drug Avastin).

86. *But see* Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2154 (2000) (suggesting that "health and safety agencies like the FDA have become more beholden to groups that purport to represent the public interest" than to the regulated industries); Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 480 (1997) ("[A]ny pro-industry bias or influence that may exist with regard to the new drug approval process in the FDA has been outweighed by countervailing risk aversion born of concern about public and congressional calumny in the event of the approval of a new drug that turns out to be a successor to thalidomide."); Mary K. Olson, *Regulatory Agency Discretion Among Competing Industries: Inside the FDA*, 11 J.L. ECON. & ORG. 379, 404 (1995) ("[T]he FDA appear[s] very responsive to the consumer signals in the case of [pharmaceuticals] . . . . From the FDA's perspective, the threat of adverse feedback from consumers seems to dominate the complaints of the drug industry regarding regulatory delay.").

87. John Abraham, *The Pharmaceutical Industry as a Political Player*, 360 LANCET 1498, 1498 (2002).

88. ALICIA MUNDY, DISPENSING WITH THE TRUTH: THE VICTIMS, THE DRUG COMPANIES, AND THE DRAMATIC STORY BEHIND THE BATTLE OVER FEN-PHEN 53 (2001). In 1992, the FDA hired a scientist who had invented a diet drug combination. *Id.* at 48–49. As an FDA employee, the scientist continued to promote his product aggressively in the media and at public meetings, downplaying the evidence that it could have devastating side effects. *Id.* at 61, 70–71. The agency approved its employee's drug, but it was removed from the market after reports surfaced that it caused fatal heart and lung diseases. *Id.* In the late 1990s, several FDA scientists who released documents concerning troglitazone, a diabetes drug, to Congress because of their concerns about post-market risks received threats of disciplinary action from agency management. Abraham, *supra* note 87, at 1498.

89. Abraham, *supra* note 87.

senior agency officials to alter their conclusions.[90]

Concerns about agency capture have also arisen due to close relationships between FDA regulators and manufacturers, as well as instances where the FDA's regulatory decisions appear to favor manufacturers. While industry influence over Congress and medical researchers is well known, FDA regulators often have similarly close relationships with the manufacturers they are meant to monitor.[91] For example, while the FDA was debating whether to allow the diabetes drug Avandia to remain on the market, Dr. John Jenkins, who was then the director of the FDA's Office of New Drugs, argued that Avandia should remain on the market and "briefed the [manufacturer] extensively on the agency's internal debate."[92] Given these conflicts of interest, it is unsurprising that the FDA has been criticized for making questionable decisions that have ultimately benefitted manufacturers.[93]

FDA decision-making has also been hampered by manufacturer malfeasance. As mentioned above, the FDA depends on drug and device manufacturers for the information it needs to make effective regulatory judgments. However, evidence suggests that companies have deliberately avoided discovering possible drug or device harms. For example, after studies linked Baycol, a medicine used to lower cholesterol and prevent cardiovascular disease, to thirty-one deaths and many more hospitalizations, Bayer, the drug's manufacturer, removed the drug from the market in 2001.[94] Litigation documents later revealed that Bayer had received reports suggesting the presence of fatal risks as early as 1999 but

90. *Id.* Similarly, Dr. Rosemary Johann-Liang, a former supervisor in the FDA's drug safety office, was disciplined for recommending that diabetes drug Avandia's heart warnings be strengthened. Gardiner Harris, *Diabetes Drug Maker Hid Test Data, Files Indicate*, N.Y. TIMES, July 13, 2010, at A1, *available at* http://www.nytimes.com/2010/07/13/health/policy/13avandia.html.

91. For example, the FDA's drug advisory committees are composed of "experts" who recommend whether to approve a product based on data submitted with an NDA. *USA Today* found that 54 percent of these experts had a financial stake in the outcome, including ownership of stock, research grants and consulting arrangements with the company submitting the NDA. Dennis Cauchon, *FDA Advisers Tied to Industry*, USA TODAY, Sept. 25, 2000, at A1. These financial ties create obvious conflicts of interest.

92. Harris, *supra* note 90.

93. *See* GAO REPORT, *supra* note 53, at 1 (criticizing the FDA "for taking too long to tell physicians and patients about studies linking the use of antidepressants among children to an increased risk of suicidal behavior" and for "not act[ing] quickly enough on evidence it obtained . . . about the cardiovascular risks of Vioxx, an anti-inflamatory drug"); Kurt R. Karst, *Going 90 in a 55 M.P.H. Speed Zone: Reprocessing of Used Single-Use Medical Devices and the Food and Drug Administration's Non-Enforcement of the Food, Drug, and Cosmetic Act*, 56 FOOD & DRUG L.J. 57, 58 (2001) (criticizing the FDA's refusal to enforce the requirement that medical devices designated for single use not be reused).

94. Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 309 (2007); *Baycol (cerivastatin sodium tablets) Aug. 2001*, FDA, http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm172268.htm (last visited Mar. 14, 2010).

did not process all of them.[95] A memorandum from a company official stated, "If the FDA asks for bad news, we have to give, but if we don't have it, we can't give it to them."[96]

In other cases, manufacturers may deliberately conceal information about known adverse effects. For example, studies emerged a few years after the approval of the antipsychotic Zyprexa linking the drug to weight gain and diabetes.[97] Documents uncovered from Zyprexa litigation revealed that the drug's manufacturer, Lilly, had long downplayed and kept secret research that linked use of the drug to weight gain and hyperglycemia, telling its salespeople, "Don't introduce the issue!!!"[98] Similarly, drug manufacturer SmithKline Beecham hid evidence of its diabetes drug Avandia's effects on the heart from the FDA and the public for nearly eleven years.[99] According to an email written by a SmithKline executive, "Per Sr. Mgmt request, these data should not see the light of day to anyone outside of" the company.[100]

The FDAAA sought to limit the opportunities for such malfeasance by requiring manufacturers to disclose data from drug and device trials to the FDA for inclusion in the agency's Clinical Trial Registry Databank.[101] The disclosures, however, "are often little more than cryptic references, so the issue is far from resolved."[102] Because the FDA relies on the information it receives from manufacturers and has limited power to demand information from those manufacturers, such instances of malfeasance are difficult, if not impossible, for it to uncover.

### *5. The FDCA Does Not Create a Private Right of Action or Provide a Mechanism to Compensate Patients Injured by Approved Drugs.*

The FDA does not compensate patients for injuries caused by drugs or

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95. Kesselheim & Avorn, *supra* note 94.

96. *Id.* Similarly, documents uncovered in lawsuits over Johnson & Johnson's Propulsid, a drug used to treat acid reflux, revealed that the company did not conduct safety studies urged by the FDA and its own consultants, which could have revealed the drug's danger early on. Gardiner Harris & Eric Koli, *Lucrative Drug, Danger Signals and the F.D.A.*, N.Y. TIMES, June 10, 2005, at A1, *available at* http://www.nytimes.com/2005/06/10/business/10drug.html.

97. Kesselheim & Avorn, *supra* note 94.

98. *Id.* Merck similarly failed to disclose clinical trial results that indicated that painkillers like Vioxx might be dangerous to the heart. Alex Berenson, *Despite Vow, Drug Makers Still Withhold Data*, N.Y. TIMES, May 31, 2005, at A1, *available at* http://www.nytimes.com/2005/05/31/business/31trials.html.

99. Harris, *supra* note 90.

100. *Id.*

101. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85 § 801, 121 Stat. 823, 904–22 (codified as amended at 42 U.S.C. § 282, 21 U.S.C. §§ 331, 333, 335, 360).

102. Harris, *supra* note 90.

medical devices.[103] Nor does the FDCA create a private right of action that would allow people like Carol Ernst to sue manufacturers for failing to comply with FDA regulations.[104] Even in some cases where manufacturers deliberately lied to the FDA, injured patients and their families have no way to be compensated, as the Supreme Court ruled that state law "fraud-on-the-FDA" claims are preempted by the FDCA.[105]

### *B. State Tort Claims Permit Injured Patients to Sue Drug Manufacturers and Recover for Their Injuries.*

For decades, private enforcement of tort law has worked in concert with FDA regulation to protect the health and safety of the American public. Because FDA approval of a drug does not ensure absolute safety, it often does not preclude a finding of negligence in tort. In most states, courts have traditionally viewed these common law tort claims as supplementing the minimum safety thresholds established by the FDA.[106] This means that drug manufacturers cannot escape tort liability to injured patients simply by stating that the manufacturers complied with FDA regulations.[107] These liability rules permit patients to be compensated for drug- and device-related harms. In doing so, these rules punish negligent manufacturers and also shift the economic losses associated with harms to the manufacturer who caused the harm.[108] These rules thus deter manufacturers from marketing harmful products.[109]

Tort liability complements FDA regulation by offering injured patients and their families a number of limited remedies. A patient injured by a drug or device may sue her physician for medical malpractice and/or the retailer of the drug or device for distributing a defective product or failing to exercise reasonable care at or near the time of sale.[110] She may also sue the drug or device manufacturer in negligence or strict product

103. Wyeth v. Levine, 129 S. Ct. 1187, 1199 (2009) ("Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the [original] 1938 statute or in any subsequent amendment.").

104. *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001).

105. *Id.* at 353.

106. *See, e.g.*, James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure To Warn,* 65 N.Y.U. L. REV. 265, 320 (1990) ("[C]ourts have not deferred to the determinations of product safety agencies such as the Food and Drug Administration . . . . The analysis usually begins and ends with the statement that agency standards are minimum, not maximum, standards and that courts are therefore free to disregard them.").

107. Sylvia A. Law, *Tort Liability and the Availability of Contraceptive Drugs and Devices in the United States*, 23 N.Y.U. REV. L. & SOC. CHANGE 339, 352 (1997).

108. *See* Randall R. Bovbjerg & Frank A. Sloan, *No-Fault for Medical Injury: Theory and Evidence*, 67 U. CIN. L. REV. 53, 57 (1998).

109. *See id.*

110. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1998).

liability. Manufacturers can therefore be held accountable for distributing unreasonably harmful products,[111] distributing products with manufacturing defects,[112] failing to warn patients of risks,[113] or fraudulently misrepresenting products.[114]

### *C. Tort Law Helps Fill the Gaps in the FDA's Regulatory Scheme.*

State tort claims complement the FDA's regulatory efforts. By permitting patients to sue drug and device manufacturers, the common law corrects for the FDA's inability to accurately assess product safety by discouraging manufacturer malfeasance. In addition, tort litigation "can help uncover previously unavailable data on adverse effects, questionable practices by manufacturers, and flaws in drug regulatory systems."[115] In the absence of a federal remedy for drug or device harms, state tort law provides the only avenue for injured patients to be compensated for their injuries.

#### *1. Tort Suits Deter Bad Behavior.*

The threat of litigation incentivizes drug manufacturers to properly disclose pre-market and post-market safety information by creating the threat of substantial monetary damages and reputational costs in cases of misconduct. Moreover, common law claims based on wrongful manipulation of the regulatory process "provide a necessary counterforce to discourage 'sweetheart' deals in which the agency shirks its regulatory responsibilities in order to curry favors from regulated industries."[116] At

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111. *Id.* § 6(c) ("A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.").

112. *Id.* § 2(a) ("A product . . . contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.").

113. *Id.* § 6(d) ("A prescription drug or medical device is not reasonably safe because of inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.").

114. *Id.* § 9 ("One engaged in the business of selling or otherwise distributing products who, in connection with the sale of a product, makes a fraudulent, negligent, or innocent misrepresentation of material fact concerning the product is subject to liability for harm to persons or property caused by the misrepresentation.")

115. Kesselheim & Avorn, *supra* note 94, at 308.

116. Thomas O. McGarity, *Beyond* Buckman*: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 564 (2002). *See also* Paula

the same time, the causation requirements in tort claims, as well as the expense of bringing suit, deter patients from bringing frivolous claims.

### 2. *Tort Suits Produce Valuable Information About the Safety of Drugs and Devices and Educate the Public About Agency and Manufacturer Practices.*

Litigation has the unique ability to bring to light valuable information about the risks associated with drugs and devices through the discovery process, in which each side shares previously unavailable information relating to the issue in dispute.[117] Because lawyers in discovery have "the right to subpoena relevant information from any source," they have more extensive information-gathering tools than the FDA.[118] Litigation thus brought to light the risks associated with the sleeping medication Halcion, the arthritis medication Zomax, ultra-absorbent tampons, and the weight loss pill Ephedra; these suits led the FDA to take Halcion, Zomax, and Ephedra off the market, and encouraged the agency to regulate tampons more rigorously.[119]

In some cases, tort suits have uncovered information that was in the FDA's possession but was never made available to doctors who were prescribing the medication for off-label use.[120] For example, the drug Bextra was submitted for approval in 2001 for treatment of dysmenorrhea, osteoarthritis, rheumatoid arthritis, and acute pain.[121] The FDA approved the drug for use in treating the first three ailments, but not for treating acute pain.[122] The agency acquiesced to the manufacturer's request not to release safety and efficacy data from the pain-related trials, even though physicians were likely to use the drug "off label" for that purpose.[123] It was only after the consumer advocacy group Public Citizen initiated a lawsuit that the FDA released most of the contested safety information, including

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Jacobi, *Pharmaceutical Tort Liability: A Justifiable Nemesis to Drug Innovation?*, 38 J. MARSHALL L. REV. 987, 999 (2005) (noting that opponents of an FDA regulatory compliance defense argue that "[w]ithout the overarching deterrence provided by tort liability, the FDA is more vulnerable to agency capture—where the FDA is 'controlled' by the industry it is charged with regulating").

117. *See* McGarity, *supra* note 116, at 571. Others, however, have argued that "litigation does not collect post-market drug safety information systematically enough to be useful to regulators." James R. Copland & Paul Howard, *In the Wake of* Wyeth v. Levine*: Making the Case for FDA Preemption and Administrative Compensation*, 1 PROJECT FDA REPORT 5 (2009).

118. Kessler & Vladeck, *supra* note 64, at 492.

119. Wagner, *supra* note 59, at 711–12 & n.82 (Halcion); *id.* at 709 n.73 (Zomax); *id.* at 711 (ultra-absorbent tampons); *id.* at 711–12 (Ephedra).

120. Kesselheim & Avorn, *supra* note 94, at 308.

121. *Id.*

122. *Id.*

123. *Id.*

the fact that a FDA medical officer found "an excess of serious adverse events including death."[124]

In other cases, litigation has uncovered evidence that companies deliberately withheld information from the FDA. For instance, in 2005, litigation against Pfizer uncovered a previously unpublished clinical study from 1999 that showed a statistically significant increase in heart attacks among users of Pfizer's Celebrex.[125] Similarly, breast implant litigation "was uniquely successful in divulging important, asymmetric information about the risks of implants held by implant manufacturers," including information that one major manufacturer of implants not only knew its implants were leaking, but suppressed internal research that assessed the risks associated with the leakage.[126]

Litigation also spurs additional research by manufacturers and independent academics about the safety of drugs and devices. Research on breast implant safety, for example, resulted largely from the pressures created by litigation. In the wake of early plaintiff verdicts, manufacturers began investing in implant safety research.[127] Without the litigation, there may have been little additional research.[128]

By bringing to light new data and prompting new research, tort law plays a unique role in facilitating public access to information about drugs and devices, the companies that manufacturer them, and the agency that regulates them. Tort scholar Robert Rabin, among others, has highlighted the "singular role of the courts in educating the public about unscrupulous and socially dangerous business practices detrimental to the public health."[129] As described above, the FDA cannot independently investigate drug safety, but must rely on the information provided to it by manufacturers. As such, we are "substantially dependent on the tort system to provide the educational function of revealing massive cover-ups

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124. *Id.*

125. Alex Berenson & Gardiner Harris, *Pfizer Says 1999 Trials Revealed Risks with Celebrex*, N.Y. TIMES, Feb. 1, 2005, at C1, *available at* http://www.nytimes.com/2005/02/01/business/01drug.html. Pfizer did not submit the study to the FDA until 2001 and never published it. *Id.*

126. Wagner, *supra* note 59, at 715.

127. *Id.* at 718.

128. *See, e.g.*, David A. Kessler, *The Basis of the FDA's Decision on Breast Implants*, 326 NEW ENG. J. MED. 1713, 1715 (1992) (observing the likelihood that, "[h]ad the FDA failed to intervene, the uncontrolled and widespread availability of breast implants would probably have continued for another 30 years—without producing any meaningful clinical data about their safety and effectiveness. Such a situation is obviously unacceptable"); Marcia Angell, *Shattuck Lecture—Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 NEW ENG. J. MED. 1513, 1515 (1996) ("After the [FDA] ban, under Kessler's prodding, the breast-implant manufacturers began to do what they should have done years earlier: they began to fund serious studies of the safety of breast implants.").

129. Rabin, *supra* note 43, at 2068.

of health information . . . or occasional efforts to conceal risk information from regulatory agencies like the FDA . . . ."[130] For example, litigation has uncovered malfeasance by the manufacturers of Vioxx and other drugs.[131] Similarly, while information about the health risks of tobacco reached the public through Surgeon General's warnings and mass media,[132] it was only through discovery in litigation that "a sharply defined picture emerged of industry indifference to health concerns and suppression of information in the manufacturing and marketing of tobacco."[133]

### *D. The Benefits of Tort Claims for Drugs and Devices Outweigh Their Costs.*

Tort law is not a substitute for, but a supplement to, a perfect regulatory system. Some commentators have argued that tort law ultimately decreases, rather than increases, public health. In other cases, litigation may not, in itself, protect consumer safety, as some of the drugs that generate significant amounts of litigation are withdrawn before litigation commences.[134] However, given the inadequacies of the FDA's regulatory regime, tort law's safety benefits ultimately outweigh its costs.

First, critics have argued that courts do not have the specialized knowledge necessary to make accurate decisions about drug safety. As early as 1991, the American Law Institute's Reporters' Study argued that "the tort system is ill-equipped to handle" public risks, such as harm from pharmaceuticals and medical devices, particularly in cases requiring "specialized experience in assessing risks and control measures."[135] In most tort cases, a jury made up of ordinary citizens will make the ultimate finding of fact regarding whether a particular drug or device "caused" the alleged harm. Yet state court jurors typically lack specialized experience in medicine or epidemiology.[136] The tort system has thus been "criticized for

130. *Id.*; Kesselheim & Avorn, *supra* note 94, at 308.

131. *Id.*

132. Rabin, *supra* note 43, at 2070.

133. *Id.* (*citing* PETER PRINGLE, CORNERED: BIG TOBACCO AT THE BAR OF JUSTICE (1998)).

134. Richard Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. COLLOQUY 54, 60–61 (2008). Others have argued that "litigation typically heightens awareness of the potential risks of just one product, thus shifting market share to products that may have their own unknown risks." Copland & Howard, *supra* note 117, at 5. While this may be factually true, it is not necessarily a negative or even irrational consequence.

135. 2 AM. LAW INST., ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY: REPORTERS' STUDY 87 (1991), *cited in* Victor E. Schwartz and Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 136 n.4 (2005).

136. *See* Mark Seidenfeld, *Who Decides Who Decides: Federal Regulatory Preemption of State Tort Law,* 65 N.Y.U. ANN. SURV. AM. L. 611, 617 (2009). Regulators, by contrast, "come from professions that are often trained in matters relating to the industry they regulate." *Id.*

allowing hired guns to confuse even fairly accepted issues of scientific fact."[137]

Second, critics have argued that that tort law over-deters manufacturers, dissuading them from developing beneficial drugs and devices. Because tort claims focus on the harm suffered by a particular patient, rather than the benefits received by others, they may not produce efficient results. Jurors considering patients' tort claims are not required to assess the benefits as well as the risks of a particular drug. Nor are jurors required to consider the potential effect of a large damage award on the continued availability of that drug. For example, Bendectin, an anti-nausea drug that is still widely used outside of the U.S., was withdrawn from the U.S. market because lawsuits based on flawed scientific foundations charged that it caused fetal anomalies—accusations that later turned out to be false.[138] Some commentators thus argue that tort law ultimately over-deters manufacturers from producing certain drugs and discourages drug and device development in critical areas, such as reproductive health.[139] Tort law also cannot help patients who are denied access to a valuable drug or device due to such over-deterrence.

Similarly, critics argue that the FDA already over-regulates drugs and devices, and that tort law cannot correct for this over-regulation. Patients cannot sue the FDA in order to gain access to beneficial drugs and devices that the FDA did not approve.[140]

Finally, while tort law permits recovery for drug and device harms, it does not guarantee compensation. Tort suits can be lengthy and expensive, making them unappealing and/or inaccessible for the most vulnerable, low-income patients. While some of these transaction costs can be overcome through the use of class action mechanisms, courts have historically been unfriendly to certifying these kinds of mass torts for class action.[141] In addition, problems establishing causation in tort suits lead to uneven

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137. *Id.* at 618.

138. Kesselheim & Avorn, *supra* note 94, at 310. Commentators have argued that "a manufacturer may decide not to continue producing a product even if it provides net benefits to society because consumers often overreact to fears of potential harm from a product, especially when that harm has been publicized due to a high profile tort suit." Seidenfeld, *supra* note 136, at 621.

139. Copland & Howard, *supra* note 117, at 9–10.

140. Epstein, *supra* note 134, at 60.

141. *See, e.g.*, In re Rhone-Poulenc Rorer, Inc., 51 F.3d 1293 (7th Cir. 1995) (decertifying a class of hemophiliacs who argued they were infected with AIDS as a result of using the defendant manufacturers' blood products). Courts may refuse to certify such classes because of the *in terrorem* effect of class certification on settlement, *id.*; the lack of predominance due to the need to determine individual causation; or either lack of predominance or manageability problems arising from choice of law issues, Seidenfeld, *supra* note 136, at 622 n.51 (noting that the failure of the Class Action Fairness Act to establish a uniform choice of law doctrine "effectively means that the law will differ for plaintiffs from different states, which in turn may render the class action unmanageable").

recovery, denying compensation to patients who were harmed and awarding it to others who were not. It is often difficult to prove by a preponderance of the evidence that a patient's injury or death was caused by a particular drug or device, particularly when she was using several different products at once. After Robert Ernst died in 2001 after taking Vioxx, his widow, Carol, sued the drug's manufacturer in state court.[142] The case did not go to trial until 2005.[143] While Carol won in the trial court, a state appellate court overturned the verdict in 2008, holding that there was not sufficient proof that Robert's death was caused by Vioxx.[144] On the other hand, a jury may find that a particular illness was "caused" by a drug when this is not the case from a medical or scientific perspective.

Tort law is not a perfect regulatory system. Yet tort law is a necessary supplement to the equally imperfect FDA. For every Bendectin, there is a Vioxx—and a Celebrex, and a Bextra. As it currently stands, the FDA cannot adequately identify the risks associated with drugs and devices before they are on the market, nor can it effectively monitor and regulate those products once they are in widespread use. Without tort law, many drug and device harms may never come to the attention of the public or the FDA. Because the FDA's powers are limited, in the absence of tort law manufacturers may create riskier products or turn a blind eye to regulatory demands, safe in the knowledge that their malfeasance will likely be unobserved. And without tort law, injured patients cannot be compensated for their injuries. Together, the benefits of tort claims likely outweigh their costs.

## III.
## THE SUPREME COURT INCREASINGLY DEFERS TO AGENCY INTERPRETATIONS OF THE PREEMPTIVE EFFECT OF REGULATIONS AND FEDERAL LAW.

Courts have "long presumed that Congress does not cavalierly pre-empt state-law causes of action."[145] Yet, since the 1980s, this presumption against preemption has given way in approximately 50 percent of Supreme Court cases.[146] Rather than relying on this presumption, the Supreme

142. Alex Berenson, *Courts Reject Two Major Vioxx Verdicts*, N.Y. TIMES, May 30, 2008, at C2, *available at* http://www.nytimes.com/2008/05/30/business/30drug.html.

143. *Id.*

144. *Id.*

145. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

146. See Michael S. Greve & Jonathan Klick, *Preemption in the Rehnquist Court: A Preliminary Empirical Assessment*, 14 SUP. CT. ECON. REV. 43, 57 (2006) (finding that 58 of 105 preemption decisions from the Rehnquist Court era, or 52 percent, were decided in favor of preemption); Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 HARV. L. REV. 1604, 1612–13 (2007) ("Between the 1983 and 2003 Terms the Supreme

Court increasingly defers to agency opinions about the preemptive effect of their own regulations and the underlying federal law.[147] The Supreme Court's recent cases interpreting the FDCA exemplify this trend. While the Court did not find preemption in the most recent case dealing with drug and device claims, *Wyeth v. Levine,* neither did the Court disturb the underlying logic that permits the FDA to unilaterally preempt state law.[148] Though the Court held that the FDA's regulatory regime does not currently preempt state failure-to-warn claims,[149] it indicated that the FDA could preempt these and other state claims in future regulations.[150]

### *A. The Quiet Death of the Presumption Against Preemption.*

When Congress acts within its enumerated Constitutional powers, a federal statute or regulation may preempt state law if Congress intends to supplant that state law.[151] Congress may preempt state law either expressly, by incorporating a preemption clause in a statute,[152] or implicitly.[153] Courts find implicit preemption where Congress has occupied the field of possible regulation[154] or where state law materially conflicts with the federal statute in such a way that it becomes impossible to comply with the mandates of both.[155] When federal agencies promulgate regulations at the behest of Congress, those agencies may also independently preempt state law by promulgating regulations that conflict with state law either explicitly or implicitly.[156] Agencies may also interpret the preemptive effect of the authorizing statute, whether in litigation or through rulemaking.[157]

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Court decided 127 cases involving federal preemption of state law, finding state law preempted approximately half of the time.").

147. *Products Liability Preemption*, *supra* note 14, at 455.

148. *But see, e.g.*, Mary J. Davis, *The "New" Presumption Against Preemption*, 61 HASTINGS L.J. 1217, 1247 (2010) ("[t]he Court [in *Wyeth*] has made it clear that the presumption against preemption of historic state police powers continues to operate in cases of both express and implied preemption. Only clear and manifest intent of Congress to the contrary will defeat the presumption.").

149. Wyeth v. Levine, 129 S. Ct. 1187, 1199, 1204 (2009).

150. *Id.* at 1204.

151. Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 212–13 (1983).

152. Riegel v. Medtronic, Inc., 522 U.S. 312, 316 (2008).

153. *See, e.g.*, Savage v. Jones, 225 U.S. 501, 533 (1912).

154. *Pacific Gas*, 461 U.S. at 212–13.

155. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963).

156. Geier v. Am. Honda Motor Co., 529 U.S. 861, 883–84 (2000).

157. Courts have generally treated agency statements of preemption with deference, Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. L. REV. 695, 698 (2008); however, it is unclear what level of deference is due, *compare* Lawrence Cnty. v. Lead-Deadwood Sch. Dist. No. 40-1, 469 U.S. 256, 262 (1985) (stating that the Court would give "substantial deference" to agency interpretation of the preemptive effect of the authorizing statute); *and* Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 (1996) (stating that the Court would give "substantial weight" to the same and citing *Chevron*); *and* Wachovia

Courts' preemption analyses traditionally started with the presumption that "the historic police powers of the States [a]re not to be superseded . . . unless that was the clear and manifest purpose of Congress."[158] This presumption was designed to preserve the balance of powers between federal and state governments.[159] The presumption against preemption was heightened in areas that the states have traditionally regulated, such as health and safety.[160] Given the traditional "primacy of state regulation of matters of health and safety,"[161] courts had long assumed "that state and local regulation related to [those] matters . . . can normally coexist with federal regulations."[162]

In the last two decades, the presumption against preemption has become a jurisprudential myth rather than a fundamental guiding principle. Federal agencies have increasingly exercised their power to preempt state law, including issuing "preemptive statements in preambles to agency rulemaking documents."[163] In cases where state common law claims are at issue, the Supreme Court now finds preemption in more than 60 percent of cases.[164] This contrasts so sharply from the longstanding presumption against preemption that tort scholar Catherine Sharkey has noted, "The present trend, paradoxically, is for the Court to apply the presumption when interpreting express preemption provisions, but not when called upon to engage in implicit preemption analysis."[165] Instead, the agency's views are the most accurate predictor of whether the Supreme Court will find preemption. In the sixteen years from 1992 to 2008, "the Supreme Court's position in every products liability preemption case . . . aligned with the relevant underlying federal agency's [opinion] on preemption" in that case, regardless of whether that view was pro-

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Bank v. Watters, 431 F.3d 556, 560 (6th Cir. 2005) (using the *Chevron* framework to evaluate whether the agency had authority to preempt state law), *aff'd on other grounds*, 127 S. Ct. 1559 (2007); *with* Mass. Ass'n of HMOs v. Ruthardt, 194 F.3d 176, 180–85 (1st Cir. 1999) (independently analyzing a federal Medicare statute even though the agency had presented its interpretation of that statute) (cited in Mendelson, *A Presumption Against Agency Preemption*, *supra*). *See generally* Nina A. Mendelson, Chevron *and Preemption*, 102 Mich. L. Rev. 737 (2004) (analyzing the state of the law regarding the deference owed to agency interpretations of statutory preemption and arguing that such interpretations should only be given *Skidmore*, not *Chevron*, deference).

158. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

159. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977).

160. N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995).

161. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

162. Hillsborough Cnty. v. Automated Medical Labs., Inc., 471 U.S. 707, 718 (1985).

163. Mendelson, *supra* 157, at 697.

164. *See* Greve & Klick, *supra* note 146, at 52–53 (finding 62.5 percent preemption rate in thirty-two cases involving preemption of state common law tort claims from 1986 to 2004; the rate increases to 67.6 percent when cases are restricted to the "Second Rehnquist Court," beginning in 1994).

165. *Products Liability Preemption*, *supra* note 14, at 458.

preemption or anti-preemption.[166]

### *B. While the FDCA Explicitly Preempts State Laws that Impose "Requirements" on Medical Devices, It Does Not Explicitly Preempt State Laws Concerning Drugs.*

The changing relationship between FDA regulation and state tort law exemplifies the trend of "silent tort reform."[167] Two separate provisions of the FDCA govern the preemption of laws related to pharmaceuticals and medical devices. The MDA explicitly preempts state laws that impose requirements "different from, or in addition to" requirements under the MDA.[168] The FDA is also explicitly authorized to exempt state requirements from preemption.[169] By contrast, the rest of the FDCA, including the portion that regulates prescription drugs, does not contain an express preemption clause.

Despite these statutory differences, judges and scholars have argued that courts should evaluate the preemption of drug and device claims using the same standards.[170] In *Medtronic, Inc. v. Lohr*, for example, the Supreme Court found that the MDA's preemption provision was "substantially informed" by other FDA regulations governing the preemption of state requirements already in place at the time of the MDA's enactment.[171] Both drugs and Class III devices undergo a similarly

166. *Id.* at 471.

167. Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 227 (2007). *See generally* Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353 (2006) (describing a general trend towards the federalization of substantive law).

168. 21 U.S.C. § 360k(a) (2006) ("Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.").

169. *See id.* § 360k(b).

170. *See* Wyeth v. Levine, 129 S. Ct. 1187, 1215–16 (2009) (Thomas, J., concurring); Riegel v. Medtronic, Inc., 552 U.S. 312, 339–407 (2008) (Ginsburg, J., dissenting); *see also* Robert Leflar & Robert Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 704 n.71 (1997) ("Surely a furor would have been aroused by the very suggestion that . . . medical devices should receive an exemption from products liability litigation while new drugs, subject to similar regulatory scrutiny from the same agency, should remain under the standard tort law regime."); Porter, *supra* note 28, at 11 (1997) ("[With preemption, the] FDA's regulation of devices would have been accorded an entirely different weight in private tort litigation than its counterpart regulation of drugs and biologics. This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress . . . .").

171. Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996); *see also id.* at 498–99 (citing 21 C.F.R. § 808.1(d) (1995) ("State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device . . . .").

rigorous pre-market approval process,[172] and tort claims for both products are often brought on the same grounds.[173] It can also be difficult to determine whether a product is a drug or device.[174]

There are strong arguments against preemption of common law claims for drug and device harms. As the states have long played an important role in regulating both the health and safety of their citizens and the compensation for injuries,[175] the presumption against preemption is heightened.[176] Yet, while the role of states has not changed, Supreme Court and FDA interpretations of the effect of federal regulation have changed.

### C. *The Ascendency of the Agency-Deference Model of Preemption in FDCA Cases:* Lohr, Buckman, *and* Riegel.

The Supreme Court first ruled on the preemptive effect of the FDCA in 1996 in *Medtronic, Inc. v. Lohr.* The plaintiff, Lora Lohr, had been implanted with a Medtronic pacemaker.[177] A defect in the wire that transmitted the pacemaker's signal to Lohr's heart caused the pacemaker to fail just three years later, resulting in a "complete heart block" that required emergency surgery.[178] Lohr sued in a Florida court, arguing that Medtronic should be held strictly liable for its defective device, among other claims.[179] Medtronic argued that the plain language of the MDA preempted *all* common law claims brought by an injured plaintiff against a manufacturer of medical devices.[180]

The Solicitor General of the FDA filed a brief supporting the injured plaintiff, arguing that no part of the FDCA preempted state tort law.[181]

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172. *See Riegel*, 552 U.S. at 339–40 (Ginsburg, J., dissenting).

173. Lawrence O. Gostin, *Regulating the Safety of Pharmaceuticals: The FDA, Preemption, and the Public's Health*, 301 JAMA 2036, 2037 (2009).

174. *Id.*

175. *Lohr*, 518 U.S. at 485.

176. *See* N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995), *cited in Riegel*, 552 U.S. at 334 (Ginsburg, J., dissenting).

177. *Lohr*, 518 U.S. at 480. The pacemaker had been approved by the FDA without going through the FDA's normal approval process because the device was "substantially equivalent" to other devices already on the market. *Id. See infra* Part II for a more detailed description of the FDA approval process for devices.

178. *Id.* at 480–81.

179. *Id.* at 481. She also alleged that Medtronic negligently breached its "duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker" in several respects, including failing to warn or properly instruct Lohr or her physicians that the pacemaker had a tendency to fail, despite the manufacturer's knowledge of similar failures. *Id.*

180. *Id.* at 486.

181. Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioners, Medtronic v. Lohr, 518 U.S. 470 (1996) (Nos. 95-754, 95-886), 1996 WL 118035, at *9–*11.

The agency argued that, while the obligations created by state tort law may constitute preempted "requirements" under the MDA, state tort remedies and other remedial provisions did not.[182]

The Supreme Court's decision in *Lohr* mirrored the FDA's view. A plurality of the Court[183] held that the MDA did not preempt state tort law. According to the Court, the FDA approval process established no federal requirement "applicable to a particular device" within the meaning of the MDA.[184] The Court explained that the process "did not 'require' Medtronic's pacemaker to take any particular form for any particular reason."[185] Moreover, the general common law standards that formed the basis of Lohr's tort claims were "not specifically developed 'with respect to' medical devices" and thus were "not the kinds of requirements that . . . would impede the ability of federal regulators to implement and enforce specific federal requirements."[186] Finally, because Congress did not provide a private right of action under the statute, it could not have intended to prevent a state from providing "a traditional damages remedy."[187]

In his concurrence, Justice Breyer, the deciding fifth vote in *Lohr*, noted that he agreed with the four dissenting justices that common law causes of action for negligence and strict liability do impose "requirement[s]" and would be preempted by federal requirements specific to a medical device.[188] Nonetheless, Justice Breyer explicitly deferred to the opinion of the FDA that the MDA did not preempt state tort law in this case, explaining that the agency has a "special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether . . . state requirements may interfere with federal objectives," and thus its opinion was entitled to deference.[189] According to Justice Breyer,

> [I]n the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect. . . . The FDA can translate these understandings into particularized pre-emptive intentions accompanying its various rules and regulations. . . . It can communicate those intentions, for

182. *Id.* at *10.

183. The plurality was composed of Justices Stevens, Kennedy, Souter, and Ginsburg.

184. *Lohr*, 518 U.S. at 500–01.

185. *Id.* at 493.

186. *Id.* at 501.

187. *Id.* at 495.

188. *See id.* at 503–05 (Breyer, J., concurring); *Id.* at 512 (opinion of O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., dissenting).

189. *Id.* at 506.

> example, through statements in "regulations, preambles, interpretive statements, and responses to comments . . . ."[190]

Because the FDA did not intend to preempt state requirements in this instance, preemption was not necessary.[191] However, Breyer implied that the background principles of the presumption against preemption would only apply "in the absence of any indication of a contrary congressional (or agency) intent, to read the preemption statute (and the preemption regulation)."[192] Breyer's concurrence foreshadowed the increasing deference the Court would give to FDA interpretation of the FDCA in subsequent cases.

By 2001, when the Supreme Court again confronted the question of the preemptive effect of the MDA in *Buckman Co. v. Plaintiffs' Legal Committee,* the landscape had changed.[193] The defendant, Buckman Company, had created a set of orthopedic bone screws that it intended to market for use in spinal surgery.[194] After the FDA twice refused to approve the bone screws as a new device, the defendant split the device into its component parts, renamed them, and filed separate applications for each component under the MDA's approval process for "substantially equivalent" devices.[195] The FDA approved these components for sale. After several patients suffered injuries, these patients sued in state court, claiming that Buckman had lied to the FDA.[196] Buckman argued that the plaintiffs' "fraud-on-the-agency" claims were expressly preempted by the MDA or, alternatively, that the claims amounted to an improper assertion of a private right of action under the MDA.[197]

In *Buckman*, unlike in *Lohr*, the FDA filed an amicus brief on behalf of the defendant manufacturer, arguing that the plaintiffs' claims would impose impermissible "requirements" under the MDA.[198] The Solicitor General argued that the "multiplicity of tribunals and a diversity of procedures" inherent in state adjudication of tort claims "are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law."[199] The Solicitor General also stated that permitting

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190. *Id.* at 505–06.

191. *See id.* at 507.

192. *Id.* at 508.

193. *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001).

194. *Id.* at 346.

195. *Id.* Buckman also specified a new intended use, seeking permission to market the plates and screws for use in the long bones of the arms and legs in addition to in the spine. *Id.*

196. *Id.* at 346–47.

197. *See id.* at 347 ("The District Court dismissed these "fraud-on-the-FDA" claims . . . on the ground that they were expressly pre-empted by the MDA . . . .").

198. Brief for the United States as Amicus Curiae Supporting Petitioner, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1364441, at *23.

199. *Id.* (internal citations and internal quotations omitted).

such fraud-on-the-agency claims would cause manufacturers to "flood FDA with information that FDA does not need" so that no jury could find that the manufacturers withheld information.[200] This would "mak[e] it more difficult for FDA to perform its central mission of protecting the public health."[201] The Solicitor General concluded that fraud-on-the-agency claims conflicted with the federal enforcement scheme even in cases where, unlike in *Buckman*, the FDA had publicly determined that it was defrauded and had taken all the necessary steps to remove a device from the market.[202]

Although neither the underlying regulatory scheme nor the composition of the Supreme Court had changed since *Lohr*, the Court split along dramatically different lines—transforming from a plurality against preemption to a Court unanimously in favor of preemption. While the seven-person majority in *Buckman*, consistent with *Lohr*, focused on the regulatory effects of fraud claims, it substantially changed its interpretation of the MDA and of the preemptive intent of Congress.

The majority changed its interpretation of Congress' preemptive purpose. In *Lohr*, the plurality found that the absence of a private right of action implied that Congress did not intend to preempt the state law right.[203] In *Buckman*, the majority stated that, because Congress only authorized the federal government to enforce the provisions of the FDA, it must have intended to preempt common law claims.[204] The Court offered no explanation for the change in interpretation. Only Justices Stevens and Thomas, writing separately in concurrence, considered the fact that preemption would eliminate the only remedy available to patients injured by fraudulent representations to federal agencies.[205]

*Buckman* directly contradicted *Lohr*'s holding that a state damages remedy for violations of FDA requirements does not impose an additional requirement but "merely provides another reason for manufacturers to

200. *Id.* at *29–*30.

201. *Id.* at *30.

202. *Id.* at *24, *30. *But cf. Buckman*, 531 U.S. at 354 (Stevens, J. and Thomas, J., concurring) (arguing that whether the MDA preempted the plaintiffs' "fraud-on-the-FDA" claim depended on whether the FDA itself had determined that the defendant manufacturer had committed fraud during the pre-market approval process and taken steps to remove the product from the market). Justices Stevens and Thomas reasoned that if the FDA had taken such action, "state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." *Id.* However, as the FDA had not taken such action in *Buckman*, the plaintiffs could not prove that the product would have reached the market "but for" the defendant's fraud and the case could not proceed. In so concluding, Justices Stevens and Thomas noted that their opinion was consistent with the FDA's former position while appearing to discount the FDA's recently altered thinking. *See id.* at 354 n.2.

203. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 487 (1996).

204. *Buckman*, 531 U.S. at 351–52.

205. *Id.* at 355 (Stevens, J., joined by Thomas, J., concurring).

comply with . . . federal law."[206] Yet, although the Court's ruling marked a departure from *Lohr*, it was consistent with the FDA's position at the time. Chief Justice Rehnquist, writing for the majority, substantially adopted the Solicitor General's reasoning, stating that,

> As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants . . . Would-be applicants may be discouraged from seeking . . . approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates . . . to unpredictable civil liability.[207]

Rather than focusing on whether the actual state *requirement* was "equal to, or substantially identical to, requirements imposed" under federal law, as *Lohr* instructed,[208] the majority found that state law was preempted because the two requirements produced different *effects*.[209] Again echoing the Solicitor General, the majority speculated that state tort claims might conflict with the FDA's policy objectives, particularly its permissive attitude toward off-label use, and that it might burden the agency with paperwork.[210]

In 2008, the Court again increased the preemptive power of FDA regulations in *Riegel v. Medtronic*.[211] The case presented the Court with substantially the same issue the Court had resolved in *Lohr* more than a decade prior.[212] While plaintiff Charles Riegel was undergoing a coronary angioplasty, his doctor inserted an Evergreen Balloon Catheter marketed by Medtronic into his coronary artery in an attempt to dilate the artery.[213] The catheter ruptured, causing Riegel to develop a heart block that required him to be placed on life support and undergo emergency

206. *Lohr*, 518 U.S. at 495.

207. *Buckman*, 531 U.S. at 350.

208. *Lohr*, 518 U.S. at 497.

209. In doing so, the Court loosened its definition of what constituted a federal or state "requirement," as well as when these two "requirements" were impermissibly in conflict. The majority ignored the Court's holding in *Lohr* that the FDA's approval process for "substantially equivalent" devices did not impose any federal requirements within the meaning of the MDA. Given that federal law already criminalized the alleged fraud (*see* 18 U.S.C. § 1001 (2006) (making it a crime to make a fraudulent statement to a federal agency) *and* 21 C.F.R. § 807.87(k) (2009) (requiring every pre-market notification to contain a statement that the information contained is believed to be truthful)), the majority did not argue that the plaintiffs' tort claims imposed any conflicting requirements of truthfulness or disclosure that would trigger preemption. Instead, the majority speculated that state tort claims might conflict with the FDA's policy objectives. *See id.* at 348.

210. *Buckman*, 531 U.S. at 350–51.

211. Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

212. *See generally Lohr*, 518 U.S. 470.

213. *Riegel*, 552 U.S. at 320.

coronary bypass surgery.[214] Riegel sued in federal court on common law claims of strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter.[215] Medtronic argued that Riegel's claims were preempted by the MDA. The Solicitor General agreed and filed an *amicus* on behalf of the defendant manufacturer.[216]

In an 8-1 decision,[217] the Supreme Court ignored *stare decisis* and followed the FDA's change in opinion.[218] Where in *Lohr* the Court held that tort law would not "impede the ability of federal regulators to implement and enforce specific federal requirements,"[219] the *Riegel* Court relied on the same statutory language to hold that the plaintiffs' tort claims were preempted. The Court established a new presumption that, "[a]bsent other indication," the Court would consider "common law duties" imposed on manufacturers as "requirements" preempted by the MDA.[220] It held that "safety and effectiveness are the very subject of the . . . common law claims."[221] As such, tort law necessarily imposed requirements that were "relate[d] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device."[222] These claims were thus preempted.[223]

Although the Court found that there was nothing in *Lohr* to contradict this new presumption,[224] the *Riegel* decision is only consistent with *Lohr* in so far as both decisions mirror the opinion of the agency. Although the Court's ruling did not explicitly rely on the FDA's brief in *Riegel*,[225] it appears to have given some deference to the FDA's position. The *Riegel* Court also reiterated that an "agency's reading of its own rule is entitled to substantial deference"[226] and indicated that it would defer, if necessary, to the current opinion of the agency.[227]

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214. *Id.*

215. *Id.* at 320–21.

216. *Id.* at 314.

217. *Id.* at 313. Justice Ginsburg was the lone dissenter. *Id.*

218. *Id.* at 321–25.

219. Medtronic, Inc. v. Lohr, 518 U.S. 470, 501 (1996).

220. Riegel v. Medtronic, Inc., 552 U.S. 312, 324 (2008). Justice Stevens did not concur in this part of the opinion, although he did concur in the decision. *Id.* at 313.

221. *Id.* at 323.

222. 21 U.S.C. § 360k(a) (2009).

223. *Riegel*, 552 U.S. at 325 (arguing that "[s]tate tort law that requires a manufacturer's catheters to be safer . . . than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect").

224. *Id.* at 322–24.

225. *Id.* at 326 (finding that it did not need to rely on the FDA's opinion because the MDA is unambiguous and thus not subject to *Chevron* deference).

226. *Id.* at 328.

227. *See id.* at 326. While the Court stated that "[w]e have found it unnecessary to rely upon that agency view because we think the statute itself speaks clearly to the point at

### *D.* Wyeth v. Levine *Lays the Foundation for Further Preemption of State Tort Claims.*

Several commentators hailed the Supreme Court's 2009 decision in *Wyeth v. Levine* as the end of the Court's trend toward preemption.[228] Far from it. The Court's decision in *Wyeth* preserves, and in fact encourages, the essential driving force behind this trend: the power of the FDA to preempt state tort claims through federal regulations.

*Wyeth* presented the Court with its first opportunity to rule on the preemptive effect of FDA regulation outside of the MDA. As noted earlier, unlike the MDA, the portions of the FDCA governing pharmaceuticals are silent on the issue of preemption.[229] In *Wyeth*, the plaintiff, Diana Levine, had gone to a local clinic for treatment of a

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issue," it noted that the agency's current opinion would be entitled to some deference. *Id.* By contrast, the agency's former opinion was entitled to no deference. *Id.*

228. *See, e.g.*, Eric S. Almon, *Preemption of State Failure-to-Warn Claims After* Wyeth v. Levine*: The Regulatory Function of State Tort Law*, 45 U.S.F. L. REV. 215, 215 (2010) (arguing that, under the logic of *Wyeth*, FDA pronouncements about preemption are accorded little deference); Mary J. Davis, *The "New" Presumption Against Preemption*, 61 HASTINGS L.J. 1217 (2010) (arguing that the Supreme Court in *Wyeth* reaffirmed a new presumption against preemption); Kyle D. Logue, *Coordinating Sanctions in Tort*, 31 CARDOZO L. REV. 2313, 2348 (2010) (arguing that *Wyeth* stands for the proposition that state tort law and FDA regulation are complementary); Robert S. Peck, *A Separation of Powers Defense of the "Presumption Against Preemption,"* 84 TUL. L. REV. 1185, 1185 (2010) ("In *Wyeth v. Levine*, the United States Supreme Court revitalized the sometimes dormant 'presumption against pre-emption' by declaring it one of two cornerstones of preemption jurisprudence."); Jamelle C. Sharpe, *Toward (a) Faithful Agency in the Supreme Court's Preemption Jurisprudence*, 18 GEO. MASON L. REV. 367, 395 (2011) (arguing that the Court "has also been reluctant, and in *Wyeth* explicitly refused, to acknowledge that agencies may be well positioned to undertake a primary role in all but a handful of cases"). *But see* Anthony Gostanian, *How the FDA Can Overturn* Wyeth v. Levine, 36 AM. J.L. & MED. 248, 248 (2010) (arguing that the FDA has the power to "overturn" *Wyeth v. Levine* by formally promulgating a federal regulation to the contrary, and that the Supreme Court would defer to such a regulation); Gillian E. Metzger, *Federalism and Federal Agency Reform*, 111 COLUM. L. REV. 1, 14-15 (2011) ("It is thus hard to assess the long-term impact [*Wyeth* and other preemption decisions in the same term] will have . . . . [S]ome key questions were left open, in particular the extent to which federal administrative regulations with the force of law—that is, substantive regulations or decisions that impose binding legal obligations, as opposed to regulations that simply interpret governing statutes or provide general guidance—can preempt state law. . . . [Moreover,] the Court continues to believe that liability under state common law can constitute a state law requirement or prohibition for purposes of an express preemption clause."); Victor E. Schwartz & Cary Silverman, *Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance that Protects Public Safety*, 84 TUL. L. REV. 1203, 1215 (2010) ("Some commentators, perhaps hastily, questioned the continued viability of conflict and obstacle preemption following the *Levine* case. Those who suggest that the case represents the death knell for implied or agency preemption exaggerate its scope. Rather, the Court found no preemption for reasons particular to the case before it.").

229. *See infra* Part II.

migraine.[230] There, clinic staff intravenously injected her with Phenergen, an antihistamine marketed by Wyeth to treat nausea using the "IV-push" method, which permits the drug to be injected directly into the vein.[231] The drug came in contact with her blood, causing gangrene and forcing the amputation of her arm.[232] Levine sued the treating physician for medical malpractice and Wyeth for failure to warn of the risks associated with administering Phenergen via the IV-push method.[233] Wyeth argued that, by mandating the contents of prescription drug warning labels, the FDA preempted state-law-based failure-to-warn claims, as these claims were premised on the theory that different labeling is necessary to make the drug reasonably safe for use.[234]

As in *Buckman* and *Riegel*, the FDA submitted an *amicus* brief in support of the manufacturer.[235] In 2006, the FDA had inserted language into the preamble of its new regulation on labeling requirements stating that FDA regulations preempted "not only claims against manufacturers . . . but also against health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the labeling."[236] The agency had interpreted the FDCA to establish both a regulatory "'floor' and a 'ceiling,' preventing a manufacturer from strengthening a warning without prior FDA approval.[237] In the preamble, the FDA emphasized that "[e]xaggeration of risk could discourage appropriate use of a beneficial drug."[238]

In a 6-3 decision, the *Wyeth* Court held that the FDCA generally does not preempt state failure-to-warn claims, rejecting the FDA's position for the first time since *Lohr*.[239] The majority acknowledged that the regulatory effect of tort law is attenuated[240] and that state law also serves a distinct

230. Wyeth v. Levine, 129 S. Ct. 1187, 1191 (2008).

231. *Id.* Doctors can also administer drugs via the "IV-drip" method—what most non-professionals think of as an IV—in which the drug is introduced into a saline solution in a hanging intravenous bag and slowly descends through a catheter inserted in a patient's vein.

232. *Id.*

233. *Id.* at 1191–92.

234. *See id.*

235. Brief for the United States as Amicus Curiae, *Wyeth v. Levine*, No. 06-1249, 2007 WL 4555760 (Dec. 21, 2007).

236. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3936 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, & 601).

237. *Id.* at 3935.

238. *Id.*

239. *Wyeth*, 129 S. Ct. at 1204.

240. *See id.* at 1194 (noting that the Vermont court found that "the jury verdict established only that Phenergan's warning was insufficient. It did not mandate a particular replacement warning, nor did it require contraindicating IV-push administration: 'There may have been any number of ways for [Wyeth] to strengthen the Phenergan warning without completely eliminating IV-push administration.'" (internal citation omitted)).

compensatory function.[241] As in *Lohr*, the Court reasoned that, because the FDCA provided no remedy for injured consumers, Congress had "determined that widely available state rights of action provided appropriate relief for injured consumers" and did not wish to preempt tort law.[242] The Court also returned to the notion in *Lohr* that "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly preempt state-law causes of action.'"[243]

However, the Supreme Court did not hold that the FDCA did not preempt state tort claims, or that the FDA could not preempt such claims through formal regulations. Instead, the case turned on a narrow dispute about whether the pharmaceutical manufacturer was permitted to change its label without prior FDA approval.[244] The *Wyeth* Court refused to defer to the FDA's exercise of its regulatory power to preempt state law because it disagreed with the *process* by which it did so, not the act of preemption itself. The FDA chose to avoid the formal notice-and-comment process by slipping its preemption clause into the preamble of another regulation.[245] Because it was not promulgated through the normal regulatory process, the Court found that the opinion was a "mere assertion that state law is an obstacle to achieving its statutory objectives," not an exercise of the agency's expert judgment.[246] The majority thus disregarded the FDA's opinion in this instance because that particular opinion did not have the "force of law." [247] The majority did not preclude the FDA from

241. *Id.* at 1202.

242. *Id.* at 1199. The Court further stated: "As Justice O'Connor explained in her opinion for a unanimous Court: 'The case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" (internal citations omitted). *Id.* at 1200.

243. *Id.* at 1195 n.3 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

244. *See id.* at 1197–98. Much as in the pre-market approval process of medical devices, the FDA's pre-market approval of a new drug application includes the approval of the exact text in the proposed label. *See* 21 U.S.C. § 355(b)(1)(F), (d) (2006) (requiring manufacturers to submit the proposed label and stating that where "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; [the FDA] shall issue an order refusing to approve the application"); 21 C.F.R. § 314.105(b) (2009). However, while generally a manufacturer may only change a drug label after the FDA approves a supplemental application, FDA regulations permit a manufacturer to unilaterally change its label before receiving the agency's approval under certain circumstances, such as when a manufacturer wished to change a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." 21 C.F.R. §§ 314.70(c)(6)(iii)(C). The Court found that manufacturers could do so, emphasizing that "[f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Wyeth*, 129 S. Ct. at 1202.

245. *Id.* at 1201.

246. *Id.*

247. *Id.* at 1203.

promulgating the same rule through a formal regulatory process. In his concurrence, Justice Breyer specifically reaffirmed the FDA's power to preempt state tort law:

> The FDA may seek to determine whether and when state tort law acts as a help or a hindrance to achieving the safe drug-related medical care that Congress sought .... It may seek to embody those determinations in lawful specific regulations describing, for example, when labeling requirements serve as a ceiling as well as a floor.[248]

Preemption of state pharmaceutical drug claims by the FDA thus remains a very real possibility.[249]

### *E. The Supreme Court's Permissive Treatment of Preemption Leaves Americans' Health and Safety at Risk.*

The Supreme Court has already eliminated state tort claims for harms caused by medical devices, including manufacturer liability for common law claims of fraud on the agency.[250] The holding in *Wyeth* leaves state tort claims for other drug and device harms in a precarious position. While the Supreme Court in *Wyeth* preserved state failure-to-warn claims for the time being, it signaled that future attempts at preemption would likely succeed so long as the FDA follows the normal regulatory process.[251] The availability of state tort remedies is thus in the hands of the agency. In future administrations, the FDA could unilaterally reduce our nation's health and safety protections.

It is likely that future administrations will continue to extend the preemptive power of federal drug and device regulation. Catherine Sharkey argues that recent instances of agencies like the FDA including preemption language in preambles to regulation—which are not subject to the notice and comment process—are "a harbinger of a future where federal agency regulations come armed with directives that displace competing or conflicting state regulations or common law as a matter of course."[252] As many presidential administrations have been "overtly hostile to tort law,"[253] it is likely that future presidents may support the use of

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248. *Id.* at 1204.

249. *See supra* note 229 and accompanying text for a description of the current debate surrounding the meaning and effect of *Wyeth.*

250. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001).

251. It is unclear how the changing composition of the Supreme Court bench will affect the Court's preemption jurisprudence. According to one commentator, "The supposition that the jurisprudence may shift yet again seems even more likely with the retirement of Justice John Paul Stevens, the author of *Levine* and a frequent champion of the presumption against preemption ...." Peck, *supra* note 228, at 1186.

252. *Preemption by Preamble, supra* note 167, at 227–28.

253. John C.P. Goldberg & Benjamin C. Zipursky, 123 HARV. L. REV. 1919, 1920

regulations to further preempt tort law. At the same time, federal preemption of state tort claims is supported by the pharmaceutical and medical device industry. Considering the influence of these manufacturers within the FDA and the halls of government generally, it is likely that the agency will seek to preempt more tort claims through future regulations.[254]

While President Obama is not hostile towards tort law, it is unlikely that his administration will significantly reverse the trend toward preemption. President Obama has directed the heads of federal agencies to review preemptive statements and to amend those that are not legally justified.[255] However, the actions of the Obama Administration paint a more mixed picture: while "several agencies have issued regulations that disavowed preemption positions previously taken during the Bush Administration," the Administration has occasionally defended Bush-era preemption positions in the courts or pursued new federal standards that would preempt state law.[256] At the same time, "[t]ort law is appropriately low on the list of this Administration's priorities . . . [and] may not fare well in times of economic crisis, particularly insofar as the White House is imbued with a technocratic outlook that favors expert agencies and systemic solutions over a system of one-off adjudications."[257] The Administration has already used tort reform as a bargaining chip in its negotiations with political adversaries, pledging $25 million to fund state projects exploring alternatives to tort litigation for medical malpractice claims.[258] As such, it is unlikely that the Obama Administration will take the steps necessary to permanently reverse the trend toward preemption.

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(2010). *See also, e.g.*, Steve Lohr, *Bush's Next Target: Malpractice Lawyers*, N.Y. TIMES, Feb. 27, 2005, at B1, *available at* http://query.nytimes.com/gst/fullpage.html?res=9C0CE5DD143DF934A15751C0A9639C8B63.

254. *See* Epstein, *supra* note 134, at 63 (arguing that, if a preemption preamble were sufficient to tip the balance, then "flip-flop will not be a simple random event. It will be a target of opportunity that will embolden lobbyists of all stripes"); Gillian E. Metzger, *Administrative Law as the New Federalism*, 57 DUKE L.J. 2023, 2079–80 (2008) (noting that "politics rather than institutional position often seems to be the driving force behind federal administrative limitations on (or deference to) the states").

255. Preemption: Memorandum for the Heads of Executive Departments and Agencies (May 20, 2009), 74 Fed. Reg. 24,693, 24,693–94 (May 22, 2009).

256. Michele E. Gilman, *Presidents, Preemption, and the States*, 26 CONST. COMMENT. 339, 353–59 (2010).

257. Goldberg & Zipursky, *supra* note 253, at 1921. *See also* Sheryl Gay Stolberg, *Next Steps on Obama's Medical Malpractice Offer?*, N.Y. TIMES (Sept. 10, 2009, 5:50 p.m.), http://prescriptions.blogs.nytimes.com/2009/09/10/next-steps-on-obamas-medical-malpractice-offer/ (quoting President Obama as saying, "I don't believe malpractice reform is a silver bullet . . . but I have talked to enough doctors to know that defensive medicine may be contributing to unnecessary costs").

258. Annie Underwood, *Experiments in Tort Reform*, N.Y. TIMES (Oct. 13, 2009, 6:00 a.m.), http://prescriptions.blogs.nytimes.com/2009/10/13/experiments-in-tort-reform/?scp=4&sq=cap%20on%20noneconomic%20damages&st=cse.

Finally, President Obama's Executive Order does not carry the weight of a federal law; subsequent administrations may rescind or simply ignore the directive. Further agency preemption of state tort law remains likely.

## IV.
## A WELL-DESIGNED NO-FAULT COMPENSATION SCHEME COULD LARGELY SUBSTITUTE FOR STATE TORT LAW.

As described in Part II, the FDA is currently incapable of ensuring the health and safety of patients in the absence of tort law. FDA regulation, on its own, cannot replicate the benefits of state tort law, including its ability to compensate victims for their injuries, to uncover and gather critical information about drug and device safety, and to hold both manufacturers and the FDA accountable for their actions and failures. Indeed, in the short term, the elimination of tort remedies, in the absence of alternative forms of compensation, may increase the likelihood of overregulation. Robert Rabin has argued that a regulatory compliance defense for manufacturers might create significant political pressure for the FDA to set higher standards for the safety of the drugs and devices it approves in order minimize the number of injuries from these products.[259] The same result may occur now that tort claims for medical devices are preempted, as it may be less acceptable to the public for the FDA to approve a device that carries substantial risks when compensation is no longer available to patients who are harmed by it. However, because pharmaceutical and device manufacturers have significant influence within the FDA, it is likely that these manufacturers will convince the FDA to return to its current standard of assessing a drug's costs and benefits. Legislative action is necessary to restore and preserve the positive aspects of tort law.

One proposed solution worth exploring is a no-fault compensation scheme for drugs and medical devices. The idea is not a new one; since the early 1990s, a handful of commentators have advocated creating such a scheme for drugs and/or devices based on the National Vaccine Injury Compensation Program (NVICP).[260] However, a no-fault compensation scheme is a particularly appealing solution to the problem of preemption because it provides a way for patients to receive compensation for their injuries without either high litigation costs or crippling manufacturer liability from high jury awards. No-fault compensation schemes can be thought of as a form of mandatory insurance that partially or completely

259. Rabin, *supra* note 43, at 2076.

260. Copland & Howard, *supra* note 117, at 13; Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 235–36 (1992); Malika Kinodia, *The Fate of the Injured Patient in the Wake of* Riegel v. Medtronic: *Should Congress Interject?*, 32 HAMLINE L. REV. 791, 834–40 (2009).

replaces state tort law. Potential tortfeasors are forced to "buy" liability insurance by paying into a centralized, government-administered fund. When victims like Robert Ernst are injured, they or their families are compensated by the fund directly, without having to sue the entity responsible for the injury in state court.

While no-fault compensation schemes can take many different forms, all schemes tend to share several common features. No-fault schemes are generally operated by an impartial third party, often the government, and are thus independent of both the injured and the injurers. They are usually population-specific: for example, focusing on individuals injured by birth accidents[261] or nuclear accidents.[262] Most importantly, victims access compensation through an administrative process rather than litigation. Victims seeking compensation from the fund must demonstrate, usually by a preponderance of the evidence, that their injuries were caused by a harm covered by the fund. To do so, they provide evidence of the injury to the fund through written filings or formal hearings. Although an attorney can represent individuals in these proceedings, some schemes are simple enough to be navigated without the aid of counsel.

Because no-fault schemes vary greatly in their scope and structure, they also vary significantly in their capacity to replicate both the compensatory and regulatory effects of tort law. As noted above, most commentators have argued that a no-fault compensation for drugs and devices should be modeled on the NVICP. However, this scheme has encountered significant obstacles that limit its effectiveness.

In this Part, I discuss several models for such a scheme. Learning from the experiences of existing schemes, I propose one form that an effective no-fault scheme for drugs and devices could take. My proposal attempts to take the most effective elements from current schemes while correcting for the obstacles encountered in implementing them.

### *A. There Are Several Potential Models for a No-Fault Scheme for Drugs and Devices.*

Currently, there are several domestic no-fault compensation schemes for medical harms that could be used as a model for a federal program for prescription drugs and medical devices.[263] While none of these models

261. Virginia Birth-Related Neurological Injury Compensation Act, VA. CODE ANN. §§ 38.2-5000–5021 (1994).

262. Price-Anderson Act, 42 U.S.C. § 2210 (1994).

263. Because of the unique problems presented by medical harms, no-fault schemes for other kinds of harms, such as workers' compensation, are not good models. Similarly, countries like Sweden have successfully implemented no-fault schemes for pharmaceuticals. *E.g.*, Gregory C. Jackson, *Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 227 (1992). However, Swedish pharmaceutical insurance is not an ideal model for a U.S.-based no-fault scheme

should be adopted wholesale, many offer valuable insights into how Congress might construct an effective no-fault compensation scheme for drug and device harms.

### *1. National Childhood Vaccine Injury Program*

Created in 1988 as part of the National Childhood Vaccine Injury Act (NCVIA),[264] the NVICP is the only federal no-fault scheme currently in operation that is targeted specifically at medical harms. Congress passed the NCVIA in response to a perceived national "vaccine crisis," in which vaccine manufacturers claimed they were being driven out of the market by tort liability.[265] The NVICP compensates patients injured by certain vaccines for non-reimbursable medical expenses, rehabilitation, lost wages, and a pain and suffering award that may not exceed $250,000.[266] To avoid delay and controversy over causation issues, the Act creates a Vaccine Injury Table that outlines a number of injuries for which compensation eligibility is presumed.[267] The Table was "derived based on epidemiological studies of adverse reactions to the covered vaccines and reports of the American Medical Association and the American Academy of Pediatrics,"[268] and can be amended by the Secretary of Health and Human Services.[269]

To fund the scheme, the Act imposes an excise tax on each dose of covered vaccines,[270] which goes into a trust fund used to compensate

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because its design assumes the existence of a larger system of social insurance that does not have an equal in the U.S. *See id.* at 228 n. 193 (noting that the small awards distributed through the system are "are nonetheless generally adequate because the program is only one of a wide network of medical insurance plans" and that "lost wages, medical treatment, and nursing care are covered by other national programs").

264. 42 U.S.C. §§ 300aa-1 to -34 (2006).

265. Schafer v. American Cyanamid Co., 20 F.3d 1, 2 (1st Cir. 1994) ("Vaccine manufacturers (potential tort defendants) complained about litigation expenses and occasional large recoveries, which caused insurance premiums and vaccine prices to rise, and which ultimately threatened the stability of the vaccine supply.").

266. 42 U.S.C. § 300aa-15(a) (2006).

267. *See* 42 U.S.C. §§ 300aa-13(b) to -14 (2006).

268. MOLLY TREADWAY JOHNSON, CAROL E. DREW AND DEAN P. MILETICH, FED. JUDICIAL CTR., USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND CASE-MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 13–14 (1998).

269. *See* 42 U.S.C. §300aa-19(f)(2) (2006).

270. *See* 26 U.S.C. §§ 4131–4132 (2006). There is some evidence that the excise tax rate of seventy-five cents, which was set by the Taxpayer Relief Act of 1997 (Pub. L. No. 105-34, 111 Stat. 788), "overcharges" vaccine manufacturers compared to the needs of the program. As of 2005, the Fund had a balance of about $2.1 billion and over the previous three years has grown at an average rate of seven percent. *See* GEN. ACCT. OFF., VACCINE INJURY TRUST FUND: REVENUE EXCEEDS CURRENT NEED FOR PAYING CLAIMS 4, 29 (2000).

injured patients.[271] While the NCVIA expressly preempts civil actions for damages caused by unavoidably unsafe vaccines,[272] there is currently some debate as to whether the Act preempts all common law claims for design defects or only those claims where a court has made an individual determination that a particular vaccine is unavoidably unsafe.[273] Moreover, although the NVICP is not an exclusive remedy,[274] claimants must generally fully adjudicate their claims through the program before filing any civil claims against the vaccine manufacturer.[275] Accepting compensation under the Act or failing to file a tort claim within ninety days of a judgment under the Act precludes any further claim against a manufacturer.[276] As of September 9, 2011, 2,709 eligible claimants have received compensation from the NVICP.[277]

In order to be compensated by the NVICP, patients must file a claim in the United States Court of Federal Claims, which determines eligibility and award amounts for compensable injuries.[278] The court appoints a special master to assist in obtaining evidence and to prepare findings of fact and proposed conclusions of law for the court.[279] While NVICP claimants are often represented by attorneys, attorneys cannot claim more than $30,000 in fees.[280] The special master decides whether the fees are appropriate once a case is concluded, and often compares figures between cases in order to make her determination.[281]

Claimants are eligible for compensation under the Act where the court determines by a preponderance of the evidence that their injuries are

271. 42 U.S.C. § 300aa-15(i) (2006).

272. *See* 42 U.S.C. § 300aa-22(b)(1) (2006) ("No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.").

273. *Compare, e.g.*, Bruesewitz v. Wyeth Inc., 561 F.3d 233, 235 (3d Cir. 2009) (the NCVIA preempts all design defect claims) *with* Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236, 242 (Ga. 2008) (the NCVIA does not preempt all design defect claims; courts may determine whether a vaccine is unavoidably unsafe on a case-by-case basis).

274. 42 U.S.C. § 300aa-21(a) (2006).

275. 42 U.S.C. § 300aa-11(a)(2)(A) (2006).

276. 42 U.S.C. § 300aa-21(a) (2006).

277. *National Vaccine Injury Compensation Program: Statistics Reports,* DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. AND SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/statisticsreports.html#Stats (last visited September 29, 2011).

278. 42 U.S.C. §§ 300aa-12 to -13 (2006).

279. 42 U.S.C. § 300aa-12(c)-(d) (2006).

280. 42 U.S.C.A. § 300aa-15(b)(3) (2006). *See also* Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 64 (1999).

281. Saxton v. Sec'y of the Dep't of Health and Human Servs., 3 F.3d 1517, 1520 (1993).

vaccine-related.[282] In order to receive compensation for an injury listed in the Table, claimants must show: 1) that they received a vaccine; 2) that they suffered an injury enumerated in the Table; and 3) that they suffered the injury within the time period prescribed in the Table.[283] However, the presumption that the injury was caused by the vaccine can be rebutted if a preponderance of the evidence shows that the injury in question resulted from factors unrelated to the vaccine.[284] Nearly all NVICP claimants take advantage of the Table to establish causation.[285] If a claimant's injury is not on the Vaccine Injury Table, the claimant must produce medical records or opinions that establish the causal connection between the vaccine and the harm by a preponderance of the evidence.[286] Few claimants successfully argue causation without the use of the Table.[287]

Litigation in NVICP focuses on whether the claimant's injury constitutes a compensable event—i.e., whether a covered vaccine caused the injury.[288] No inquiry is made into whether there was misfeasance or malfeasance on the part of the vaccine manufacturer or regulatory failure on the part of the FDA.[289] Nor is any inquiry made into the adequacy of the manufacturer warning.[290] For this reason, discovery is truncated.[291] In general, the only issues to be resolved in NVICP compensation cases "can

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282. *See* 42 U.S.C. § 300aa-13 (2006).

283. *Id.*

284. *See* 42 U.S.C. § 300aa-13(a)(1)(B) (2006).

285. Ridgway, *supra* note 280, at 70.

286. Susan G. Clark, *The National Childhood Vaccine Injury Act, The National Vaccine Injury Compensation Program*, 94 ED. L. REP. 671, 677 (1994).

287. Ridgway, *supra* note 280, at 70.

288. *Id.* at 63 ("[T]his no-fault model depends only on showing that the vaccination caused the injury and on compliance with the technical rules of the statute.") *See also* 42 U.S.C. § 300aa-22(b) ("No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings. . . . [A] vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) . . . ."); *id.* at § 300aa-22(c) ("No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.").

289. 42 U.S.C. § 300aa-12(d)(2)(E) ("The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of Title 28. Such rules shall . . . provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.").

290. Benshoof, *infra* note 322, at 414.

291. Ridgway, *supra* note 280, at 69.

be classified as challenges to the applicant's compliance with technical requirements, disagreement over the cause of the vaccinee's injury, doubts about the credibility of witnesses, and disputes over the amount of compensation."[292]

The NVICP also includes a modest information-gathering component. The Act mandates that healthcare providers administering vaccines must report all occurrences of adverse events of the types listed in the Vaccine Injury Table.[293] The NCVIA also established the Vaccine Adverse Event Reporting System (VAERS).[294] Like the AERS, this passive reporting system allows the FDA, in collaboration with the Centers for Disease Control (CDC), to monitor vaccines for possible new side effects, identify patient risk factors for side effects, and assess the safety of new vaccines down to the level of specific vaccine lots.[295] According to the CDC, more than 30,000 VAERS reports are filed annually, with 13 percent classified as serious.[296]

The NVICP has been criticized on a number of grounds, from the lack of predictability in its judgments to the difficulties petitioners have in finding representation. These criticisms are discussed more fully in Section C, below.

#### 2. *Virginia Birth-Related Neurological Injury Compensation Act*

The Virginia Birth-Related Neurological Injury Compensation Act (VBIA) was the first reform effort in the United States to adopt no-fault compensation for specific medical harms.[297] Unlike other U.S. no-fault schemes, such as the NVICP described above, participation in the fund is not mandatory. Rather, physicians have the option to purchase no-fault medical malpractice insurance that requires their patients to use an administrative remedy for certain injuries.[298] The scheme only compensates for total and permanent neurological injuries to infants resulting from deprivation of oxygen or mechanical injury during labor, delivery, or certain types of resuscitation.[299] Nor is the remedy exclusive: a claimant may sue in tort if she alleges that the harm was caused by willful

292. Ridgway, *supra* note 280, at 64.

293. *See* 42 U.S.C. § 300aa-25(b) (2006) (mandating reporting of any event listed specifically in Vaccine Injury Table that occurs within seven days of vaccine administration).

294. *About VAERS*, VACCINE ADVERSE EVENT REPORTING SYSTEM, http://vaers.hhs.gov/index/about/index (last visited Sept. 6, 2010).

295. *Id.*

296. *Id.*

297. Benshoof, *infra* note 322, at 420.

298. *Id.* at 421.

299. VA. CODE ANN. § 38.2-5001 (2005).

mistreatment.[300] Subsequent to establishment of the VBIA, a similar program was enacted in Florida.[301]

The VBIA piggybacks on the state's existing workers' compensation program, requiring covered claims to be adjudicated by the Virginia Workers' Compensation Commission.[302] After the Commission receives a petition for compensation, a panel of physicians reviews the medical evidence and submits a report to the Commission stating its opinion on whether the injury is birth-related.[303] However, while the Commission must consider this opinion, the panel's determination is not binding.[304] After the Commission has received this report, the program, as the "defendant," files a response to the petition[305] and the Commission holds a hearing to determine whether the petitioner has a compensable claim.[306] While discovery is generally limited to medical records and documents relevant to determining the appropriate level of compensation,[307] parties may apply to the Commission for permission to serve interrogatories or depose witnesses.[308]

The Fund only covers extremely serious birth-related neurological injuries—cases where a live infant is permanently disabled and "in need of assistance in all activities of daily living."[309] Claimants who put forth evidence that "the infant has sustained a brain or spinal cord injury caused by oxygen deprivation or mechanical injury, and that the infant was thereby rendered permanently motorically disabled" raise a rebuttable presumption that the injury was birth-related.[310] Claimants may then recover for "medically necessary and reasonable expenses of medical and hospital, rehabilitative, residential and custodial care and service, special equipment or facilities and related travel,"[311] loss of earnings from the ages of 18–65,[312] and reasonable expenses incurred in filing the claim.[313]

The results of the VBIA have been mixed. The Act has reduced

300. *Id.* § 38.2-5002(C) (2005).

301. FLA. STAT. ANN. §§ 766.301-.316 (West 1997); Bovbjerg & Sloan, *supra* note 108, at 82. Because these two programs are substantially similar, I focus my analysis primarily on the Virginia program.

302. VA. CODE ANN. § 38.2-5003 (2005).

303. VA. CODE ANN. § 38.2-5008(B) (2005).

304. *Id.* § 38.2-5008(C) (2005).

305. *Id.* § 38.2-5004(D) (2005).

306. *Id.* § 38.2-5006 (2005). The hearing itself is now fairly robust, including the right to call and cross-examine witnesses. § 38.2-5008.1 (2008).

307. *Id.* § 38.2-5004 (2005).

308. *Id.* § 38.2-5007 (2005).

309. *Id.* § 38.2-5001 (2003).

310. *Id.* § 38.2-5008 (1994).

311. *Id.* § 38.2-5009(A)(1) (2008).

312. *Id.* § 38.2-5009(A)(2).

313. *Id.* § 38.2-5009(A)(3).

obstetrical insurance premiums in Virginia both compared to the national average and absolutely.[314] However, some commentators argue that the VBIA has been less effective at deterring medical malpractice. While the statute provides for the review of claims by the Board of Medicine and the Department of Health, a process that can result in sanctions including revocation of physician's professional licenses, it is unclear whether this threat has any teeth.[315] Several commentators have criticized the program for failing to reach out to the "full, intended population of eligible claimants."[316] They have also criticized a similar program in Florida for failing to significantly decrease the number of tort claims filed.[317] At the same time, it is unclear whether the VBIA has had any effect on quality of care.[318] The scheme does not use "experience rating" to force physicians who injure more patients to pay higher premiums. Until recently, the scheme did not notify physicians when claims were filed, involve them in proceedings, or inform them of any findings.[319] The statute was amended in 2003 to require that the report of the reviewing panel of physicians be mailed to all involved parties.[320] The amendments also required that the state Board of Health Professions or Department of Health investigate health care providers and participating hospitals if the conduct in question warrants disciplinary action.[321]

### *B. Based on These Schemes, a No-Fault System For Drugs and Devices Would Improve on Tort Law in Several Important Ways.*

In general, no-fault schemes have few of the drawbacks of tort law. Unlike tort law, in which the potential for liability can vary widely from jurisdiction to jurisdiction and jury to jury, both the "pay-in" by corporations into the fund and the "pay-out" to the injured are fairly predictable in no-fault schemes. This would be a particular boon to firms in the drug and medical device industries, in which the fear of unpredictable liability has prevented manufacturers from producing certain products—such as birth control drugs and devices—despite market demand.[322] Eliminating the risk of unpredictable liability might induce manufacturers

314. Bovbjerg & Sloan, *supra* note 108, at 99–100.

315. Jane R. Ward, *Virginia's Birth-Related Neurological Injury Compensation Act: Constitutional and Policy Challenges*, 22 U. RICH. L. REV. 431, 452 (1988).

316. Bovbjerg & Sloan, *supra* note 108, at 115.

317. *Id.* at 104.

318. *See id.* at 102–05.

319. *Id.* at 102–05.

320. Id. § 38.2-5008(C) (Supp. 2003).

321. Id. § 38.2-5004(B)-(C) (Supp. 2003).

322. *See* Janet Benshoof, *Protecting Patients, Prodding Companies, and Preventing Conception: Toward a Model Act for No Fault Liability for Contraceptives*, 23 N.Y.U. REV. L. & SOC. CHANGE 403, 405 (1997).

to reenter these important drug and device markets.

In addition, no-fault schemes are also more efficient at compensating victims, as a larger percentage of the money expended by no-fault schemes goes toward compensating the injured, as opposed to compensating attorneys. For example, a 1986 study by the RAND Institute for Civil Justice found that only 46 cents of every dollar spent on tort litigation went to petitioner awards.[323] By contrast, of the $370 million the NVICP spent from 2001 to 2004, $318 million (86%) was used for petitioner awards.[324] Of the remaining $52 million, 11 percent was used for federal administrative costs and 3 percent for attorneys' fees.[325] Similarly, in Florida's Birth-Related Neurological Injury Compensation Act, administrative costs, including attorneys' fees, account for only 10.3 percent of total spending.[326] In part, these lower costs are due to lower attorneys' fees because of caps on fees, more limited discovery, and the elimination of expensive trials. In the NVICP, for example, transaction costs are as much as 56 percent lower than what they would be in tort litigation.[327]

An effective and efficient no-fault scheme might be better at spreading the financial risk of drug and device harms by providing more certain compensation for a larger portion of the population. Under the current system, when injured patients do not wish to engage in a lengthy litigation process, are not able to afford an attorney, or cannot find an attorney willing to take their case, they bear the costs of their injuries alone. According to one study of medical malpractice lawsuits, of the 27,179 patients who suffered adverse events due to medical personnel negligence, less than 3 percent filed claims.[328] However, in a no-fault scheme with lower transaction costs and a streamlined claims process, more injured patients may take advantage of the fund to recover for their injuries. A no-fault system might be a particularly appealing alternative for lower-income individuals who do not have the money to retain an attorney. It would also

323. JAMES S. KAKALIK & NICHOLAS M. PACE, RAND INST. FOR CIVIL JUSTICE, COSTS AND COMPENSATION PAID IN TORT LITIGATION 70 (1986).

324. Office of Mgmt. & Budget, *Detailed Information on the Vaccine Injury Compensation Program*, EXPECTMORE.GOV, http://www.whitehouse.gov/omb/expectmore/detail/10003807.2005.html (last visited Apr. 26, 2009).

325. *Id.*

326. Randall R. Bovbjerg, Frank A. Sloan & Peter J. Rankin, *The Administrative Performance of "No-Fault" Compensation for Medical Injury*, 60 LAW & CONTEMP. PROBS. 71, 93 (1997).

327. Office of Mgmt. & Budget, *supra* note 324.

328. A. Russell Localio, Ann G. Lawthers, Troyen A. Brennan, Nan M. Laird, Liesi E. Hebert, Lynn M. Peterson, Joseph P. Newhouse, Paul C. Weiler & Howard H. Hiatt, *Relation Between Malpractice Claims and Adverse Events Due to Negligence*, 325 NEW ENG. J. MED. 245, 247–48, Figure 1 (1991).

encourage individuals whose injuries are significant but not sufficiently serious to generate an award large enough for an attorney to take the case on a contingency-fee basis to pursue their claims.

### C. *There Are Several Obstacles to Creating a No-Fault Scheme That Would Replicate the Benefits of Tort Liability Effectively.*

A handful of commentators have proposed using the NVICP as a model for a no-fault scheme for prescription drugs and devices.[329] However, while the NVICP has been fairly successful at both compensating injured patients and reducing manufacturer liability, the scheme has encountered significant difficulties in critical areas.

#### *1. Determining Causation*

One of the major obstacles to developing an effective and fair no-fault scheme for drugs and devices is determining how to assess causation. All no-fault schemes addressing product liability claims are "premised on the existence of a causal link between a particular product and a particular kind of injury."[330] In order for a no-fault system to maintain low transaction costs, including administrative costs and attorneys' fees, the scheme must be able to determine causation quickly and with minimal discovery. Causation is particularly difficult to determine in the case of drugs and devices because, unlike in the case of vaccines, the overwhelming majority of these products are used by unhealthy people.[331] As such, it is difficult to determine whether the treatment (the drug or device) or the underlying medical condition caused the patient's injury. The issue is further complicated by the fundamental disconnect between legal and medical understandings of causation.[332] The legal inquiry into causation is retrospective and specific, seeking to identify whether a drug is both a general cause (can it cause this type of injury?) and a specific cause (did it cause the injury in this person?). By contrast, the medical inquiry is prospective and general, seeking to identify "how often, if ever, one observation leads to another" on a statistical basis.[333] Unlike lawyers, "the scientist rarely expects to prove causation in an individual case," because "no clinical trial can expose identical subjects to alternative treatments."[334] Therefore, it is often difficult to fit medical harms into a legal framework, even when applying a more lenient preponderance standard of proof, as

329. *See* sources cited *supra* note 266.

330. Benshoof, *supra* note 322, at 411.

331. Breast implants and contraceptive drugs and devices are notable exceptions. *See id.*

332. Ridgway, *supra* note 280, at 71–72.

333. *Id.*

334. *Id.*

physicians are reluctant to definitively conclude that the harm suffered was caused by a particular drug or device.

As explained in the preceding section, the NVICP attempts to solve this problem by creating a table of adverse events for which causation is presumed. However, in practice the Vaccine Injury Table has not increased the efficiency of the NVICP. Although the Table negates the necessity to litigate whether a vaccine *can* cause a particular harm, parties still dispute whether the vaccine *did* cause the harm.[335] Lawyers have complained that it has become harder to demonstrate causation under the Act than to prove causation in similar tort claims in state court.[336] Because of these disputes over causation, attorneys for the government have been accused of making the process more adversarial than Congress had intended.[337] One petitioner's attorney commented, "[G]overnment lawyers want to defeat every claim at all costs and for any reason . . . . There is now no difference in the level of litigation than if the case were in state or federal court."[338] A special master similarly argued, "Instead of speed, certainty, and fairness, costly lengthy case presentations, inconsistent outcomes, and disparate treatment of similarly-situated litigants has resulted."[339] As a result, the fund is less efficient than intended. By increasing the rigor of the compensation process, it may also prevent some individuals who would otherwise be compensated by the fund from being compensated.

Moreover, creating an effective injury table for drug and device harms would be challenging. The drug and device market is much larger than the vaccine market, comprising thousands of products[340] by dozens of manufacturers[341] instead of a small number of vaccines by five major manufacturers.[342] Creating and maintaining a list of known drug and device injuries would present a significant logistical challenge. Moreover, while vaccine-related injuries are relatively well-known to the medical community and have a short latency period,[343] many drugs and devices are relatively unknown to the medical community and their injurious effects

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335. *See id.*

336. See *Katherine E. Strong,* Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day, 75 GEO. WASH. L. REV. 426, 446–47 (2007).

337. *See* Johnson, *supra* note 268, at 44–45.

338. *Id.* at 45.

339. Stevens v. Sec'y of the Dep't of Health and Human Servs., No. 99-594V, 2001 WL 387418 at *7 (Fed. Cl. Mar. 30, 2001), *abrogated by* Althen v. Sec'y of the Dep't of Health and Human Servs., 418 F.3d 1274 (2005).

340. *See, e.g.*, Wadman, *supra* note 9, at 465.

341. *List of Pharmacuetical Companies,* WIKIPEDIA.ORG, http://en.wikipedia.org/wiki/List_of_pharmaceutical_companies (last visited Sept. 29, 2011).

342. *See Shot in the arm,* THE ECONOMIST, May 2003, at 64 (noting that five manufacturers control eighty percent of the vaccine market).

343. Benshoof, *supra* note 322, at 414.

may not be discovered by the medical community due to the limitations of pre-market testing and the FDA's post-market monitoring system. As such, many of the injured patients seeking compensation from the fund are likely to suffer injuries that are not on the injury table. Without extensive fact-finding to determine causation, such unanticipated injuries could not be deemed compensable events.[344] While the NVICP permits recovery for people with off-table injuries pursuant to a fact-finding process, establishing causation in these instances has been problematic.[345]

### *2. Information-Gathering*

A no-fault compensation scheme like the NVICP or VBIA, on its own, will not replace the positive information-gathering effects of tort law. Injured patients applying for no-fault compensation will not have the opportunity to conduct discovery against drug or device manufacturers. Without these tort-related investigations, fraud on the agency might only be discovered through a leak within the company, a congressional investigation, or media scrutiny.[346]

Moreover, unlike tort law, a no-fault scheme is unlikely to spur additional research by manufacturers. Without the pressure of potentially large jury verdicts looming, manufacturers may be less likely to invest in pre- and post-approval testing. Indeed, without fear of later tort suits as a deterrent, manufacturers may be even more inclined to adopt a "see no evil, speak no evil" approach to adverse effects.

While the NVICP does collect information on adverse events through VAERS, the scheme does not offer an effective solution to this problem. VAERS "cannot . . . establish causation because the information collected is relatively incomplete."[347] Moreover, the FDA is not required to act upon the reports it receives through VAERS.

### *3. Predictability*

One of the often-cited advantages of no-fault over tort law is its potential to offer similarly situated victims consistent recovery in predictable amounts.[348] However, no-fault is not inherently better at creating predictable results than the so-called tort law "lottery."[349] A

344. *Id.* at 411.

345. *See* Ridgway, *supra* note 280, at 69.

346. Rabin, *supra* note 43, at 2069.

347. Copland & Howard, *supra* note 117, at 12.

348. *See, e.g.*, Marc A. Franklin, *Replacing the Negligence Lottery: Compensation and Selective Reimbursement*, 53 VA. L. REV. 774, 790–96 (1967).

349. *See generally* Timothy D. Lytton, Robert L. Rabin & Peter H. Schuck, *Tort as Litigation Lottery: A Misconceived Metaphor*, 52 B.C. L. REV. 267, 269–70 (2011) (arguing that no-fault is not inherently more predictable or equitable than tort law and that

poorly designed no-fault scheme may not produce predictable awards for injured patients and fund administrators. This makes the fund both difficult to administer (it is hard to predict how much money the fund needs) and unfair (similarly situated victims may receive different awards). Under the NVICP, while the liability of the vaccine manufacturers is certain—all vaccine manufacturers pay the same excise tax on their drugs—injured patients have highly variable rates of recovery. In some cases, patients are able to recover despite strong scientific evidence of lack of causation.[350] It is likely that similar difficulties would be encountered under a no-fault scheme for drugs and medical devices. If the scheme is experience-rated—i.e., manufacturers pay into the fund based on the risk associated with their drugs—such a policy runs the risk of both over-deterring "good" manufacturers and under-deterring "bad" manufacturers. As in the tort system, malfeasant manufacturers may escape a finding of causation, and thus have a lower financial burden, than is warranted by the culpability of their conduct. By the same token, manufacturers whose drugs are, in fact, safe may lose the no-fault lottery and may be required to pay more into the fund than is warranted.

#### *4. Public Education and Agency Failure*

A no-fault compensation scheme is unlikely to educate the public about the behavior of drug and device manufacturers and the interactions of those manufacturers with the FDA. As discussed above, by limiting the ability of injured patients to conduct discovery, no-fault claims will not uncover manufacturer malfeasance or regulatory failure within the FDA. Moreover, without the drama of a trial, the possibility of significant jury verdicts, or any advantage to be gained from waging a battle in the court of public opinion,[351] claims may not draw significant media coverage, making it difficult for the public to become aware of the scheme's findings and determinations.

#### *5. Funding*

Regardless of the method of funding for a no-fault scheme, it will be difficult to predict the costs of such a fund and thus ensure that it can remain solvent. At the time the NVICP was created, a great deal of information about the likelihood of vaccine-related injuries was available and Congress was able to devise precise excise tax amounts with relative ease.[352] Likewise, the Virginia Birth Injury Act appears to have calculated

arbitrariness is endemic in compensation schemes).

350. Ridgway, *supra* note 280, at 85–86.

351. Defendant manufacturers, for example, may wish to posture that their case is particularly strong in order to prevent their stock prices from going down.

352. Benshoof, *supra* note 322, at 428.

the likelihood of injury based on prior experience, much like a private insurance company would.[353] It is unlikely that a similar assessment could be done for drugs and devices because dozens of new drugs and devices are approved each year with an undiscovered and unpredictable potential to cause harm. Because it is so difficult to assess the risks associated with a drug or device before it enters the market, it is also difficult to assess, in advance, the costs associated with compensating injured parties.

### *6. Representation*

Finally, because of the $30,000 cap on attorneys' fees, injured patients have had difficulty finding good representation for their NVICP claims.[354] Because attorneys' hourly rates—at least to some degree—reflect experience, competence, and the ability to perform the same work in fewer hours, some commentators have argued that the cap discourages more experienced and competent attorneys from taking NVICP cases.[355] According to one source, "several attorneys and law firms who participated in early NVICP litigation have complained of financial hardship."[356] At the same time, because NVICP attorneys' fees are awarded regardless of case outcome, there is less financial motivation for vigorous advocacy by the plaintiffs' bar.[357] This, in turn, may decrease the positive impacts of the fund. Less-motivated attorneys may not perform sufficient due diligence in collecting the relevant records to present a claim. By failing to present complete information about their client, these attorneys may inhibit the information-collecting function of the fund. And without vigorous advocacy on their behalf, injured patients may be more likely to receive adverse determinations on their claims, preventing them from receiving compensation.

## V.
## AN EFFECTIVE NO-FAULT SCHEME FOR PRESCRIPTION DRUGS AND DEVICES WOULD BORROW FROM THE BEST PRACTICES OF SEVERAL EXISTING SCHEMES.

Despite the potential pitfalls described in the preceding section, a properly designed no-fault compensation scheme could be an effective solution to the problems presented by preemption of drug and device suits. A no-fault scheme must not only replicate the compensatory function of tort law, but also its information-gathering and educative side effects. In

353. *Id.*
354. Ridgway, *supra* note 280, at 75.
355. *Id.*
356. *Id.* at 76.
357. *Id.*

order to avoid the problems outlined in the previous sections, a no-fault scheme should: 1) provide compensation for harms caused by both drugs and devices; 2) use a panel of medical experts, rather than a special master, to evaluate claims; 3) create a federal right of action for "fraud-on-the-FDA" claims; 4) permit appeals in a designated federal court and an "opt-out" option for cases that raise issues of manufacturer malfeasance or agency capture; and 5) create a robust data collection and injury reporting system.

### *A. Covered Products*

Any no-fault scheme in this area should cover both prescription drugs and medical devices. As discussed in more detail in the next Part, the uncertainty following the Supreme Court's decision in *Wyeth* has created a unique moment of interest-convergence in which creating a no-fault scheme for prescription drugs may be politically feasible. However, medical devices should not be left out of the bargain. When these devices fail, the consequences range from additional painful or risky operations to death.[358] Following the Supreme Court's decision in *Riegel*, it is unlikely that injured patients and their families will be able to recover for these harms, creating a compensation gap.[359] By including devices, a no-fault scheme would fill that gap.

### *B. Location*

A no-fault compensation scheme will likely require coordination among several different federal agencies in order to permit efficient administration while insulating the fund from political forces.[360] In order to facilitate seamless transmission of information between the fund and the FDA, the administrative functions associated with the fund, such as the distribution of awards, should be housed within the U.S. Department of

358. In 2010, for example, Johnson & Johnson recalled several hip replacement devices. These devices had failed prematurely in hundreds of patients, "requiring expensive and painful operations to put in new hip replacements." Natasha Singer, *Hip Implants Are Recalled By J.&J. Unit*, N.Y. TIMES, Aug. 27, 2010, at B1. Similarly, patients have died in procedures to remove faulty Sprint Fidelis heart leads. Barry Meier, *Study Finds More Failure of Heart Device*, N.Y. TIMES, Feb. 24, 2009, at B9.

359. For example, hundreds of lawsuits were filed after the Sprint Fidelis heart leads were recalled by their manufacturer, Medtronic. Meier, *supra* note 358. According to the *New York Times*, "a federal judge in Minneapolis dismissed all those lawsuits, citing a Supreme Court ruling last year that found federal law shielded makers of certain medical devices from product liability lawsuits." *Id.*

360. The NVICP, for example, involves coordination between the Department of Health and Human Services, the Department of Justice, and the U.S. Court of Federal Claims. *National Vaccine Injury Compensation Program (VICP)*, DEP'T OF HEALTH & HUMAN SERVS., HEALTH RESOURCES & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/ (last visited Mar. 6, 2011).

Health and Human Services. The administrative responsibilities of the fund could be located in a department of the Healthcare Systems Bureau, which also houses the NVICP.[361] This would allow the fund to draw on the existing expertise of that Bureau in administrating no-fault schemes, such as the NVICP.

However, in order to ensure that the scheme's actions are relatively independent, actual fund adjudications should occur outside of HHS. As with the NVICP, patients seeking compensation from the drug and device scheme should be required to file a claim in the United States Court of Federal Claims.[362] Separating the fund from the FDA will insulate it from undue agency influences on its decision-making, such as agency culture. As noted in Part II, the FDA's perception of its relationship with pharmaceutical and drug manufacturers has influenced its decision-making in the past.[363] Even if fund administrators and adjudicators were separated from other decision-makers in the agency, agency culture could still influence fund decisions. By separating the fund from the FDA entirely, the fund can preserve its independence and objectivity. Housing the fund in the Court of Federal Claims would also avoid the potential federalism issue that might arise if Congress required the right to compensation, a traditional judicial right, to be adjudicated by an executive branch agency.[364]

### *C. Funding the Scheme*

A no-fault drug and device scheme should be funded by an annual fee paid by manufacturers. As noted above, the NVICP is funded through an excise tax on each dose of a covered product. However, because drugs, unlike vaccines, are not one-time purchases, the incremental increase in medication costs imposed by a direct excise tax could have a significant impact on the annual cost of medications. As an excise tax is also highly visible to patients, the threat of increased costs could be used to create opposition to the creation of the scheme. Instead, Congress should levy an annual tax against manufacturers to fund the scheme.[365] While manufacturers will likely shift some of these costs to patients in the form of higher drug and device prices, insurance will likely absorb at least part of this cost increase. As any increase in drug costs will be less visible to

361. *Id.*

362. 42 U.S.C.A. § 300aa-11(a)(1) (2006).

363. *See supra* Part II.

364. *See* N. Pipeline Constr. Co. v. Marathon Pipe Line Co., 458 U.S. 50, 70 (1982) (holding that Article I courts may not render final judgments in cases involving life, liberty, and private property rights, with limited exceptions).

365. Janet Benshoof proposed that a similar tax be used to fund her proposed no-fault scheme for contraceptives. Benshoof, *supra* note 322, at 431.

consumers, it will also increase the likelihood that the public will support the creation of the scheme.

The amount of the fee paid by each manufacturer should initially depend on market share and should eventually be "risk-assessed" annually based on the size of the payouts made by the fund to patients.[366] As noted in the preceding section, because a no-fault scheme does not eliminate the possibility of arbitrary awards, determining the annual fee through risk assessment may not produce optimal deterrence for manufacturers. However, much like the tort system, which is equally "arbitrary," a no-fault scheme that employs risk assessment will provide some encouragement to manufacturers to produce safer drugs. The fee should pay both for the actual compensation given to patients and for the administration of the fund. As such, the fund will not require Congress to either raise taxes or increase the deficit, which should increase the political feasibility of the scheme.[367]

One of the biggest challenges for the fund will be to ensure it is financed sufficiently to cover the number of claims—which, as noted in the previous section, will be difficult to determine ex ante. The authorizing legislation should require the size of the fund—and thus the fee that should be assessed against the manufacturers—to increase as necessary to reflect actual demand. In order to preserve the division between administrative and adjudicative functions, the Healthcare Systems Bureau should have responsibility to determine when to increase the fee assessed on manufacturers. While granting the Healthcare Systems Bureau jurisdiction could increase the political pressures involved in fee determination, it would preserve the independence of the adjudicators. Because so many drug and device harms are unknown at the time of FDA approval, these measures would ensure that the fund could respond to unpredictable increases in the number of claims without compromising the level of compensation provided to injured patients.

### *D. Preemption*

Congress should explicitly state that neither the FDCA nor this scheme preempts state tort suits for harms caused by drugs or medical devices. As in the NVICP, Congress should instead require that injured patients exhaust the administrative remedy provided by the scheme before pursuing a claim in tort law, with a few major exceptions as described below. As noted above, a similar exhaustion requirement funnels vaccine claims through the NVICP. A similar condition in a no-fault scheme

366. Copland & Howard, *supra* note 117, at 15.

367. *See* Jeb Barnes, *Rethinking the Landscape of Tort Reform: Legislative Inertia and Court-Based Tort Reform in the Case of Asbestos*, 28 JUST. SYST. J. 157, 160 (2007).

would ensure that recovery remains available in tort in the case of extraordinary harms.

Congress should also expressly state in the statute that the purpose of the scheme is to ensure that patients are compensated for their injuries and to gather more information about drug and device harms. By doing so, Congress can assure that subsequent interpretations of the preemptive effect of the statute consider the effect of preemption on these important goals.[368]

### *E. Defining the Compensable Event*

An injured patient should be able to request compensation for unknown risks (i.e., risks not found during the routine NDA process) associated with the drug or device that she was using.[369] James Copland and Paul Howard have argued that this "would have the salutary effect of encouraging drug manufacturers to disclose adverse events as they occurred during routine use," as claimants would not be able to recover for known side effects.[370] Claimants would only be able to recover for known side effects if the claimant alleged that the risk of harm is more prevalent or more severe than the FDA was aware of at the time of approval. This would disincentivize manufacturers from trying to game the system by disclosing the existence of a side effect in order to prevent recovery (and thus a larger risk-assessed fee) while also downplaying its prevalence in order to avoid including a warning with the drug itself. Permitting patients to recover for risks that were known at the time of approval also serves as a vital means of correcting regulatory failure, mitigating the harm caused when the FDA fails either to appropriately weigh or to adequately convey the risks associated with the drug. Just as important, permitting patients to seek compensation for these injuries will also ensure that a record of the adverse impact of that drug or device is created and can be passed on to the FDA, enhancing the information-gathering function of the fund.

### *F. Finding Fault*

One of the most significant obstacles to developing no-fault scheme for drugs and devices is determining an effective and efficient method for finding fault. As noted above, there are significant practical difficulties in constructing a causation table for drugs and devices. However, creating the table would streamline the process for both injured patients and the fund

368. *See* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992). Because the "purpose of Congress [in enacting a statute] is the ultimate touchstone of pre-emption analysis," a clear statement from Congress would likely be determinative in any future analysis by the Supreme Court. *Id.*

369. Copland & Howard, *supra* note 117, at 14.

370. *Id.*

in those few cases where the causal links between particular adverse events and certain drugs and devices are known. A no-fault scheme for drugs and devices should employ both an injury causation table and a fact-finding process to determine causation of injuries not appearing in the table. In order to fully capture the efficiency advantages of an injury table, the enabling statute must require frequent updates of the table. The statute should mandate a timeline and a process by which the table will be timely updated to incorporate new conditions. For example, the statute could require that the Secretary of HHS update the table every two to five years. The statute could also include a trigger mechanism to require that the Secretary explicitly rule on whether to include an adverse reaction in the table if the scheme administrators find that a product causes an adverse reaction in a particular number of cases. By mandating periodic agency action, the table would remain as up-to-date as possible. This would speed recovery for injured patients and increase the efficiency of the scheme as a whole by decreasing the number of cases in which causation is in dispute.

However, compensation should not be limited to known linkages included on the injury causation table. In the majority of cases, the patient will be seeking compensation for an injury not on the table; thus, the scheme must allow for a relatively robust fact-finding process. Discovery should be truncated in order to reduce costs, but it should also permit the use of expert testimony. In order to decrease the adversarial nature of the procedure, the case should not be adjudicated by a special master, as in the NVICP. Rather, a panel of medical experts should review the case. This panel would find causation—and thus a right to compensation—in those cases where a preponderance of the evidence supports the conclusion that a particular drug or device caused the adverse event. Because causation is so difficult to establish in drug and device cases, the panel would use a lenient preponderance standard. This standard would require that the panel give substantial weight to both evidence of a statistical relationship between the product and the adverse event, as well as evidence of a chronological connection between the two.

### *G. Amount of Compensation*

As with the NVICP, the scheme should cover non-reimbursable medical expenses, rehabilitation, and lost wages—damages that are generally compensable under the tort system. The scheme should also cover pain and suffering capped at a definite amount in current dollars that would be adjusted for inflation over time. A cap on pain and suffering awards is necessary in order to ensure that the size of individual awards, and thus the overall operation cost of the fund, is sufficiently predictable. The fund should not compensate patients for emotional harm. Emotional harm is very real and, in some cases, may exceed more tangible harms such

as medical expenses. However, because emotional harm is inherently difficult to measure and prove,[371] it is difficult to evaluate the appropriate level of compensation consistently and fairly, decreasing the efficiency and predictability of the fund.

The level of compensation described above should be sufficient to encourage injured patients to accept compensation from the fund in lieu of continuing to pursue their claims in tort. Not only will the fund generally compensate for the same harms as the tort system (with the exception of emotional harm), but injured patients will receive a greater share of compensation due to the lower transaction costs of filing a claim with the scheme. Nevertheless, the Secretary should be permitted to make upward revisions in the amount of the cap on pain and suffering awards, as well as reevaluate the denial of compensation for emotional harms, in order to encourage full participation in the scheme.

### *H. Attorneys' Fees*

Despite the difficulties posed by a cap on attorneys' fees under the NVICP, a no-fault scheme for drugs and devices must nevertheless incorporate a similar cap. A cap of some sort on attorneys' fees is necessary in order to maintain the efficiency of the scheme and allow its costs to remain predictable. In passing the scheme, Congress should solicit testimony from the plaintiffs' bar and administrators of the NVICP program to determine the appropriate level for the cap. As in the NVICP, attorneys' fees should be awarded regardless of claim outcome in order to ensure that claimants can have access to representation if they wish, even if they cannot afford to pay. While automatically rewarding attorneys' fees may remove the financial incentive for vigorous advocacy, counsel are still bound by their fiduciary duty and professional responsibility, and will likely suffer reputational harms if they do not vigorously represent claimants. Moreover, the claimant should be permitted to recover attorneys' fees for the claim process even if the claimant ultimately chooses to opt-out of the compensation scheme and attempt to recover in tort after the claim has been adjudicated. By permitting recovery of attorneys' fees, the scheme will remove a potential conflict of interest between the attorney, who wishes to recover for her fees, and the claimant, who may wish to take a chance on a higher award. There is little danger that attorneys will litigate meritless tort cases in the hopes of getting a "second bite" of the attorneys' fees apple, as the tort litigation itself would have to be financed either through upfront payments or contingency fees by potential plaintiffs.

371. Claire Finkelstein, *Is Risk a Harm?*, 151 U. PA. L. REV. 963, 977 (2003).

### *I. Opt-Out and Appeal*

As mentioned above, claimants should be required to exhaust the administrative remedy available before pursuing their claims in tort law. However, claimants should also be able to opt out of the scheme in cases where the litigation is reasonably likely to uncover manufacturer malfeasance and/or agency capture. In order to facilitate this process, Congress should create a federal right of action for cases alleging fraud on the FDA. By permitting exceptions to the exclusivity of the remedy in the case of willful wrongdoing, such as lying to the FDA, the scheme would help deter dishonest behavior on the part of manufacturers who might otherwise escape reputational damage.[372]

Since the "opt-out" provision is sufficiently narrow, most injured patients will seek compensation through the scheme rather than through tort law. While injured patients (or their attorneys) may be tempted to allege fraud simply in the hopes of getting a larger damage award in the tort system, the heightened federal pleading standard announced by the Supreme Court in *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal* is likely to deter claimants from bringing meritless fraud claims.[373]

If claimants receive an adverse finding, they should be permitted to appeal in a designated federal court. Similarly, if claimants are not satisfied with the amount of their award, they should also be permitted to appeal their claim in a designated federal court on the limited factual issue of whether the fund accurately determined their damages. These appeals should be centralized in a particular federal court in order to enhance the efficiency of the fund.

### *J. Data Collection and Injury Reporting*

In order for the scheme to effectively replicate the information-gathering effects of tort law, it must incorporate a robust data collection component. However, the data collection component need not be complex in order to be effective. As noted in the previous section, the data collection elements of the NVICP have been relatively ineffective because

372. Benshoof, *supra* note 322, at 428.

373. Under *Twombly* and *Iqbal*, plaintiffs must "state a claim to relief that is plausible on its face," *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007), in the opinion of the court by pleading facts which "permit the court to infer more than the mere possibility of misconduct," *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). Injured patients thus could not simply state that the defendant manufacturer had defrauded the FDA, but would have to allege sufficient facts to persuade a court that such fraud is more likely than other, lawful explanations for the conduct. *Id.* (describing *Twombly*, an antitrust case, as holding that the plaintiffs had not stated a claim on which relief could be granted because the plaintiffs "did not plausibly suggest an illicit accord because [the defendants' behavior] was . . . more likely explained by, lawful, unchoreographed free-market behavior"). Injured patients with meritless claims of fraud likely will not be able to meet this heightened standard.

the data collected is incomplete and because the FDA is not required to act on that data. In order to correct for these failures, the scheme should collect a broad set of data and include action-forcing provisions to require FDA review.

Rather than creating a separate data collection program as suggested by Copland and Howard,[374] the scheme should automatically report all claims as adverse events through the AERS system. By funneling the data from the scheme through the existing post-market data collection system, the scheme would increase the data available for analysis without creating an additional layer of bureaucracy that might interfere with the FDA's ability to process that data accurately and effectively.

The scheme should report all claims to AERS, rather than just those that are substantiated, in order to provide the maximum amount of data for the FDA's post-marketing surveillance efforts. There is no need to filter this data, as the reports in AERS are independently evaluated by clinical reviewers at the FDA.[375] By funneling claim data through AERS, the scheme will arm the FDA with more complete information with which to make accurate regulatory judgments. Given the fundamental difference between medical and legal understandings of causation, medical professionals reviewing a broad area of epidemiological data may notice trends that identify a drug or device as the cause of a particular harm, even if the fund's panel of experts may find the opposite in an individual case. At the same time, the fund may unwittingly compensate for injuries that were not, in fact, caused by drugs or devices. With a full picture of the claims universe, the agency may be able to identify the existence of hazards that are difficult to perceive on a case-by-case basis, and to discredit illusory causal relationships.

In order to ensure that the FDA actively pursues post-market review in the absence of high-profile tort suits, the scheme's enabling legislation should mandate that, once the fund has received a certain number of claims regarding substantially similar adverse events caused by the same drug or device, the FDA engage in some formal review of the scientific findings in those cases. It should also require the manufacturer to perform Phase IV testing of that drug.

The creation of a no-fault scheme for drugs and devices should not be taken lightly because it raises fundamental questions about the role of government and the place of private ordering in our increasingly complex administrative state. It also presents unique complications that are not present in the current scheme of tort compensation. The amount of

374. Copland & Howard, *supra* note 117, at 15.

375. *Adverse Event Reporting System (AERS)*, FDA, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm (last visited Apr. 25, 2009).

compensation in tort is determined by the jury, any state legislation limiting recovery, and the solvency of the manufacturer. A no-fault scheme adds another constraint, as political factors may influence the fund's ability to assess sufficient fees on manufacturers to maintain its solvency. Moreover, even a well-designed no-fault scheme may not be able to replicate all the benefits provided by tort law. As noted above, it is unlikely that a no-fault scheme would educate the public about drug and device harms or agency capture in the same way that highly-publicized tort litigation can. It may also change the incentives for manufacturers and other scientists to continue to research and report the existence of drug and device harms. A no-fault scheme may also replicate many of the flaws of tort law. Because determining causation may be difficult, it is possible that compensation may be as arbitrary under a no-fault scheme as in the so-called tort "lottery."

### *K. While There Are Several Policy Changes That Could Protect Against Drug and Device Harms, a No-Fault Scheme Is the Most Feasible Option.*

No-fault is one among many possible solutions to the problem of preemption of state tort claims for drugs and devices. Given the limitations of no-fault, it is worth considering whether alternatives, such as creating a private right of action, are more beneficial or politically feasible. In this Part, I evaluate several possible reforms that could reverse the trend toward preemption or limit its negative effects. Despite its limitations, a no-fault compensation scheme for prescription drugs and medical devices may be the best option because it is the most politically viable. Given the uncertain future of state tort claims, the proposed no-fault scheme would likely be supported by drug and device companies, tort reform advocates, consumers, and the plaintiffs' lobby.

#### *1. The President Could Reform the FDA.*

Many of the flaws in the FDA—such as inadequate funding and insufficient information about post-market harms—can and should be fixed through traditional measures. While the FDAAA is imperfect,[376] the legislation granted the FDA important new powers that will enable it to better ensure the health and safety of Americans.[377] Similarly, presidential administrations can influence FDA behavior by making drug and device harms a priority, appointing strong agency leaders, and creating a culture within the agency that attracts talented, dedicated line workers. The FDA under Obama Administration, for example, has recently been praised for

376. *See supra* Part II.A.4.

377. *See supra* Part II.A.3.

its unusual transparency about the FDA decision-making process and the flexible, creative approaches it has adopted to deal with drug and device harms.[378]

Unfortunately, as the current Congress has focused primarily on cutting federal programs rather than improving them, broad-based FDA reform is unlikely to occur in the near future.[379] Moreover, such legislative and executive changes are inherently fragile. While legislative inertia may prevent the outright repeal of empowering legislation,[380] it is relatively easy for Congress to simply starve the FDA of funds. Because Congress is required to consider budget issues on an annual basis, budgetary decisions are not subject to the same inertia that prevents repeal of legislation. Congress has thus had frequent opportunities to cut the FDA budget either to deliberately limit the agency's activities or to shift resources to other, high-priority efforts. As Congress has historically failed to allocate sufficient resources to the FDA,[381] this is more than a speculative threat.

More importantly, some of the flaws in the way the FDA deals with drug and device harms may be difficult, if not impossible, to fix. As noted above, the FDA's current pre-market approval process fails to uncover many drug and device harms.[382] Yet it is difficult to conceive of a different process that would be both practical and politically feasible.[383] Even if the

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378. Gardiner Harris, *New FDA: Transparency and Flexibility*, N.Y. TIMES, Sept. 25, 2010, at A9 (describing how such changes "have accelerated under the Obama administration, driven by increasingly sophisticated measures of drug safety and growing skepticism about whether the F.D.A. is making the right decisions and making them appropriately"). In what the *New York Times* described as a "landmark decision" on Avandia, a diabetes drug, the FDA "decided on an unusual middle path—allowing sales, but with tight restrictions" and acknowledged internal disagreement about the decision by posting memorandums offering competing recommendations on the agency's website. *Id.*

379. *See, e.g.*, Carl Hulse & Jackie Calmes, *Democrats Open Talks by Offering $6.5 Billion More in Cuts*, N.Y. TIMES, Mar. 3, 2011, at A18; Carl Hulse, *House Advances Budget and Cuts $4 Billion*, N.Y. TIMES, Mar. 1, 2011, at A16.

380. *See, e.g.*, Elizabeth Garrett, *The Purposes of Framework Legislation*, 14 J. CONTEMP. LEGAL ISSUES 717, 753 (2005) ("Legislators generally find it somewhat difficult to change the status quo because change requires collective action; thus procedures tend to be sticky, remaining effective past the life of the enacting coalition. All laws have elements of this type of entrenchment because the enactment of any statute changes the status quo against which future legislators act; outcome-oriented frameworks vary the procedural status quo rather than the substantive baseline.").

381. *See supra* Part A(1).

382. *See supra* Part A(2).

383. For example, the FDA could require manufacturers to undertake longer studies involving more participants. This could uncover more harms by testing the drug in a broader sample of the population and by collecting data on how the drug affects people across time. However, this would likely increase the time it takes for a drug to reach the market as well as the expense of drug development. Alternatively, the FDA could decide to conduct all drug and device testing in-house, paying for the tests through a user-fee paid by the manufacturers. Even if this proposal was budget neutral, it would likely be rejected by conservatives who would argue that it unnecessarily increases the size and scope of government.

FDA is well-equipped to act upon news of drug and device harms, in order to uncover some of these harms, the FDA will simply have to wait until patients are injured.

### 2. *Congress Could Pass a Law Stating that the FDCA, Including the MDA, Does Not Preempt State Tort Claims.*

Congress could reverse the preemption of tort claims for medical device harms and prevent the preemption of claims for drug harms by passing a law stating clearly that neither the FDCA nor the MDA preempts these claims. As the FDA's current power to preempt tort claims derives from these statutes, amending them would quickly put an end to the practice. Moreover, because the Supreme Court has held that the "purpose of Congress [in enacting a statute] is the ultimate touchstone of pre-emption analysis," a clear statement from Congress would be determinative in any future analysis by the Court.[384]

Since *Riegel*, several bills have been introduced in Congress that would clarify the MDA and reverse the trend toward preemption. In 2008, after the Supreme Court decided *Riegel*, Senator Edward Kennedy introduced the Medical Device Safety Act.[385] The Act would amend the MDA's express preemption clause to include language specifying that "nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State."[386] The day after the Supreme Court ruled in *Wyeth*, Representatives Frank Pallone (D-N.J.) and Henry Waxman (D-Calif.) re-introduced the Act.[387] However, the legislation has failed to gain momentum or even leave committee.[388]

It will be very difficult for Congress to pass a bill stating that the FDCA does not preempt state tort claims for drug and device harms because it would likely be strongly opposed by the Republican Party, which has historically supported tort reform efforts[389] and recently promised to enact medical malpractice reform as part of its Pledge to

384. Cipollone v. Liggett Grp, Inc., 505 U.S. 504, 516 (1992) (internal citation omitted).

385. Medical Device Safety Act of 2008, S. 3398, 110th Cong. (2008). A similar bill was introduced in the House. Medical Device Safety Act of 1998, H.R. 6381, 110th Cong. (2008)

386. S. 3398.

387. Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. 1st Sess. (2009). A similar bill was introduced in the Senate. Medical Device Safety Act of 2009, S. 540, 111th Cong. 1st Sess. (2009).

388. H.R. 1346.

389. *See, e.g.*, Robert Pear & David M. Herszenhorn, *G.O.P. Counters With a Health Plan of Its Own*, N.Y. TIMES, Nov. 4, 2009, at A20 (describing the Republicans' proposed health care reform bill, which would impose "a $250,000 limit on noneconomic damages, for physical and emotional pain and suffering . . . establish new hurdles for consumers to obtain punitive damages and . . . limit contingency fees for plaintiffs' lawyers").

America.[390] Several politically powerful constituencies, such as device manufacturers, would also oppose legislation that does not preempt state tort claims because device manufacturers are currently protected from state tort claims and damages. Drug manufacturers may also oppose the bill in hopes that a friendly presidential administration will eliminate their tort liability. Both interests would likely use their significant lobbying power to prevent the passage of the bill.[391]

*3. Congress Could Create a Private Right of Enforcement.*

Congress could also pass a bill that would create a private right of action under the FDCA. Private rights of action permit ordinary people to sue regulated entities—in this case, drug and device manufacturers—for failing to comply with federal regulations. Hence, a private right of action under the FDCA would permit injured patients to sue pharmaceutical or medical device companies for failure to comply with the FDA's requirements, such as failing to report adverse events to the FDA or failing to use or update a warning label in accordance with federal drug and device regulations. It could also permit injured patients to sue manufacturers where they violated these regulations by deliberately hiding information, thereby providing an avenue for injured patients to receive compensation. However, a private right of action under the FDCA would provide a more limited remedy than currently exists under tort law.

In order to create a private right of action, Congress would have to act. While the FDA has the power to preempt state law, including common law, by issuing regulations,[392] it does not have the power to create a private right of action.[393] The political viability of a bill creating a private right of action under the FDCA would depend on whether it would preempt other state claims for drug and device harms. If it did not preempt the claims, the bill would encounter opposition from drug and device manufacturers as described above. If the bill included a preemption provision, drug manufacturers might choose to support it. Because a private right of action

390. REPUBLICANS IN CONGRESS, A PLEDGE TO AMERICA 27 (2010), *available at* http://www.gop.gov/pledge.

391. In 2009, the pharmaceutical and health products industry spent $271,490,334 lobbying Congress. *Lobbying Database: Top Industries*, CENTER FOR RESPONSIVE POLITICS, http://www.opensecrets.org/lobby/top.php?showYear=2009&indexType=i (last visited Sept. 24, 2010).

392. *See, e.g.*, Geier v. Am. Honda Motor Co., 529 U.S. 861, 883–84 (2000); Hillsborough Cnty. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985).

393. Alexander v. Sandoval, 532 U.S. 275, 291 (2001) ("Agencies may play the sorcerer's apprentice but not the sorcerer himself."). Given this asymmetry, Catherine Sharkey worries that "regulatory preemption, combined with renewed vigor towards evisceration of federal private causes of action, could lead to a nearly complete substitution of public for private enforcement of the law." *Preemption by Preamble*, *supra* note 167, at 248.

would specify—and thus limit—the instances in which an injured patient could sue, it would reduce manufacturers' exposure to liability. Some drug manufacturers might prefer a guaranteed reduction in their tort liability immediately over the possibility of preemption in the future. It is unlikely that device manufacturers would support the bill, however, as it would expose them to liability they hoped to escape after *Riegel*.

*4. A No-Fault System For Drugs and Devices Could Be Feasible.*

A no-fault compensation scheme offers the best opportunity for Congress to preserve the positive aspects of tort law threatened by federal preemption. While a no-fault scheme is not a perfect replacement for tort law, it can replicate many of its benefits while minimizing some of its drawbacks. Furthermore, unlike legislation either stating that the FDCA does not preempt state law or creating a private right of action, legislation creating a no-fault scheme may find broad political support.

Admittedly, the proposal for creating a no-fault scheme for pharmaceutical and medical device harms is an ambitious proposal that may encounter significant obstacles. Although tort reform remains a hotly debated issue in the public sphere,[394] "trying to create new administrative compensation schemes is always an uphill battle and may be particularly steep" when the scheme seeks to replace tort law.[395] Many scholars suggest that tort law, once it is in place, is politically difficult to replace and that "reforms will tend to work only at the margins."[396] In 2005, for example, Congress proposed a no-fault trust for asbestos harms that foundered and was ultimately defeated in 2006 due to political difficulties.[397] Conservatives in Congress worried that the trust would become "a permanent fixture in the federal bureaucracy," while liberals argued that the bill was underfunded, overly restrictive, and unfairly favored big business interests.[398]

The Supreme Court's decisions in *Wyeth* and *Riegel* have created a moment of interest-convergence among several powerful constituencies. Unlike in other instances of replacement reform, which generally involve curtailing individual rights to tort relief, the future of tort claims for drug and device harms is already uncertain. This shifts the political dynamics of the bill. Pharmaceutical companies, disappointed that *Wyeth* preserved

394. The health policy magazine *Health Affairs* recently devoted an issue to the subject of medical malpractice reform. HEALTH AFFAIRS, *Medical Malpractice & Errors*, 29 HEALTH AFFAIRS NO. 9, Sept. 2010, *available at* http://content.healthaffairs.org/content/vol29/issue9/ (last visited Sept. 24, 2010).

395. Barnes, *supra* note 367, at 160.

396. *E.g., id.* at 158.

397. *Id.* at 157–58.

398. *Id.* at 157.

Vermont's ability to adjudicate prescription drug claims and its $8 million award, will likely continue to pressure Congress and the FDA to preempt common law claims. Patients and plaintiffs' lawyers, facing a future without an avenue of recovery for medical device injuries and fearing further preemption of state tort law, may support an alternative system of compensation for drug and device injuries.[399] A no-fault compensation scheme for drug and device injuries could address the concerns of the pharmaceutical industry, patients, and the plaintiffs' bar.

I first started writing and thinking about this issue in 2008—before the passage of the health care reform bill (and the legal challenges to it), before the rise of the Tea Party as a powerful driving force within the Republican Party. The political landscape has changed significantly in the years since. Given the Tea Party's antigovernment stance, it is unlikely that Tea Party Republicans would support the creation of a new government program. However, the proposal could still attract the support of Republicans interested in tort reform.[400] At the same time, the Democrats who supported the Medical Device Safety Act may also support a no-fault compensation bill as a way to similarly protect patient rights. A no-fault scheme could thus satisfy both Democratic and moderate Republican agendas.

As noted in the preceding Part, this scheme must cover both drugs and devices. While proposals for a no-fault scheme by conservative institutions like the American Enterprise Institute have excluded recovery for device harms,[401] the inclusion of medical devices might be politically feasible. As noted above, several congressional representatives have introduced legislation specifically targeted at reversing *Riegel*; because this legislation would again open them up to tort liability, manufacturers may have an interest in supporting the inclusion of devices in the fund.

399. If measured in terms of contributions, lawyers and law firms wield significant power on Capitol Hill, contributing $65,008,505 to members of Congress during the 2009-2010 election cycle. *Top Industries Giving to Members of Congress, 2010 Cycle,* CENTER FOR RESPONSIVE POLITICS, http://www.opensecrets.org/industries/mems.php (last visited 6/11/11). This is nearly four times the amount given by the pharmaceutical and health products industry. *Id.*

400. The VBIA was similarly passed as part of tort reform efforts in that state. *See* Jane R. Ward, *Virginia's Birth-Related Neurological Injury Compensation Act: Constitutional and Policy Challenges*, 22 U. RICH. L. REV. 431, 431–32 (1988) (stating that the VBIA was passed in response to a perceived medical malpractice crisis after a lower court struck down a prior limit on tort recovery).

401. For example, while Copland and Howard argue that Congress should preempt state tort claims for both drugs and devices, it is unclear whether their proposed scheme would offer compensation for these device harms.

## VI.
## CONCLUSION

For decades, state tort law and the FDA have worked hand-in-hand to protect health and safety. However, in the last few years, this symbiotic relationship has begun to erode, as the FDA has increasingly argued that FDA regulation of drugs and medical devices preempts state tort law. Injured patients are already barred from receiving compensation for injuries caused by medical devices. Given the Supreme Court's growing tendency to defer to the FDA's opinions on preemption, the preemption of state tort claims for injuries caused by pharmaceutical drugs is likely to follow. The sudden absence of state tort law will leave significant gaps in the regulatory scheme, decreasing the FDA's ability to monitor drugs effectively once they have entered the market, reducing the transparency of both drug and device manufacturers' practices and the regulatory process, and preventing compensation of injured patients entirely.

A no-fault scheme presents the most feasible solution to the problems presented by preemption. Given the influence of the pharmaceutical and medical device industries in Congress,[402] simply reversing *Wyeth*, *Riegel*, and *Buckman* by clarifying the preemptive effect of the FDCA may not be politically possible. By contrast, the trend towards preemption has created a moment of interest-convergence: tort reform advocates, drug and device manufacturers, patients, and the plaintiffs' bar alike could support a no-fault solution. If constructed well, a no-fault scheme could replicate many of the positive aspects of tort law. Congress should seize this unique opportunity to preserve the beneficial effects of tort law and protect the health and safety of Americans.

402. *See, e.g.*, Robert Cohen, *Drugmaker lobbying hits record $168 million was spent in 2007*, NEWARK STAR-LEDGER (N.J.), June 25, 2008, at 35; Michelle Singer, *Under The Influence:* 60 Minutes' *Steve Kroft Reports On Drug Lobbyists' Role in Passing Bill That Keeps Drug Prices High*, CBS NEWS – 60 MINUTES (July 29, 2007), *available at* http://www.cbsnews.com/stories/2007/03/29/60minutes/main2625305_page2.shtml?tag=contentMain;contentBody.