

NOTE

WHEN AND HOW TO DEFER TO THE FDA: LEARNING FROM MICHIGAN'S REGULATORY COMPLIANCE DEFENSE

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INTRODUCTION

How FDA approval of a drug should affect pharmaceutical products liability litigation is one of the most debated topics in the law today. Whether states should defer (through a regulatory compliance defense), or should be forced to defer (through preemption) to the FDA's finding that a drug is safe, or should make independent determinations through the tort litigation process is the question that is being asked and answered by legislators, academics, and the United States Supreme Court.

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Michigan's legislature has decided that the FDA's determination should be granted almost absolute deference,¹ and this answer can provide insight on what role litigation should play in regulating drugs for the rest of the nation.

Drug makers in the United States are directly regulated by the Food and Drug Administration ("FDA")² and "are indirectly co-regulated by the tort litigation system."³ Some commentators have criticized the role that state tort law plays in this process—what Professor Lars Noah terms the "judicial regulation of drug labeling . . ."⁴ Others recognize an asymmetry in the tort system: in most states, compliance with regulations is no defense to a tort claim, but "failure to comply with a safety standard is a per se violation of the standard of care imposed by tort law."⁵ This asymmetric result is avoidable if courts find that federal regulation preempts state tort law claims in the pharmaceutical context or if states voluntarily adopt a regulatory compliance defense for FDA-approved drugs.

"Michigan alone provides for a complete regulatory compliance defense" for FDA-approved drugs.⁶ This may change if other states find that complying with FDA regulations should immunize a pharmaceutical company from all relevant state tort liability. Many commentators recognize that Michigan's statute could form a model for other states,⁷ and

1. See MICH. COMP. LAWS § 600.2946(5) (2000).

2. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321–399a (2006).

3. Elissa Levy, Note, *The HEALTH Act's FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 *FORDHAM L. REV.* 2425, 2425 (2006).

4. Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 *GEO. L.J.* 2147, 2148 (2000).

5. Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 *U. MICH. J.L. REFORM* 461, 462 (1997).

6. Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 *ROGER WILLIAMS U. L. REV.* 73, 74 (2008). See also Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 *J.L. & POL'Y* 1013, 1023 (2007) [hereinafter Sharkey, *Federalism in Action*] ("Today, Michigan stands alone in having adopted, by statute, blanket immunity based upon federal regulatory compliance."); Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 *Nw. U. L. REV.* 841, 850 (2008) [hereinafter Sharkey, *Fraud Caveat*] ("Michigan stands alone in having adopted a complete, blanket immunity based upon federal regulatory compliance.").

7. See Sean M. Basquill, Comment, *Prescription Drug Liability and Postmarketing Surveillance: A Modest Proposal*, 25 *TEMP. J. SCI. TECH. & ENVTL. L.* 69, 80 (2006) (recognizing that some may use "the Michigan statute as a template for widespread liability change"); James T. O'Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 *FOOD & DRUG L.J.* 287, 296 (2003) (predicting that other states will consider similar legislation); Jonathan V. O'Steen & Van O'Steen, *The FDA Defense: Vioxx® and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 *ARIZ. L. REV.* 67, 91 (2006) ("The Michigan statute is considered a model by drug companies pushing for similar laws in other states. [Thus,] the manufacturers likely will turn to state

some say that it should.⁸ The significance of Michigan's regulatory compliance defense has been widely discussed,⁹ the provision and its results have been criticized,¹⁰ and the statute has even come before the United States Supreme Court.¹¹

Michigan's regulatory compliance defense properly recognizes that an FDA-approved drug carrying an FDA-approved label should not be considered defective. However, the statute's absolute immunity provides no compensation for injured parties in any circumstance, including situations where the FDA process has failed. Nevertheless, it is possible to treat the FDA's approval as significant without eliminating the possibility of all state actions against drug makers by providing a litigation back-up through state attorneys general ("AGs"). This Note examines the question of FDA approval in state tort actions in Part I, discusses Michigan's answer to that question in Part II, and offers a proposal that would block most private actions against FDA-approved drugs (as Michigan has done), but would allow a state AG to bring suits in certain circumstances in Part III.

legislatures, with lawmakers being urged to enact highly restrictive laws similar to Michigan's."); Megan Rhyne, *High Bar Set for Michigan Drug Claims*, NAT'L L.J., April 21, 2003, at B1 ("[M]any more states will follow Michigan's lead.").

8. See, e.g., W. Wylie Blair, *Implied Preemption of State Tort Law Claims Against Prescription Drug Manufacturers Based Upon FDA Approval*, 37 J. LEGAL. MED. 289, 302 (2006) ("Others should follow suit by adopting a similar statute."); Schuck, *supra* note 6, at 110 ("[E]very other state should adopt the defense . . .").

9. See, e.g., Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 664 n.210 (2007) ("[T]he strongest limitation on state tort law is Michigan's statute."); Howard L. Dorfman, Vivian M. Quinn & Elizabeth A. Brophy, *Presumption of Innocence: FDA's Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate*, 61 FOOD & DRUG L.J. 585, 606-07 (2006) (discussing Michigan's statute); James T. O'Reilly, *Pin the Tail on the Other Donkey: Allocating and Avoiding Injury Losses After Drug or Device Approval*, 62 FOOD & DRUG L.J. 559, 569 (2007) (commenting that Michigan law offers "virtually total immunity" to makers of FDA-approved drugs); O'Reilly, *supra* note 7, at 295-96 (discussing "abdication in Michigan"); Abigail E. Rosen, Note, *Analysis of an FDA Compliance Defense for Pharmaceutical Tort Litigation*, 1 N.Y.U. J.L. & BUS. 241, 263-66 (2004) (noting "the controversy over the law during its brief history").

10. See, e.g., Green, *supra* note 5, at 489 n. 100 ("The Michigan statute . . . is the most problematic of the existing state reform provisions."); O'Reilly, *supra* note 7, at 295 (describing Michigan law as an "abdication"); O'Steen & O'Steen, *supra* note 7, at 91 ("Michigan legislators placed their state in the dubious position of being the only state in the nation to prohibit lawsuits against manufacturers of defective drugs.").

11. Warner-Lambert Co. v. Kent, 128 S. Ct. 1168 (2008) (per curiam), *aff'd by an equally divided Court* Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006); see also discussion *infra* Part II.B.

I. WHAT ROLE SHOULD FDA-APPROVAL PLAY IN THE STATE TORT SYSTEM?

The battle over whether FDA approval should prevent state tort litigation “is the fiercest battle in products liability litigation today.”¹² This debate is “the collision between common-law tort and the modern administrative state.”¹³ One side focuses on the jobs lost at pharmaceutical companies because of litigation like the Vioxx lawsuits,¹⁴ while the other emphasizes the injuries caused by drugs like Vioxx.¹⁵ Traditional state common law does not consider the FDA’s approval as conclusive, though either federal preemption of state tort law or voluntary state adoption of an FDA-approval regulatory compliance defense would change that. The United States Supreme Court recently weighed in, finding in *Wyeth v. Levine* that, without clear evidence of a direct conflict between a state tort ruling and the FDA’s labeling requirements, preemption would not be found.¹⁶ The broader debate will likely continue and shift to substantive state law. To understand what role the FDA approval should play—no role, some role, or a determinative role—in state law, one should first consider the role of state tort law. Tort law has two goals, “victim-specific compensation and regulatory deterrence.”¹⁷

A. Compensation and Deterrence

Compensating victims for their injuries may be one of the goals of tort law, but private “litigation is an extremely expensive way to com-

12. Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 450 (2008).

13. *Id.*

14. See Jason T. Ams, Note, *Reviving Lazarus: Status of the FDA Compliance Defense after Bates v. Dow Argosciences and the New FDA Regulations*, 95 KY. L.J. 765, 765 (2007) (discussing the adverse effects of lawsuits on pharmaceutical companies and those who depend on them).

15. O’Steen & O’Steen, *supra* note 7, at 91 (“The result is that Michigan residents injured by dangerous drugs like Vioxx are prevented from pursuing claims against the manufacturers.”).

16. *Wyeth v. Levine*, 129 S. Ct. 1187, 1198 (2009) (“But absent clear evidence that the FDA would not have approved a change to Phergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements. Wyeth has offered no such evidence.”).

17. Sharkey, *supra* note 12, at 459; see also *Wyeth*, 129 S. Ct. at 1202 (“State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information.”); Rosen, *supra* note 9, at 256 (“In the abstract, the tort system satisfies two goals: it provides manufacturers an incentive to cause harms only if they are justified by cost-benefit analysis; it also eases the burdens of harm on the population by forcing manufacturers to pay for the harms they cause.”).

pensate victims”¹⁸ Litigation can be duplicative, which can drive up costs, like the tens of thousands of lawsuits filed over Vioxx.¹⁹ More importantly, litigation may not be an efficient way to compensate victims. The net compensation paid to victims may be less than half of the total cost of the litigation.²⁰ Similarly, class actions often benefit the plaintiffs’ attorneys, not the actual victims, with settlements that can bring big fees to the attorneys but not necessarily meaningful benefits to the victims.²¹ Unfortunately, despite the inefficiency of the litigation process, suing pharmaceutical companies remains the only option for those injured by drugs.

A person injured by a defective drug cannot sue the FDA for approving the drug or the label,²² but private tort litigation can offer a remedy in the event that the FDA approves defective drugs.²³ Tort litigation has generated billions of dollars in payments and settlements from pharmaceutical companies for tort victims and their lawyers.²⁴ Some are happy with this “because pharmaceutical companies are profiting from the development and sale of new drugs, they should also be responsible when consumers are injured as a result of their unsafe products and intense marketing campaigns.”²⁵ However, others find that “taking that compensation through the tort system from a defendant who has complied with the law is not the sound public policy answer.”²⁶ Regardless of whether drug companies are morally culpable for the injuries that occur post-approval, the tort litigation process consumes too much of the money that should go to the victim.²⁷ Thus, “[l]itigation has proven to be too expensive a mechanism to compensate injuries unless deterrence of

18. Rosen, *supra* note 9, at 257; see also Deborah R. Hensler, *Trends in Tort Litigation: Findings from the Institute for Civil Justice’s Research*, 48 OHIO ST. L.J. 479, 492 (1987) (detailing the high costs of litigation); Schuck, *supra* note 6, at 99 n.110 (discussing costs of tort litigation).

19. See TED FRANK, CLASS ACTION WATCH: THE VIOXX LITIGATION (2007), http://www.fed-soc.org/doclib/20080407_TheVioxxLitigation.pdf.

20. See Charles Silver, *Does Civil Justice Cost Too Much?* 80 TEX. L. REV. 2073, 2078–79 (2002).

21. DEBORAH R. HENSLER ET AL., CLASS ACTION DILEMMAS: PURSUING PUBLIC GOALS FOR PRIVATE GAIN 424 (2000).

22. Anne Erickson Haffner, Comment, *The Increasing Necessity of the Tort System in Effective Drug Regulation in a Changing Regulatory Landscape*, 9 J. HEALTH CARE L. & POL’Y 365, 368–70 (2006).

23. *Id.* at 387–90.

24. Anita Bernstein, *Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation*, 15 J.L. & POL’Y 1051, 1054 (2007).

25. Haffner, *supra* note 22, at 399.

26. Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 168–69 (2005).

27. HENSLER ET AL., *supra* note 21, at 424 (class action attorneys reap significant rewards even where meaningful benefits are not received by victims); Silver *supra* note 20, at 2078–79 (only half the net compensation goes to victims).

irresponsible conduct is simultaneously being achieved.”²⁸ Deterrence occurs if the threat of tort suits prompts drug makers to be more cautious.

Perhaps “[t]he best policy argument against preemption is that consumers gain additional leverage when their tort recoveries act as cautionary measures to inhibit misconduct”²⁹ By taking compensation for injured parties from the drug makers, tort suits are “an engine of deterrence.”³⁰ Drug companies are deterred from misconduct by the threat of tort litigation and are given a strong financial incentive to make products safer prior to entering the market because of the potential cost of the litigation and the payments to injured parties if the drug is unsafe. However, a regulatory compliance defense “would insulate drug manufacturers from liability, although they are in the best position to make products safer.”³¹ Immunizing drug makers from liability based on FDA approval, as Michigan’s regulatory compliance defense does, could also affect behavior after a drug hits the market because it would “create a disincentive to manufacturers to act promptly based on acquired evidence of risk”³² or at least remove whatever incentives litigation provides.

Some argue that, beyond mere deterrence, litigation has other positive attributes, praising “the checks and balances that adversary litigation provides,”³³ or the “adversarial nature of litigation.”³⁴ Products liability litigation thwarts inappropriate marketing and scientific fraud³⁵ and encourages more product research.³⁶ Suits against drug makers also “inform the public about risks”³⁷ associated with using that drug. Perhaps

28. W. Kip Viscussi et al., *Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1480 (1994).

29. O’Reilly, *supra* note 7, at 297.

30. Schuck, *supra* note 6, at 75.

31. Haffner, *supra* note 22, at 398.

32. Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1151 (2007).

33. O’Reilly, *supra* note 7, at 297.

34. Christina Marie Martin, Note, *Hugs and Drugs: Research Ethics, Conflict of Interest, and Why the FDA’s Attempt to Preempt Pharma Failure-To-Warn Claims Is a Dangerous Prescription*, 6 AVE MARIA L. REV. 587, 616 (2008).

35. Teresa Curtin & Ellen Relkin, *Preamble Preemption and The Challenged Role of Failure to Warn and Defective Design Pharmaceutical Cases in Revealing Scientific Fraud, Marketing Mischief, and Conflicts of Interest*, 35 HOFSTRA L. REV. 1773, 1787–95 (2007) (explaining the process by which litigation exposes scientific fraud, marketing mischief, and conflicts of interest).

36. Lucinda M. Finley, *Female Trouble: The Implications of Tort Reform for Women*, 64 TENN. L. REV. 847, 849 (1997) (“The legal system can also prod research into product safety and health risks that should have been done before the product was marketed.”).

37. *Id.* at 849.

most significantly, litigation “often stimulate[s] regulatory agencies, such as the FDA, to take stronger action to safeguard public health.”³⁸ Litigation as a regulator-stimulant and a check on the drug makers may be necessary given the strength of the industry, because “pharmaceutical sales representatives have increasing influence on the drugs that physicians prescribe, and the pharmaceutical industry is the largest lobbying group in the United States”³⁹ Litigation and the threat of litigation checks that influence.

Moreover, “tort suits define and signify basic social values about what human activities are worthy of protecting”⁴⁰ For instance, juries in torts suits may prioritize fertility,⁴¹ although regulators might not place as much emphasis on punishing or deterring drugs that accidentally cause infertility. Thus, one scholar claims that a regulatory compliance defense “has particularly problematic implications for women.”⁴² However, even in the absence of litigation, drug makers have incentives to make their products safe.

Drugs that have negative side effects are vulnerable to competitors that lack those side effects in the market place.⁴³ And, “unlike manufacturers of other types of goods, drug manufacturers cannot sell their products before they receive a government proclamation of safety and effectiveness, and they reap extraordinary profits when they can promote their goods as better than their competitors’.”⁴⁴ Drug makers already have market-based, financial incentives to produce safe products because consumers can take their dollars elsewhere. Further, litigation can even generate the wrong incentives for drug makers. One of the problems with dual regulation is that drug makers may be afraid to disclose information to regulators when it can be used against them in future torts cases.⁴⁵ While the tort system may provide additional safety incentives, the FDA may already be providing sufficient incentives to produce an optimal level of safety. If that is the case, then tort litigation results in over-deterrence in the pharmaceutical industry. Moreover, a drug maker can only use the regulatory compliance defense if it complied with the applicable regulations. The question is whether the FDA provides the optimal level of regulation or whether the additional market force of state tort

38. *Id.*

39. Davis, *supra* note 32, at 1153.

40. Finley, *supra* note 36, at 849.

41. *Id.*

42. *Id.* at 868.

43. Bernstein, *supra* note 24, at 1060–61 (discussing competition incentives outside of tort litigation).

44. *Id.* at 1060.

45. See Cahoy, *supra* note 9, at 623 (describing the “significant tort-based economic disincentives for generating new information”).

liability is necessary for drugs to reach a societally-acceptable level of safety.

B. *Should Juries Second Guess the FDA?*

The FDA “is the single most important regulator in the pharmaceutical field. Currently, a vigorous debate exists over whether it should be the only regulator.”⁴⁶ Whether preemption or a regulatory compliance defense should make the FDA the sole regulator is largely a question of whether FDA regulations set an optimal level of safety. Safety regulations usually target “only the clearest and most egregious hazards.”⁴⁷ Most agencies generate minimal, rather than optimal levels of safety.⁴⁸ But where an agency like the FDA “regulate[s] the safety of particular aspects of particular products especially closely,” it has set an optimal level of safety and this should foreclose liability.⁴⁹ Specifically, “the prescription drug industry is the most heavily regulated industry (for safety purposes) in this country today.”⁵⁰ Thus, one could oppose a government standards defense in general, but support such a defense with the FDA because its level of regulation makes it the best candidate for a regulatory compliance defense.⁵¹

The FDA provides a very strong safety incentive by refusing to approve unsafe drugs.⁵² The process to receive FDA approval of a drug is long, difficult, and expensive.⁵³ In fact, some scholars are even concerned

46. Catherine T. Struve, *Greater and Lesser Powers of Tort Reform: The Primary Jurisdiction Doctrine and State-Law Claims Concerning FDA-Approved Products*, 93 CORNELL L. REV. 1039, 1039 (2008).

47. David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 17 (2005). Thus, according to Professor Owen, the regulatory compliance defense only “has a superficial appearance of fair play and common sense” because many statutes and regulations are vague. *Id.* at 13.

48. *Id.* at 474 (identifying that the FDA sets an optimal, not minimum level of safety); Noah, *supra* note 4, at 2152 (discussing “administrative efforts to set optimal—not minimal—safety standards”); Rosen, *supra* note 9, at 247–48 (discussing whether FDA regulation is efficient or optimal).

49. Owen, *supra* note 47, at 19.

50. Green, *supra* note 5, at 463.

51. *Id.* at 464 (asserting that FDA presents the “strongest case for accepting governmental safety standards as conclusive”); Owen, *supra* note 47, at 20; Sharkey, *Federalism in Action*, *supra* note 6, at 1026–27 (maintaining that FDA provides the strongest case for a government standards defense).

52. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321–399a (2006).

53. William G. Childs, *The Implementation of FDA Determinations in Litigation: Why Do We Defer to the PTO But Not to the FDA?*, 5 MINN. INTELL. PROP. REV. 155, 165–70 (2004) (discussing difficulty of FDA process); see also Andrew E. Costa, *Negligence Per Se Theories in Pharmaceutical & Medical Device Litigation*, 57 ME. L. REV. 51, 80–82 (2005) (discussing the FDA process).

that the FDA moves too slowly.⁵⁴ However, there are inherent limits to the FDA approval process:

The initial clinical testing of a new drug does not uncover all side effects because of the limitations of pre-marketing testing—the limited sample size hides complications with vulnerable groups such as babies, pregnant women, and the elderly, the tests do not reveal harms with a long latency period, and problems associated with long term use cannot be uncovered. Thus, release of the product into the market may generate additional information about the risks associated with its use. In order to accommodate this information, the FDA requires reporting of adverse events associated with the drug once it is on the market.⁵⁵

Like any agency, the FDA has its weaknesses. Specifically, “the FDA is dependent upon pharmaceutical and medical device manufacturers for the information it receives” and, ultimately, the decisions it makes.⁵⁶ There are fears about the politicization of the FDA,⁵⁷ inappropriate pressures on the FDA,⁵⁸ the FDA being “stretched too thin” to police the pharmaceutical drug industry,⁵⁹ and “agency capture.”⁶⁰ However, concerns about agency capture are not supported by significant evidence,⁶¹ as the FDA does manage to actually block bad drugs prior to release.⁶²

“Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients.”⁶³ Moreover, the “FDA has now expressly stated that it does not view its stamp of approval as a mere floor, but rather as a ceiling.”⁶⁴

54. See Green, *supra* note 5, at 483–85.

55. Rosen, *supra* note 9, at 246.

56. Costa, *supra* note 53, at 86; see also Haffner, *supra* note 22, at 365 (“Pre-marketing approval of new drugs has always relied upon clinical trials performed solely by drug companies.”).

57. Curtin & Relkin, *supra* note 35, at 1775–76.

58. Rosen, *supra* note 9, at 252–53 (noting “increased political pressure” and lobbying).

59. Martin, *supra* note 34, at 616.

60. Agency capture occurs when the industry that is being regulated actually controls the regulator, a situation often described colloquially as the “fox guarding the hen house”. See Costa, *supra* note 53, at 87.

61. Noah, *supra* note 4, at 2154.

62. Green, *supra* note 5, at 480.

63. Sharkey, *supra* note 12, at 505 (quoting Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006)).

64. Blair, *supra* note 8, at 303.

Furthermore, Congress recently gave the FDA even more authority to regulate and monitor drugs post-approval.⁶⁵ Thus, the experts at the FDA continue to attempt to set an optimal or near-optimal level of regulation after approval as well.⁶⁶

Beyond the “agency expertise” that the FDA offers,⁶⁷ the FDA is more accountable than the juries utilized in the state tort system.⁶⁸ Even if agencies are the least accountable part of the government, they have *some* theoretical accountability, while no one expects juries to be held accountable for their verdicts. Unlike a jury, the FDA can be held accountable through political means.⁶⁹ Also, the Administrative Procedure Act requires the FDA to go through notice and comment in promulgating regulations.⁷⁰ Because regulators take input from all possible sources, while courts only take input (subject to the rules of evidence) from the actual parties to the lawsuit, “the court’s decision making process is inadequate.”⁷¹ Whether to accept the FDA’s decision and decision-making process as conclusive is really a question of whether to allow juries in state tort law actions to second guess the FDA’s decision.

In tort litigation, decisions “are made by, or in the shadow of, juries.”⁷² Depending on the state, a jury may “treat the FDA’s laborious approval process as authoritative, entirely irrelevant, or something in between.”⁷³ Most state tort suits brought against drug makers are based on a failure to warn theory.⁷⁴ And unless there is clear evidence that a drug maker cannot comply with the federal labeling requirements and the state’s warning requirements as enforced through tort law, preemption will not block a jury from potentially finding that the specific FDA-approved warning is insufficient.⁷⁵ A “populist faith in laypersons and an

65. See Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823.

66. See, e.g., Green, *supra* note 5, at 474 (identifying that the FDA sets an optimal, not minimum level of safety).

67. Sharkey, *supra* note 12, at 485.

68. Noah, *supra* note 4, at 2141 (discussing FDA accountability); Schuck, *supra* note 6, at 94 (“Nor is a jury even remotely accountable to political, administrative, or technocratic controls.”).

69. Schuck, *supra* note 6, at 94–97.

70. Noah, *supra* note 4, at 2148 (citing 5 U.S.C. §§ 551–559, 701–706 (1994)).

71. Schwartz & Goldberg, *supra* note 26, at 164.

72. Schuck, *supra* note 6, at 93.

73. *Id.* at 75.

74. “The vast bulk of pharmaceutical litigation is in the warnings area and that will continue for the foreseeable future.” Green, *supra* note 5, at 472–73; see also Ams, *supra* note 14, at 765 (“Pharmaceutical products liability cases based on manufacturing or design defects are few: instead, the vast majority of the cases center upon the ‘failure to warn’ theory.”); Rosen, *supra* note 9, at 245 (identifying that failure to warn is the basis of most pharmaceutical cases).

75. *Wyeth v. Levine*, 129 S. Ct. 1187, 1197 (2009).

accompanying distrust of distant federal bureaucracies⁷⁶ is insufficient to justify disregarding the significance of a drug maker's compliance with the FDA warning. Drug safety should be a regulatory issue, not a jury issue. Juries in tort cases are being asked to make decisions about basic values, but juries are not accountable to anyone for those decisions and no one argues that they should be.

Decisions that must balance the risks and rewards of a specific drug should be done by a national regulator, not by "unsophisticated jurors in different parts of the country . . ."⁷⁷ "The best policy argument for preemption may be that generalists, including jury members, lack FDA's technical competence to assess what should or should not be included in drug labeling."⁷⁸ If the FDA has done things right, then "a properly labeled, duly-approved drug is not in fact defective."⁷⁹ If a side effect only appears after twenty years of using a drug, the only way to know of that potential injury prior to releasing it on the market is to test for twenty years. Punishing drug makers through tort litigation in that situation effectively sets the regulatory standard at twenty years of testing. This is not optimal, as it would over-deter the introduction of drugs that might be beneficial. The FDA process is designed to set the optimal level of safety, and requiring more than that will inappropriately stop the introduction of new drugs.⁸⁰ Moreover, requiring warnings beyond the optimal level, by holding drug makers liable in state court for not using those warnings, would exaggerate risk, and "[e]xaggeration of risk could discourage appropriate use of a beneficial drug."⁸¹ The extent of the FDA's regulation leads to the conclusion that "an FDA stamp of approval should carry an authoritative message."⁸² Recognizing that message will decrease the number of frivolous lawsuits.⁸³ There are two ways to recognize this message: federal preemption of state tort law or a regulatory compliance defense.

C. Preemption or a Regulatory Compliance Defense?

The two ways in which the FDA's approval of a drug can be treated as the authoritative determination of the optimal level of safety are

76. Noah, *supra* note 4, at 2153.

77. *Id.* at 2150–51.

78. O'Reilly, *supra* note 7, at 297.

79. Schuck, *supra* note 6, at 100.

80. *See, e.g.*, Green, *supra* note 5, at 466–68 (discussing over-deterrence).

81. Sharkey, *supra* note 12, at 505.

82. Blair, *supra* note 8, at 289.

83. Rosen, *supra* note 9, at 242 ("Review of jury verdicts before and after the defense suggests that the defense would decrease the number of lawsuits, particularly frivolous ones.").

(1) through federal preemption of state tort law, or (2) by states voluntarily adopting a regulatory compliance defense. The regulatory compliance (or government standards) defense is the flip-side of preemption, as the authority rests with the states, rather than the federal government.”⁸⁴ Though the regulatory compliance defense “is a ‘close cousin’ of the federal preemption defense . . . the two defenses are fundamentally distinct.”⁸⁵ Preemption is about the Supremacy Clause⁸⁶ and preventing state tort law from conflicting with federal regulation.⁸⁷ “Federal preemption of state tort law unequivocally alters the balance between federal and state power.”⁸⁸ There are many reasons why preemption of state law is inappropriate. For example, “the importance and historical prevalence of the state police power in this context,”⁸⁹ as well as the role states play as “laboratories for experimentations to devise various solutions” to difficult problems,⁹⁰ suggest that states should have flexibility. Michigan has acted as such a laboratory with the development of its regulatory compliance defense. Michigan has also demonstrated that “[i]t is possible to achieve the same effect [as preemption] through action by the States.”⁹¹ Given the tough standard a drug maker must meet to establish preemption of state tort suits after *Wyeth v. Levine*,⁹² advocates of greater deference to the FDA’s decisions will have to turn to the states. The regulatory compliance defense has been called “State-Sponsored Preemption,”⁹³ which is essentially a state adopting the federal regulation as the appropriate standard of care.

“The government standards defense concerns the standard by which a state’s substantive products liability law determines whether a product is deemed defective.”⁹⁴ In a regulatory compliance defense, a state is borrowing the safety standards “as the formal test of product

84. Schwartz & Goldberg, *supra* note 26, at 174.

85. Owen, *supra* note 47, at 13.

86. U.S. CONST. art. VI, cl. 2 (“This Constitution, and the Laws of the United States . . . shall be the supreme Law of the land . . .”).

87. Owen, *supra* note 47, at 13.

88. Sharkey, *Federalism in Action*, *supra* note 6, at 1013.

89. *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009) (noting that Congress was aware of the “prevalence of state tort litigation”); Davis, *supra* note 32, at 1141 (“The traditional role of the states in regulating food and drug safety, coupled with the historic recognition of the value of common law damages actions in that effort . . .”); Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 260 (2004) (context of regulating safety).

90. *Grutter v. Bollinger*, 539 U.S. 306, 341 (2003) (quoting *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring)).

91. Cahoy, *supra* note 9, at 664.

92. *Wyeth*, 129 S. Ct. at 1198.

93. O’Steen & O’Steen, *supra* note 7, at 89.

94. Owen, *supra* note 47, at 13.

defectiveness.”⁹⁵ “Preemption offers a blunter tool for securing judicial respect for federal standards.”⁹⁶ With a regulatory compliance defense, the state determines, “as a matter of positive law, that compliance with federal standards satisfies that state’s products liability law.”⁹⁷ It is a legislative judgment that compliance with the regulations is enough. This kind of determination is within a state’s power.⁹⁸

A few states have adopted a rebuttable presumption that FDA-approved drug labels do not constitute failure to warn.⁹⁹ Texas law, for example, establishes a rebuttable presumption of non-liability, but has an exception for unapproved uses.¹⁰⁰ Meanwhile, some states have adopted a regulatory compliance defense to bar punitive damages.¹⁰¹ However, “[t]he large majority of states that have not adopted a regulatory compliance defense have declared that FDA approval of a drug is a floor, or minimum, rather than an upper limit on liability.”¹⁰² Congress has also chosen not to adopt a regulatory compliance defense.¹⁰³ Though an FDA regulatory compliance defense to punitive damages was debated in

95. *Id.*

96. Noah, *supra* note 4, at 2158.

97. Hall, *supra* note 89, at 260 n.341.

98. Bernstein, *supra* note 24, at 1085–86 (“States may, if they wish, enact statutes that impose a contrary pro-preemption stance.”).

99. *See* COLO. REV. STAT. § 13-21-403(1) (2007); IND. CODE ANN. § 34-20-5-1(2) (West 1999); KAN. STAT. ANN. § 60-3304 (2005); KY. REV. STAT. ANN. § 411.310(2) (West 2005); N.J. STAT. ANN. § 2A:58C-4 (West 2000); TENN. CODE ANN. § 29-28-104 (2007); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (Vernon 2005); UTAH CODE ANN. § 78-15-6(3) (2005). For a more detailed discussion of the Texas statute, see Michael S. Hull et al., *House Bill 4 and Proposition 12: An Analysis with Legislative History, Part Two*, 36 TEX. TECH. L. REV. 51, 122–24 (2005) (discussing Texas statute); *see also* Grundberg v. Upjohn Co., 813 P.2d 89, 90 (Utah 1991) (“We hold that drug approved by the United States Food and Drug Administration (‘FDA’), properly prepared, compounded, packaged, and distributed, cannot as a matter of law be ‘defective’ in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval.”); *Perez v. Wyeth Labs, Inc.*, 734 A.2d 1245, 1259 (N.J. 1999) (“For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims. By definition, the advertising will have been ‘fairly balanced.’”).

100. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (Vernon 2005). *See* discussion in Michael R. Klatt & Elizabeth A. Cash, *A Guide to House Bill 4 Provisions that Affect Substantive Pharmaceutical Litigation Issues*, 46 S. TEX. L. REV. 1137, 1140–42 (2005).

101. *See, e.g.*, ARIZ. REV. STAT. ANN. § 12-701(a)(1) (2003); COLO. REV. STAT. § 13-64-302.5(5)(a) (2007); N.J. STAT. ANN. § 2A:58C-5(c) (West 2000); N.D. CENT. CODE § 32-03.2-11(6) (2007); OHIO REV. CODE ANN. § 2307.80(c)(1) (West 2006); OR. REV. STAT. § 30.927(1)(a) (2005); UTAH CODE ANN. § 78-18-2(1) (2002); *see also* Victor E. Schwartz, Mark A. Behrens & Joseph P. Mastro Simone, *Reining in Punitive Damages “Run Wild”: Proposals for Reform by Courts and Legislatures*, 65 BROOK. L. REV. 1003, 1028–29 (1999) (discussing regulatory compliance as bar to punitive damages).

102. Bernstein, *supra* note 24, at 1097.

103. *Id.*

Congress,¹⁰⁴ and lobbyists have pressed for “industry-friendly legislation,”¹⁰⁵ “a strong super majority of state jurisdictions [remain] opposed to the regulatory compliance defense.”¹⁰⁶

Michigan, however, has made a determination that the FDA’s approval is the optimal level of safety (and therefore a ceiling), as well as a minimal level (and therefore a floor), in adopting a regulatory compliance defense. “In Michigan, the legislature specifically yielded to FDA regulations for establishing tort liability for prescription drugs.”¹⁰⁷

II. MICHIGAN’S ANSWER: IMMUNITY FOR FDA-APPROVED DRUGS

A. Purpose and Effect

“Products liability claims in Michigan are based on a single statute, MCL § 600.2946”¹⁰⁸ In 1995, that statute was amended as a part of a broader tort reform movement in Michigan.¹⁰⁹ The regulatory compliance defense was enacted to protect the financial interests of pharmaceutical industry located in Michigan,¹¹⁰ but also because those who passed the bill thought it would be unfair for a court to call a product that complied with FDA standards defective.¹¹¹

The amended statute provides that:

[A] product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food

104. See, e.g., HEALTH Act of 2004, H.R. 4280, 108th Cong. § 7(c) (2004); Levy, *supra* note 3, at 2425–26 (“[T]he U.S. House of Representatives passed the HEALTH Act of 2005, which contains a safe harbor from punitive damages for manufacturers who comply with FDA regulations.”).

105. Bernstein, *supra* note 24, at 1052.

106. Sharkey, *Federalism in Action*, *supra* note 6, at 1024.

107. Schwartz & Goldberg, *supra* note 26, at 175–76.

108. Ryan v. Brunswick Corp., 557 N.W.2d 541, 545 n.8 (Mich. 1997). See also MICH. COMP. LAWS § 600.2946 (2000).

109. See Dana Cilla, Case Note, *Michigan Tort Reform: A Constitutional Haven for Pharmaceutical Companies and a Tough Pill to Swallow for Consumers*, 19 T.M. COOLEY L. REV. 331, 331–37 (2002); see also Adam Cohen, *They Say We Have Too Many Lawsuits? Tell It to Jack Cline*, N.Y. TIMES, Jan. 14, 2007, Week in Rev., at 11 (explaining history of Michigan legislation). Other portions of Michigan’s tort reform have generated their own controversy. See, e.g., Steve Fox, Note, *Constitutional Roadblocks to Michigan’s Cap on Non-Economic Damages in Product Liability Suits*, 47 WAYNE L. REV. 1385, 1385 (2002) (criticizing Michigan’s statutory cap on noneconomic damages); Nelson P. Miller, *No-Fault Tort Law as a “Strategic Assumption”: Throwing out the Baby with the Bathwater*, 82 U. DET. MERCY L. REV. 47, 49 (2004) (discussing tort reform movement).

110. David Eggert, *Michigan Law Makes Drug Suits Difficult*, DET. FREE PRESS (Jan. 4, 2005).

111. Cilla, *supra* note 109, at 335.

and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.¹¹²

This statute:

[D]elegates nothing to the FDA; rather, it uses independently significant decisions of the FDA as a measuring device to set the standard of care for manufacturers and sellers of prescription drugs in Michigan. It represents a legislative determination as a matter of law when a manufacturer or seller of a prescription drug has acted sufficiently reasonably, solely for the purpose of defining the limits of a cognizable products liability claim under Michigan law.¹¹³

As new drugs are developed every year, the Michigan Court of Appeals has recognized that "an ever-evolving list of drugs will be excluded as bases of liability actions."¹¹⁴ Michigan's immunity for drug makers has been applied to cover approved drugs used for off-label purposes as well,¹¹⁵ and has been applied in other states under choice-of-law provisions.¹¹⁶ The statute even thwarts common law fraud or Consumer Protection Act claims against pharmaceutical makers based on the drug or its warnings.¹¹⁷ While there is still room for some litigation,¹¹⁸ the limited

112. *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 130 (Mich. 2003). *See* MICH. COMP. LAWS § 600.2946(5) (2000) ("However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval."); *see also* Dorfman, Quinn & Brophy, *supra* note 9, at 606–07 n.162 ("The constitutionality of this provision has survived a number of attacks.").

113. *Taylor*, 658 N.W. at 137. *But see* O'Reilly, *supra* note 7, at 296 (claiming that Michigan Supreme Court did not understand the FDA process).

114. *Taylor v. Gate Pharm.*, 639 N.W.2d 53, 56 (Mich. Ct. App. 2001), *overruled by Taylor*, 658 N.W.2d at 137 (Mich. 2003).

115. *White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1030 (W.D. Mich. 2008) (statute does not limit the protection to situations when the drug is used for its approved purposes).

116. *Devore v. Pfizer, Inc.*, 2007 N.Y. Misc. LEXIS 1247 (N.Y. Sup. Ct. 2007), 3/26/2007 N.Y.L.J. 21, (col. 1), *aff'd* *Devore v. Pfizer, Inc.*, 2008 N.Y. App. Div. LEXIS 8707 (N.Y. App. Div. 1st Dep't, Nov. 20, 2008).

117. *Duronio v. Merck & Co., Inc.*, 2006 WL 1628516, at *5 (Mich. Ct. App. 2006).

118. *Ammend v. BioPort, Inc.*, 322 F. Supp. 2d 848, 876 (W.D. Mich. 2004) (illustrating that questions of fact remain for a jury regarding whether the FDA actually approved version of the vaccine at issue in the lawsuit).

data available since the statute was enacted indicates the number of lawsuits against pharmaceutical companies in Michigan has decreased.¹¹⁹

Although this appears to be the result intended by the regulatory compliance defense, some feel that it prevents consumers from bringing otherwise valid claims.¹²⁰ The Michigan statute has come under attack and there is a movement in the legislature to repeal it.¹²¹ Though the bill passed in the State House, it has stalled in the State Senate.¹²² Nevertheless, Michigan law currently provides that a drug maker is immune from liability for an FDA-approved product, unless the FDA's approval was fraudulently obtained.

B. *Fraud-on-the-FDA Exception*

Michigan's regulatory compliance defense has an exception for situations where the drug maker made intentional misrepresentations to the FDA (fraud-on-the-FDA)¹²³ or bribed the FDA to gain approval.¹²⁴ However, Michigan's fraud exception does not cover non-fraud disclosure problems (such as unintentional or negligent failure to disclose).¹²⁵ Notwithstanding these deficiencies, the fraud-on-the-FDA exception is a

119. Rosen, *supra* note 9, at 265–66. “What is not evident by looking at the cases [in Michigan] is the number of cases that were not brought because no plausible argument of lack of compliance could be made.” *Id.* at 266.

120. O’Steen & O’Steen, *supra* note 7, at 91 (“The result is that Michigan residents injured by dangerous drugs like Vioxx are prevented from pursuing claims against the manufacturers.”).

121. Legislation proposing to repeal the regulatory compliance defense includes H.B. 4136, 95th Leg., Reg. Sess. (Mich. 2009); H.B. 4317, 95th Leg., Reg. Sess. (Mich. 2009); H.B. 4318, 95th Leg., Reg. Sess. (Mich. 2009); S.B. 43, 94th Leg., Reg. Sess. (Mich. 2007); H.B. 4044, 94th Leg., Reg. Sess. (Mich. 2007); H.B. 4045, 94th Leg., Reg. Sess. (Mich. 2007). See also Sharkey, *Federalism in Action*, *supra* note 6, at 1023 n.24 (noting that Michigan's regulatory compliance defense is under attack); Progress Michigan, Tell Senate Majority Leader Bishop and His Supporters: End Drug Industry Immunity Now!, <http://progressmichigan.org/page/speakout/DIIME> (last visited Feb 9, 2009) (lobbying to repeal the regulatory compliance defense).

122. Barb Byrum, Michigan State Representative, *Give Michigan Consumers a Voice: This Week Marks One Year of Inaction On Drug Immunity by Senate* (Feb. 25, 2008), <http://www.michiganliberal.com/showDiary.do?diaryId=11513> (contending that because the Michigan State House is controlled by Democrats and the State Senate is controlled by Republicans, the bill is unlikely to pass anytime soon); LiberalLucy, *MichLib Exclusive: House Dems Speak Out on State of the State* (Jan. 30, 2008), <http://www.michiganliberal.com/showDiary.do?diaryId=11305> (last visited Dec. 9, 2008). While the law was passed to benefit the pharmaceutical industry and create pharmaceutical jobs in Michigan, the major pharmaceutical company Pfizer recently moved 2000 jobs out of Michigan, possibly undermining political support for immunity in the future. *Id.*

123. MICH. COMP. LAWS § 600.2946(5)(a) (1979).

124. *Id.* § 600.2946(5)(b). This is appropriate because the judgment of the FDA is not of independent significance when it is not a fully-informed judgment.

125. Green, *supra* note 5, at 489 n.100.

popular component of regulatory compliance defenses,¹²⁶ but the fraud exception may itself be unconstitutional because of preemption.

In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court held that state tort law claims based on fraud on a federal agency were preempted.¹²⁷ However, *Buckman* only addressed matters where the federal approval was a "critical element" in the plaintiff's case and did not address matters where fraud-on-the-FDA only served to extinguish a defense.¹²⁸ When the Sixth Circuit (which includes Michigan) confronted the issue of the fraud-on-the-FDA exception to Michigan's regulatory compliance defense in *Garcia v. Wyeth-Ayerst Laboratories*, it held that the exception is preempted in most contexts, but not when the agency itself has found fraud.¹²⁹ Thus, if the FDA found fraud on the agency, it would seemingly open up actions under Michigan's law; if not, immunity would be total.¹³⁰

The Second Circuit confronted the same issue in *Desiano v. Warner-Lambert & Co.*, but chose not to follow the Sixth Circuit's interpretation of federal law.¹³¹ Reviewing the legislative history of Michigan's statute, the Second Circuit found that the goal of the statutory reform was to limit when a person injured by drugs could recover under existing products liability law, not to punish fraud-on-the-FDA.¹³² The Second Circuit found that "the cause of action . . . cannot reasonably be characterized as a state's attempt to police fraud against the FDA."¹³³

Michigan's fraud-on-the-FDA exception is different from the cause of action preempted in *Buckman* because the process of developing the agency's regulation is not a crucial element of the cause of action. Fraud is not an element of the plaintiff's products liability case against a drug maker in Michigan, only something plaintiffs can use to defeat the defendant's state-law affirmative defense.¹³⁴ A key "difference between common law actions and 'fraud-on-the-FDA' claims, suggested in *Buckman*, is that in FDA-fraud cases, proof of fraud against the FDA is *alone*

126. See Schuck, *supra* note 6, at 83.

127. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) ("In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case.>").

128. See *id.*

129. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 967 (6th Cir. 2004).

130. See *id.* at 966 ("the same concerns do not arise when the FDA itself determines that a fraud has been committed on the agency") (emphasis in original); *Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760, 768–69 (E.D. Mich. 2006) (finding that plaintiff could not use the "fraud on FDA" exception because the FDA itself had not found fraud).

131. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006).

132. *Id.* at 94 & n.5.

133. *Id.* at 94.

134. *Id.* at 96.

sufficient to impose liability.”¹³⁵ The Second Circuit recognized that a presumption against federal preemption of state law applied in *Desiano*,¹³⁶ and ultimately upheld Michigan’s fraud on the FDA exception while applying Michigan law under choice of law.¹³⁷ The Supreme Court took up the circuit split last year, but affirmed the decision of the court below 4-4 in a per curiam opinion that had no precedential value.¹³⁸ The matter remains unsettled.

There is a fear that the combination of no federal cause of action and federal pre-emption of fraud-on-the-FDA claims means that even where intentional misrepresentation is involved, consumers might not be compensated for their injuries.¹³⁹ Thus, if the fraud exception is preempted, “even the most egregious actions by drug manufacturers may go unpunished by Michigan courts, and Michigan residents will be unable to recover for injuries caused by dangerous drugs.”¹⁴⁰ Michigan’s fraud exception should not be preempted. The Second Circuit’s position is better than the Sixth Circuit’s position because it correctly recognizes that Michigan tort law is not policing misrepresentations to a federal agency, but the right to defer to the FDA is exercised only when that agency’s decisions are fully informed. The Supreme Court may, however, adopt the Sixth Circuit’s interpretation. Michigan’s law should be amended, and other states following Michigan’s model should follow suit, to make sure that the immunity to liability does not become total if the fraud-on-the-FDA exception is ultimately preempted.

III. PROPOSAL: A NON-BINARY ANSWER THAT LEAVES SOME ROLE FOR STATES

A. Remedies Where the FDA Has Failed

The fraud-on-the-FDA exception is a vital part of Michigan’s regulatory compliance defense, but its constitutional future is uncertain. Michigan also provides immunity for drugs used for off-label purposes and does not provide a check on any creative behavior drug makers may engage in, such as inappropriate marketing, distribution, or any other conduct that takes advantage of the regulatory compliance defense while

135. *Id.* at 95.

136. *Id.* at 93.

137. *Id.*

138. *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (the Chief Justice did not participate).

139. *Curtin & Relkin*, *supra* note 35, at 1775. Michigan consumers may already be unable to recover because the fraud-on-the-FDA exception has been preempted. *Id.* at 1776 n.12.

140. *O’Steen & O’Steen*, *supra* note 7, at 89 n.181.

still evading the purpose of the law.¹⁴¹ Michigan's regulatory compliance defense correctly recognizes that the FDA sets an optimal or near-optimal level of regulation,¹⁴² but does not provide an adequate remedy in situations where the FDA process has failed nor does it provide compensation for injured parties in those situations.¹⁴³ This Note offers a solution to the situation where the FDA process has failed to provide optimal safety levels either through fraud or misrepresentation to the FDA, creative behavior by drug companies that has yet to be regulated by the FDA, or situations where the FDA lacks the resources to effectively police safety.

This solution is not designed to provide compensation where the limits of the process result in injury because the process itself is designed to set the regulatory ceiling or optimal level. Where, for example, a drug has side effects that are not visible until after decades of use, and the drug maker followed the FDA approval process initially with the drug and subsequently with reporting problems that later arose, the drug is not, in fact, defective.¹⁴⁴ Though a person may nevertheless be injured, the drug has met the optimal level of safety and is not defective such that the injured party should be able to sue. Punishing drug companies in this situation generates over-deterrence and can keep good drugs off the market. This proposal seeks to grant deference to the FDA where the FDA process has set the optimal level, but provide a litigation back-up when there are failures in the process.

"Academic discussions of a 'regulatory' defense in the tort context have been binary: either FDA compliance should provide immunity with few exceptions or the system should remain largely unchanged with some incremental modifications as to how cases are handled."¹⁴⁵ However, there are a few scholars who offer ideas other than absolute immunity or the status quo. Professor Catherine Sharkey advocates "agency-court cooperation," with the FDA more aggressively seeking out fraud and private litigants bringing suit after the FDA's findings.¹⁴⁶

141. See *White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1030 (W.D. Mich. 2008) (The statute does not limit the protection to situations when the drug is used for its approved purposes.).

142. Green, *supra* note 5, at 474 (identifying that the FDA sets an optimal, not minimum level of safety); see also Blair, *supra* note 8, at 303 (noting the "firm stance FDA is taking regarding the weight of authority that its approval should carry").

143. Haffner, *supra* note 22, at 399 ("Also, the regulatory compliance defense may leave large numbers of injured consumers with inadequate remedies—or even completely remediless.").

144. Schuck, *supra* note 6, at 100 ("a properly labeled, duly-approved drug is not in fact defective").

145. Childs, *supra* note 53, at 183.

146. See Sharkey, *Fraud Caveat*, *supra* note 6, at 866–67.

Professor James O'Reilly proposes a state-administered last resort compensation fund for medical injuries caused by FDA approved drugs.¹⁴⁷ However, the FDA may not have the resources or incentives to adequately police fraud and there may be instances where disclosure was insufficient but not fraudulent. A compensation fund has advantages, but the question of who will fund it leads back to the original debate as to whether pharmaceutical companies should be held liable for injuries caused by FDA-approved products. Compensation for victims is unlikely to come through regulation alone, as the FDA's "regulatory toolkit . . . only seldom includes compensation for the victims of conduct that violates the agency rules."¹⁴⁸ Though "state variation and experimentation . . . is decidedly unwelcome in the particular context of comprehensive FDA drug regulation,"¹⁴⁹ there is room for states in this process as long as the primacy of the FDA's role is recognized.

B. *State Attorneys General as Back-Ups to the FDA*

Michigan's regulatory compliance defense can be a model for other states, but it should be amended. First, the fraud-on-the-FDA provisions should be expanded to include negligent misrepresentations in addition to intentional misrepresentations, because in all such cases, the significance of the FDA's determination is impaired.¹⁵⁰ Second, state legislatures should establish by statute that, absent fraud on the FDA,¹⁵¹ FDA approval raises an absolute defense to liability in private suits and raises a rebuttal presumption that the drug maker is not liable in suits brought by state attorneys general ("AGs")¹⁵² on behalf of their constituents.¹⁵³ Implementing this proposal would reduce the number of private litigants (especially frivolous lawsuits), thus limiting the opportunities for state juries to regulate drugs where the FDA has made an independ-

147. See O'Reilly, *supra* note 9, at 517–72.

148. Schuck, *supra* note 6, at 76.

149. *Id.* at 110.

150. *Id.* at 85. This would cover what Schuck calls the "disclosure deficit." *Id.* at 102–09.

151. This would apply in a situation where the FDA is not pre-empted—either where the FDA has found fraud or if the fraud-on-the-FDA exception is upheld as constitutional in its entirety.

152. This would apply to all types of claims, including consumer protection claims and those against relevant intermediaries as well as the actual drug maker.

153. State AGs are able to bring actions on behalf of their constituents in other contexts. For instance, federal antitrust law allows such actions:

Any attorney general of a State may bring a civil action in the name of such State, as *parens patriae* on behalf of natural persons residing in such State, in any district court of the United States having jurisdiction of the defendant, to secure monetary relief as provided in this section for injury sustained by such natural persons to their property by reason of any violation of the Sherman Act. 15 U.S.C. § 15c(a)(1).

ent judgment. Private parties (such as class action plaintiffs' attorneys) could only bring actions where there was fraud on the FDA and the regulatory system was a clear failure.¹⁵⁴

Even if a properly-functioning FDA sets the optimal level of regulation, there may be times when the FDA fails to function properly due to fraud or disclosure errors on the part of drug makers, a lack of resources to enforce or monitor its regulations, or where the agency becomes captured by the industry it should be regulating. Explicitly limiting this proposal to specific situations might be constitutionally preempted for the reasons the Sixth Circuit rejected the fraud-on-the-FDA exception in *Garcia*,¹⁵⁵ and would fail to address future situations that are unexpected. Rather, a state back-up to the FDA should be in place that can address whatever situations might arise if the FDA process fails, thereby offering consumers an extra layer of protection.¹⁵⁶ While situations will likely be infrequent or rare (which is why tort lawsuits should be largely curtailed), they are still possible (which is why state AGs should be able to bring suits). These state AG suits would ensure that even if the FDA fails, states can generate the necessary safety incentives through state litigation.¹⁵⁷ Hopefully, the state AGs' decision-making process in bringing a suit will be an additional check on frivolous litigation and state AG-led litigation will be less expensive. State AG suits would take the place of private tort litigation, but would still leave a role for juries as the finder of fact.

As political creatures, state AGs are publicly accountable; plaintiffs' attorneys are not. Thus, when the state AG is bringing the suit, at least some accountability is injected into the jury-focused courtroom. Politics make state AGs accountable, but it also offers opportunities for drug makers to wield influence. Drug makers might invest money to elect state AGs that are less-inclined to bring suits. This may even be a good thing because, most of the time, FDA approval should be enough to establish that a drug is in fact safe. However, political checks will also keep state AGs from being too friendly to drug companies as the voters

154. Fraudulently-induced regulation is clearly sub-optimal.

155. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 967 (6th Cir. 2004) (fraud-on-the-FDA exception preempted where it requires state to find that fraud was committed on a federal agency).

156. *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009) ("Failure-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. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.").

157. *Green*, *supra* note 5, at 502 (manufacturers need incentives to be safe); *O'Steen & O'Steen*, *supra* note 7, at 94 ("state legislatures must recognize that litigation—and the threat of litigation—provides an important safeguard in America's healthcare system.").

might throw them out of office if the state AGs do not do anything about products that fall through the FDA's cracks and injure them. Even if drug companies capture some of the state AGs some of the time, they will not be able to influence all of the state AGs all of the time. All it takes is the possibility of one independent-minded state AG bringing a lawsuit where the FDA has failed, or where drug makers have become too "astute" for the public good, to establish additional incentives for safety.¹⁵⁸ Actions by state AGs are not unprecedented, as "state and local governments increasingly are pursuing claims against corporations using a variety of innovative approaches."¹⁵⁹ Last year, drug maker Pfizer entered into a settlement with thirty-three state AGs to resolve a suit about improper marketing.¹⁶⁰ Pfizer agreed to pay a multi-million dollar fine and stop deceptive marketing practices, including those that promoted their drugs for off-label purposes.¹⁶¹ Permitting state AGs to bring suits where private attorneys cannot puts a publicly accountable actor in place as a back-up to the FDA process to ensure that proper safety incentives will be there even if the FDA fails.

Allowing state AGs to bring actions and face only a rebuttable presumption, rather than a conclusive presumption, will largely cut the plaintiffs' attorneys out of the process and leave the lawsuits seeking judicial regulation of pharmaceuticals and compensation for victims in the hands of the state AG and his or her staff. Class action plaintiffs' attorneys are notorious for settlements that do little to benefit their clients but generate large attorney fees.¹⁶² State AGs have different incentives that may lead to better outcomes when suits are actually brought. The proceeds or fees from a lawsuit do not go into the state AGs' pockets, as they do with private attorneys, reducing incentives to seek benefits at the expense of those whom they represent. The overwhelming majority of state AGs are elected,¹⁶³ and generating actual compensation for victims is a way to encourage those victims to support a candidate's re-election

158. Many suits involve multiple state AGs, like the Pfizer case discussed *infra* notes 160–161 and accompanying text. Once one state AG has initiated a lawsuit and done much of the work, other states are likely to join in.

159. John B. Reiss et al., *Your Business in Court—2006*, 62 FOOD & DRUG L.J. 305, 341 (2007); see also *id.* at 319 (noting AG fraud actions).

160. *Pfizer Settles with 33 States*, MIRS Capitol Capsule (Oct. 22, 2008); Office of Illinois Attorney General, *Madigan, 33 AGs Reach \$60 Million Settlement with Pfizer*, Oct. 22, 2008, available at http://www.illinoisattorneygeneral.gov/pressroom/2008_10/20081022.html.

161. *Id.*

162. HENSLER ET AL., *supra* note 21, at 442 (noting several cases where less than half of the money spent on a class action goes to plaintiffs).

163. National Association of Attorneys General, *How Does One Become an Attorney General?*, http://www.naag.org/how_does_one_become_an_attorney_general.php (last visited Dec. 21, 2008). The rest are appointed by and thus accountable to elected officials. *Id.*

bid. Thus, state AGs have better incentives to reduce the transaction costs of litigation and actually put meaningful compensation in the hands of victims because doing so is politically beneficial.

In the limited circumstances where FDA approval is insufficient or fails to protect safety, actions brought by state AGs can also fulfill one of the other elements of the tort system—compensating victims.¹⁶⁴ As elected officials, state AGs have an incentive to compensate victims in order to win votes from those victims. State AGs should be subject to a rebuttable presumption, though, to grant at least some deference to the FDA and reduce the success and frequency of litigation.

C. A Rebuttable Presumption of Non-Liability

A rebuttable presumption of non-liability is less of a barrier to plaintiffs than the conclusive presumption Michigan currently applies to all actions. Essentially, a rebuttable presumption makes it more difficult for a plaintiff to prevail.¹⁶⁵ “The existence of a rebuttable presumption requires that the Plaintiff offer admissible evidence to rebut the presumption.”¹⁶⁶ To survive summary judgment, the “Plaintiff must point to admissible evidence in the record which, if believed by the Jury, would rebut the presumption.”¹⁶⁷ This requires actual evidence, not just conclusions.¹⁶⁸ “The rebuttable presumption indeed goes not only to the jury’s assessment of these claims but also to whether these claims should go to a jury in the first instance”¹⁶⁹ This proposal limits the problem of unsophisticated jurors making potentially incorrect determinations about drug safety not only because state AGs would likely bring fewer suits, but also because early summary judgments generated by the rebuttable presumption would keep weak claims from going to the jury at all. However, it is not impossible for a plaintiff to rebut that presumption. “A rebuttable presumption does not carry as heavy a burden. It is less preclusive than either preemption or a conclusive presumption.”¹⁷⁰ A rebuttal presumption is insufficient to stop private attorneys from bringing suits where a drug is not in fact defective because of their large financial

164. Schuck, *supra* note 6, at 76 (“compensation of victims is a central, perhaps essential, element.”).

165. *See Mut. Ins. Co. of Am. v. Royal Appliance Mfg. Co.*, 112 F. App’x. 386, 392 (6th Cir. 2005) (applying a rebuttable presumption).

166. *Lesho v. Textron, Inc.*, 408 F. Supp. 2d 329, 334 (E.D. Mich. 2005).

167. *Id. See also Mut. Ins. Co. of Am.*, 112 F. App’x. at 392 (applying a rebuttable presumption).

168. *See Lesho*, 408 F. Supp. 2d at 336.

169. *Id.* at 334 (quoting *Mut. Ins. Co. of Am.*, 112 F. App’x. at 388).

170. *Hull et al.*, *supra* note 99, at 120.

incentives; therefore, private attorneys should be subject to a conclusive presumption of absolute immunity except in cases of fraud on the FDA.

Thus, a rebuttable presumption applied to AGs would allow suits to go forward only where there was credible, admissible evidence in a suit a state AG would be willing to bring. The rebuttable presumption would help to prevent state AGs from abusing their position and pursuing suits for purely political reasons. A conclusive presumption applied to private litigants would block all suits except those involving fraud, because where there is no regulatory compliance, a regulatory compliance defense is inappropriate. The result of this proposal would be more deference to the judgments of the FDA, fewer tort suits and less regulation of pharmaceuticals by juries, and more compensation reaching the victims in the suits that actually go forward. The combination of a rebuttable presumption, less financial incentive to bring suits, state AG discretion, and political accountability will limit state AGs to bringing suits where the FDA process has failed and, consequently, avoids over-deterrence.

CONCLUSION

The debate over the proper role of the FDA in regulating drugs and holding drug makers accountable is mostly binary. Most scholars believe either that the FDA should be the only regulator, or that tort litigation should effectively co-regulate the pharmaceutical industry. There is room for a middle ground, recognizing the primacy of the FDA, the dangers of over-deterrence, and the abuse of the tort system, but also recognizing the need for a back-up that can provide deterrence and compensation in the few cases that slip through the FDA's regulatory cracks. By leaving this litigation check in the hands of state attorneys general, the problems of over-deterrence caused by unscrupulous plaintiffs' attorneys can be minimized or avoided entirely. Michigan has sought to avoid these problems by establishing an absolute regulatory compliance defense. Even if a political shift in the Michigan legislature, combined with the statute's failure to provide a vehicle for compensating victims, leads to an outright repeal of the regulatory compliance defense, other states could still learn from Michigan's experience.

Michigan's regulatory compliance defense has a valid underlying purpose because drugs duly approved by the FDA are not defective. Michigan's statute, however, could be improved by expanding the fraud-on-the-FDA exception (although this entire exception may ultimately be preempted) and creating a state AG-based litigation back-up that would be helpful in situations where the FDA process has failed. Private plain-

tiffs' attorneys have been inefficient in compensating victims; leaving this back-up in the hands of state AGs means that actual compensation and deterrence, not just settlements designed to produce attorney's fees, will be the goal of those filing suit. A back-up will be particularly helpful if the Supreme Court ultimately holds that any fraud on the FDA exception in state law is unconstitutional. Irrespective of the Court's potential holding, other states have much to learn from Michigan and should adopt a modified regulatory-compliance defense because juries should only be able to find an FDA-approved drug defective in limited circumstances.