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Consider this all-too common scenario. A drug manufacturer develops a new product and proceeds to spend hundreds of millions of dollars in order to satisfy the Food and Drug Administration (FDA) that the drug is safe and effective within the meaning of the 1962 Drug Amendments[1] to the Food, Drug, and Cosmetic Act (FDCA).[2] After the FDA spends many years analyzing these data, including commissioning a scientific review by outside experts and holding a public hearing before an advisory committee, it finally permits the company to market the drug under a carefully formulated label that describes the drug's uses, risks, proper dosages, and other limiting conditions. A consumer of the drug later becomes ill and sues the manufacturer for damages. She alleges that the drug is defective and that its labeling and advertising are false or misleading. Both the drug and the label comply with all of the FDA's rules. No new risks have come to the attention of the manufacturer or the FDA—or if they have, the manufacturer has notified the FDA and the agency has taken no further regulatory action. A jury finds the company

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1. Drug Amendments Act of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

2. 21 U.S.C. §§ 301-399(a) (2000 & Supp. V 2001-2006).

liable for large compensatory and punitive damages. A month later, another jury in a different state dismisses an essentially identical claim, upholding both the drug and its label.

What is wrong with this picture? Legally, nothing. State tort law allows juries to consider or ignore FDA approval, substitute their own judgment on whether the product is unsafe and improperly labeled, and award tort damages that are subject only to the loosest legal limits and a patchwork of hit-or-miss tort reform efforts. Michigan alone provides for a complete regulatory compliance defense, subject only to a fraud-on-the-agency exception;[3] a handful of other states offer manufacturers various forms of more limited protection.[4] Except in Michigan, a drug

3. MICH. COMP. LAWS ANN. § 600.2946(5) (2000).

4. *See, e.g.*, COLO. REV. STAT. § 13-21-403(1)(b) (2007) (rebuttable presumption that product is not defective if it complied with a code, standard, or regulation promulgated by an agency of the United States or this state at the time of sale); IND. CODE § 34-20-5-1(2) (1999) (same); KAN. STAT. ANN. § 60-3304(a) (2005) (same); N.J. STAT. ANN. § 2A:58C-4 (West 2000) (rebuttable presumption that a warning or instruction given in connection with a drug or device is adequate if approved or prescribed by the FDA); TENN. CODE ANN. § 29-28-104 (2000) (rebuttable presumption that product is not unreasonably dangerous if manufacturer or seller complied with "any federal or state statute or administrative regulation . . . prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions" at the time product was manufactured); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1) (Vernon 2005) (rebuttable presumption that defendant is not liable for failure to provide adequate warnings or information regarding a pharmaceutical product if such warnings or information were approved by the FDA); UTAH CODE ANN. § 78-15-6(3) (2002) (rebuttable presumption that product is not defective if it was "in conformity with government standards established for that industry which were in existence at the time . . . the product [was] adopted"). For limits on punitive damages, see ARIZ. REV. STAT. ANN. § 12-701(a)(1) (2003) (manufacturer or seller of a drug is not liable for punitive damages if drug "[w]as manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the [FDA]"); N.J. STAT. ANN. § 2A:58C-5(c) (West 2000) (punitive damages not permitted if drug was subject to premarket approval by the FDA and was approved, unless the manufacturer of such drug "knowlingly withheld or misrepresented information required to be submitted under the [FDA's] regulations"); N.D. CENT. CODE § 32-03.2-11(6) (1996) (punitive damages not permitted if product complied with federal statutes, administrative regulations, or premarket approval or certification by a federal agency); OHIO REV. CODE ANN. § 2307.80(C)(1) (West Supp. 2007) (manufacturer or seller of drug not liable for punitive damages if drug "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the [FDA]"); OR. REV. STAT. § 30.927(1)(a) (2005) (same); UTAH CODE ANN. § 78-18-2(1)(a) (2002) (punitive

company's full and continuing compliance with FDA requirements provides no safe harbor against tort liability. Instead, the law casts the manufacturer onto the stormy sea of litigation where a jury may, if it wishes, treat the FDA's laborious approval process as authoritative, entirely irrelevant, or something in between.

The project of harmonizing tort law and regulatory law in the public interest—the "sweet spot" of my subtitle—is inherently fraught with difficulty. This, of course, is a very old problem for American law generally. Our administrative state began during the first decade of the Republic.[5] Beacause energetic administration has always created risks of harm to persons and property, the potential for overlap and conflict with the hoary common law of torts. which likewise protects persons and property, has always been an inevitable consequence of regulatory statutes. Moreover, as Richard Nagareda explains, recent developments in both tort law and administrative regulation "increasingly cast the two less as complementary regimes than as institutional rivals."[6]

The potential conflicts between administrative regulation and tort law extend well beyond the problem of overlap; they inhere in the competing purposes and the different institutions and processes of tort and regulation.[7] Whether scholars define tort law as a vehicle of corrective justice,[8] an engine of deterrence,[9] or

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damages not permitted if drug "received premarket approval or licensure by the [FDA]").

5. *See* Jerry L. Mashaw, *Recovering American Administrative Law: Federalist Foundations 1787-1801*, 115 YALE L.J. 1256 (2006); Jerry L. Mashaw, *Reluctant Nationalists: Federal Administration and Administrative Law in the Republican Era, 1801-1829*, 116 YALE L.J. 1636 (2007).

6. Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. art. 4, 3 (2006), http://www.bepress.com/jtl/vol1/iss1/art4.

7. Tort law, particularly in its pursuit of deterrence, obviously has significant regulatory effects. For an analysis of how the Supreme Court has treated this fact, see Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. (forthcoming 2008) [hereinafter Sharkey, *Institutional Approach*] (noting that the Court has oscillated between the "competing conceptions" of tort as regulatory or compensatory, with preemption following the regulatory view, and non-preemption following the compensatory view).

8. The most thoroughgoing and rigorous advocate of this conception is Ernest Weinrib. *See* ERNEST J. WEINRIB, THE IDEA OF PRIVATE LAW (1995); Symposium, *Corrective Justice and Formalism: The Care One Owes One's*

something else, they agree that compensation of victims is a central, perhaps essential, element. They may hotly debate the appropriate measure of losses and the issue of who should properly bear them in which proportions, but all concur that tort law is concerned with the repair of victims' harms. In contrast, administrative regulation seeks to achieve specific social purposes through a public agency that typically deploys rulemaking, adjudication, informal guidance, subsidies, taxes, research, information, and a variety of other instruments. Its regulatory toolkit, however, only seldom includes compensation for the victims of conduct that violates the agency's rules.[10]

The doctrines governing federal regulatory preemption are meant to harmonize potential conflicts between (1) statutory schemes designed to regulate the behavior of firms and other actors largely through antecedent rules, and (2) tort law's use of retrospective, case-by-case common law adjudication to compensate victims while also deterring (and hence regulating) those same actors. Sometimes, policymakers make this difference explicit, as when Congress enacted the Airline Stabilization Act of 2001, which created a special agency to compensate the victims of the September 11 tragedies and preempted tort litigation against the airline industry by those victims who accepted the compensation, and limited tort claims in certain ways by those who did not.[11] In other cases, the statutes creating agencies expressly preserve, prohibit, or modify victims' tort law remedies.[12] In still others, the statute is silent or (what may have the same legal effect) sufficiently ambiguous on the questions of whether and to what extent tort remedies are preempted[13] that

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Neighbors, 77 IOWA L. REV. 403 (1992).

9. *See* RICHARD A. POSNER, THE ECONOMICS OF JUSTICE 208-09 (1981).

10. The implications of this distinction for preemption are further discussed in the Conclusion.

11. *See* KENNETH R. FEINBERG, WHAT IS LIFE WORTH?: THE UNPRECEDENTED EFFORT TO COMPENSATE THE VICTIMS OF 9/11 (2005).

12. *E.g.*, Cipollone v. Liggett Group, Inc., 505 U.S. 504, 515, 521-31 (1992) (holding that express preemption clause stating "[n]o requirement or prohibition . . . shall be imposed under [s]tate law with respect to the advertising and promotion of any cigarettes . . . labeled in conformity with the provisions of this Act" preempts certain state common law actions).

13. *E.g.*, Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 681 (2003) (Thomas, J., concurring) ("[G]iven the foregoing discussion of the text of the Medicaid Act, it cannot be read to unambiguously prohibit Maine Rx,

the courts must resolve these questions using standard interpretive techniques.[14]

It is these latter instances of silence or significant ambiguity concerning the federal regulatory preemption (hereafter "preemption") question with which this Article is concerned.[15] My discussion specifically concerns the FDA's regulation of pharmaceutical drugs for safety and efficacy,[16] but my argument would also be relevant, *mutatis mutandis*, to other areas of federal policy in which, absent an express preemption provision, a federal agency exercises comprehensive regulatory authority over an industry and sets optimal safety standards, rather than minimal safety standards.[17] By "optimal," I mean the socially best balance

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or indicate that Congress, in enacting § 1396a(a)(19), directly addressed this issue.").

14. *See, e.g.*, Sharkey, *Institutional Approach*, *supra* note 7 (discussing Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992); Medtronic v. Lohr, 518 U.S. 470 (1996); Sprietsma v. Mercury Marine, 537 U.S. 51 (2002); and Bates v. Dow Agrosciences, LLC, 544 U.S. 431 (2005)).

15. I am not concerned here with state statutes or common law rules that may preempt tort liability as a matter of state statutory or common law. That kind of preemption occurs when, and to the extent that, state law provides a regulatory compliance defense to tort liability. Although my argument for qualified FDA regulatory preemption implies the desirability of a *pro tanto* defense under state law—and, if such a defense were adopted, would compel state courts to adopt it—the fact that few states now provide one means that the issue is best discussed under the rubric of preemption rather than a regulatory compliance defense. The distinction between preemption and a regulatory compliance defense is discussed at greater length in Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL'Y 1013 (2007) [hereinafter Sharkey, *Federalism in Action*].

16. The relationship between safety and efficacy is explored in Anita Bernstein, *Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation*, 15 J.L. & POL'Y 1051 (2007). She does not focus on the preemption issue with respect to either, but seems to envision a large role for state tort litigation. *Id.* at 1074-98 (advocating that plaintiffs who suffer drug-caused harms should have claims based on drug effectiveness as well as drug safety).

17. The proposition that FDA regulation has these features is discussed in Nagareda, *supra* note 6, at 2, 5, 36-37, 53; *id.* at 26-28 (discussing the FDA's periodic reviews of whether the antidepressant SSRI caused the emergence of suicidal thoughts); Sharkey, *Institutional Approach*, *supra* note 7; Sharkey, *Federalism in Action*, *supra* note 15, at 1026-27. The National Highway Traffic Safety Agency and the Consumer Product Safety Commission have asserted that they too can preempt state tort law by preamble. *See* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 230-37

between safety, effectiveness, cost, and other relevant factors, taking into account that some individual users may be harmed even under such a standard.

When these comprehensive regulatory and optimal safety conditions are satisfied, as I believe is true of the FDA's regulation of drug safety,[18] state tort judgments that penalize manufacturers for not meeting different standards are more than simply compensatory; rather, they are regulatory in every relevant sense of the word.[19] The conflicting standards between state courts (and juries) and the federal agencies create inconsistent incentives for manufacturers. Insofar as such standards and incentives differ from state to state—and sometimes differ from jury to jury *within* a state—the inconsistencies are further magnified for pharmaceuticals produced for national and global markets in which the products' trans-jurisdictional uniformity is essential for their economic efficiency.[20] Moreover, insofar as the uncertainty arising from the prospect of liability under these varying state laws inhibits manufacturers from investing in the development of socially valuable pharmaceutical products, public safety may also be adversely affected.[21]

(2007) [hereinafter Sharkey, *Preemption by Preamble*]. In my view, however, they lack the FDA's degree of regulatory comprehensiveness and goal of optimal standard-setting.

18. There certainly are respectable arguments that the FDA does not regulate for optimal safety, including court decisions and past statements by the agency to that effect, statements that the agency recently seems to have renounced. For discussion of this evolution, see Catherine M. Sharkey, *The Roberts Court Wades into Products Liability Preemption Waters:* Reigel v. Medtronic, Inc., 8 ENGAGE: J. FEDERALIST SOC'Y PRAC. GROUPS, Oct. 2007, at 4, 7-8, http://www.fed-soc.org/doclib/20071120_Engage8.4.pdf [hereinafter Sharkey, *Roberts Court*]. For reasons elaborated *infra* Part I, Congress should remove any ambiguity on this score and affirm that optimal safety is the criterion according to which the FDA's standards are to be set.

19. *See, e.g.*, Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1007-08 (2008) (citing earlier Supreme Court decisions).

20. Many other commentators, including the Supreme Court in *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 350-51 (2001), have remarked on the seriousness of this structural conflict. For a contrary view, see Levine v. Wyeth, No. 2004-384, 2006 WL 3041078, ¶¶ 21-28 (Vt. Oct. 27, 2006), *cert. granted*, 128 S. Ct. 1118 (2008) (finding that FDA labeling requirements establish only a "floor" and that tort judgments setting a higher standard are not regulatory).

21. Recent evidence suggests that manufacturer innovation processes have bogged down. *E.g.*, Stephanie Saul, *Bristol-Myers to Eliminate 4,800*

Professor Tom Merrill notes that "[p]reemption is one of the most widely applied doctrines in public law, yet it remains surprisingly under-analyzed."[22] Be that as it may—recent work authored by Merrill and Professor Catherine Sharkey have certainly shrunk that deficit[23]—the black-letter law of federal regulatory preemption is easily stated.[24] If a federal statute expressly or implicitly preempts state tort law—an issue of statutory interpretation, except in the clearest cases—then the finding of preemption is perfectly straightforward, although the extent or domain of preemption may require further analysis.[25]

Jobs, N.Y. TIMES, Dec. 6, 2007, at C1 (FDA approval rate for new molecular entities—"drugs that are entirely new compounds rather than changes in formulations"—declined by 18% in 2007 from 2006, is well below recent norms, and is the lowest rate of FDA approvals since 1994).

22. Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. (forthcoming 2008).

23. *See, e.g.*, *id.* (advocating that absent congressional action courts are best suited to decide questions of preemption and should "draw on the expertise of agencies in helping to understand the pragmatic variables that bear on the preemption decision"); Sharkey, *Federalism in Action*, *supra* note 15; Sharkey, *Preemption by Preamble*, *supra* note 17; Sharkey, *Roberts Court*, *supra* note 18 (anticipating that the Court's then-pending decision in *Reigel* might clarify the level of deference courts should give to federal agency interpretations of ambiguous statutes on preemption issues); Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. (forthcoming 2008) [hereinafter Sharkey, *Fraud Caveat*] (arguing that state law fraud claims should be permitted against manufacturers in the event that the FDA has made a prior finding of fraud-on-the-agency); Sharkey, *Institutional Approach*, *supra* note 7 (advocating an agency reference model in which courts defer to agencies in determining whether state common law remedies are preempted when Congress "punts" on the issue). Merrill also gives prominence to an earlier article, Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767 (1994). Merrill, *supra* note 22.

24. For an insightful case-by-case analysis of the doctrine's evolution and current form, see Sharkey, *Institutional Approach*, *supra* note 7.

25. In the *Cipollone v. Liggett Group, Inc.*, for example, the Supreme Court found it necessary to distinguish among different types of tort claims in determining which were and were not preempted. *See* 505 U.S. 504, 530-31 (1992) ("[T]he 1969 Act pre-empts petitioner's claims based on a failure to warn and the neutralization of federally mandated warnings to the extent that those claims rely on omissions or inclusions in respondents' advertising or promotions; the 1969 Act does not pre-empt petitioner's claims based on express warranty, intentional fraud and misrepresentation, or conspiracy."). *See also id.* at 524-30 (discussing each of the claims); Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008) (Medical Device Amendments of 1976 preempt claims of strict liability, breach of implied warranty, and negligence); Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 434, 443-46, 452-53 (2005) (analyzing

The courts have recognized two analytically distinct types of implied preemption. Conflict preemption occurs when the demands of the regulatory scheme are inconsistent with the demands of tort law—"where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[26] Field preemption occurs when Congress intends the regulatory scheme to "occupy the field," supplanting any significant role for state law in that regulatory domain.[27]

Not surprisingly, the great difficulty arises not with these broad preemption principles themselves, but rather with courts' application of them in specific cases based on state tort law. These difficulties are especially great, of course, in cases of implied preemption. There, the court must perform at least the following analyses: interpret the essential nature of the plaintiff's claim; interpret the federal statute and any agency regulations and other authoritative guidance that flesh out and gloss the statute; determine how much *Chevron*, *Skidmore*, *Mead*, or some other level of deference to accord to the agency's own interpretations of these materials;[28] decide whether and how to

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whether § 136v(b) of the Federal Insecticide, Fungicide, and Rodenticide Act preempts common law claims of defective design, defective manufacturing, negligent testing, breach of express warranty, fraud, and negligent failure to warn).

26. Sprietsma v. Mercury Marine, 537 U.S. 51, 65 (2002) (citing Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)). Merrill notes that the "frustration of purpose" species of implied preemption does not merely trump state law (as conflict preemption does), but wholly displaces it in order to effectuate federal policy. Merrill, *supra* note 22.

27. *See* Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991) ("Congress' intent to supersede state law in a given area may nonetheless be implicit if a scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, if the Act of Congress . . . touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject . . . .") (internal quotation marks omitted).

28. Chevron U.S.A., Inc. v. National Res. Def. Council, Inc., 467 U.S. 837 (1984); Skidmore v. Swift & Co., 323 U.S. 134 (1944); United States v. Mead Corp., 533 U.S. 218 (2001). This element includes the question of how much deference, if any, the courts should accord to the FDA's assertion of its own preemptive power, including the procedural preludes to such assertion. *See* Sharkey, *Preemption by Preamble*, *supra* note 17, at 243-47.

apply the commonly-cited presumption against preemption;[29] determine the scope, limitations of, and defenses to any preemption that the court finds; allocate the burden of production and proof regarding any such limitations and defenses; and make (or instruct the jury to make) the findings of fact necessary to apply these principles to plaintiff's claim. Given these multiple occasions for a single court to exercise judgment in order to apply indeterminate legal standards, the only predictable outcome, it seems, is that their decisions will be unpredictable. In fact, unpredictability of outcomes is precisely what the case law reveals.[30] This is particularly perverse in a policy domain in which predictability is necessary to attract the immense investments required for socially desirable drug research, innovation, and marketing.[31]

The question of how courts should apply preemption principles to tort claims for alleged design and warning defects in drug products regulated by the FDA lies at the intersection of tort law, administrative law, and federalism law. Because the FDCA's

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29. Merrill notes that this presumption "is honored as much in the breach as in observance." Merrill, *supra* note 22. *See also* Sharkey, *Institutional Approach*, *supra* note 7 (criticizing "the Court's haphazard application of the presumption," most notably in implied preemption cases); Sharkey, *Roberts Court*, *supra* note 18, at 5 (same).

30. *See, e.g.*, Sharkey, *Preemption by Preamble*, *supra* note 17, at 245-47 (noting a split among courts regarding "the level of deference to accord the FDA's preemption preamble"); Sharkey, *Institutional Approach*, *supra* note 7 (noting that the Court itself has failed to consistently apply the presumption against preemption); Sharkey, *Roberts Court*, *supra* note 18, at 5 (same); *id.* at 4 (noting a split in the circuits on whether the FDA's premarket approval process for medical devices preempts state common law tort actions). Merrill, *supra* note 22 (noting the Supreme Court's conflicting propositions concerning the deference courts are to give agencies on preemption questions).

31. *See, e.g.*, Gideon Parchomovsky & Alex Stein, *The Anti-Innovation Bias of Tort Law* 25-31 (Univ. of Pa. Inst. for Law & Econ., Research Paper No. 07-31, 2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1028346. This predictability imperative also casts doubt on the utility, at least in this specific area of regulation, of claims by proponents of "cultural cognition" that diverse ways of understanding and assessing risk are all presumptively if not equally legitimate and that this may justify having separate institutions, such as tort litigation and regulatory agencies, provide competing risk and liability assessments. For a discussion of cultural cognition, see Dan M. Kahan & Donald Braman, *Cultural Cognition and Public Policy*, 24 YALE L. & POL'Y REV. 149 (2006).

drug approval provisions, in contrast with some of those governing the regulation of medical devices, do not expressly preempt state law,[32] the issue is whether and to what extent the FDA's drug safety-related decisions *impliedly* preempt state law. Since 2000,[33] and most notably in the recent work of Sharkey,[34] Merrill,[35] Richard Epstein,[36] and Richard Nagareda,[37] leading torts scholars have lavished much attention on this very question, with highly interesting and illuminating results. I am largely persuaded by their analyses and conclusions, particularly their reasons for preferring administrative regulation to state tort law in situations of conflict or frustration.

I shall augment their analyses in three main ways. First, like Merrill and Sharkey, I maintain that implied preemption should turn largely on the criterion of comparative institutional competence as between state and federal (in diversity cases) courts applying state products liability law, on the one side, and the FDA's regulatory decisions concerning drug safety on the other.[38] In support of this conclusion, however, I emphasize certain structural features of the tort system that they largely neglect—particularly, its relative deficiencies in information-processing, learning, corrigibility, and accountability. These weaknesses, I argue, should cause courts—absent clear statutory language to the contrary (thus taking the case out of the implied preemption category)—to resolve the questions that I listed two paragraphs earlier (and perhaps others that involve court-FDA conflicts bearing on design and warning defect claims) in favor of

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32. This fact precludes the more formalistic statutory interpretation approach favored by Richard Epstein and Michael Greve in their co-edited book, FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS (Richard A. Epstein & Michael S. Greve eds., 2007).

33. Symposium, *Regulatory Compliance as a Defense to Products Liability*, 88 GEO. L.J. 2049 (2000).

34. *See* Sharkey, *Institutional Approach*, *supra* note 7 (arguing that the FDA should have to make a prior determination of fraud before this finding can be wielded in state courts); Sharkey, *Fraud Caveat*, *supra* note 23.

35. Merrill, *supra* note 22.

36. Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of* Chevron *Deference and a Response to Richard Nagareda*, 1 J. TORT L. art. 5 (2006), http://www.bepress.com/jtl/vol1/iss1/art5.

37. Nagareda, *supra* note 6.

38. I say "largely" because the implied preemption analysis also entails analysis of the FDA's role under the statutory scheme.

preemption of state tort law by relevant FDA drug safety regulatory actions. As discussed below, the law should also endeavor to resolve the preemption issue as early in the litigation as possible. The case for this pro-preemption tilt, I conjecture, will likely be strengthened further by the Food and Drug Amendments Act, enacted in September, 2007, which significantly expands the FDA's authority to monitor post-approval drug safety and take action against violations in a number of ways that are, or at least should be, highly relevant to the resolution of the preemption issue.[39]

Second, this preemption would be a qualified or conditional one. Like all other tort scholars, I favor an exception to both FDA preemption of tort claims and to any state law regulatory compliance defense that might survive this preemption: cases in which the manufacturer fraudulently withholds from the agency regulation-relevant risk information. Apparently, every state legislature that has adopted regulatory compliance provisions as a complete defense (Michigan),[40] as a defense only to punitive damages,[41] or some other variant, includes such an exception.[42] Its goal, of course, is to enhance manufacturers' incentives to gather, analyze, and disclose all relevant risk information to the FDA, Congress, and the public in a timely fashion.

Professor Sharkey has carefully examined the scope and

39. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007). *See also* FDA, Law Strengthens FDA, http://www.fda.gov/oc/initiatives/advance/fdaaa.html (last visited Dec. 25, 2007). Among other provisions, the Amendments authorized the FDA to require manufacturers to adopt a "risk evaluation and mitigation strategy" in light of post-approval safety information, sec. 901(b), § 505-1, 121 Stat. at 926-38 (to be codified at 21 U.S.C. § 355-1); to require post-approval studies or clinical trials in light of possible risks, sec. 901(a), § 505(o), 121 Stat. at 922-26 (to be codified at 21 U.S.C. § 355); to impose higher civil penalties for a number of manufacturer infractions, sec. 902(b), § 303(f)(4), 121 Stat. at 943 (to be codified at 21 U.S.C. § 333); to develop a post-marketing risk identification and analysis system, sec. 905(a), §§ 505(k)(3)-(4), 121 Stat. at 944-49 (to be codified at 21 U.S.C. § 355); to encourage consumer reporting of drugs' negative side-effects, sec. 906(a), § 502(n), 121 Stat. at 949-50 (to be codified at 21 U.S.C. § 352); and to increase the frequency of reports based on the Adverse Event Reporting System database, sec. 921, § 505(k)(5), 121 Stat. at 962 (to be codified at 21 U.S.C. § 355).

40. MICH. COMP. LAWS ANN. § 600.2946(5) (2000).

41. *See supra* note 4.

42. Sharkey, *Fraud Caveat*, *supra* note 23.

application of this fraud exception, particularly in light of the Supreme Court's 2001 decision in *Buckman Co. v. Plaintiffs' Legal Committee*,[43] which held that a stand-alone fraud-on-the-FDA claim involving a regulated medical device was impliedly preempted by the possibility that state court adjudications of fraud would conflict with the FDA's own rules concerning the information that the manufacturer must provide to the agency, as well as the agency's own policing of fraud.[44] Rejecting other possible readings of *Buckman*, Sharkey, like Justice Stevens in his *Buckman* concurrence, would preempt tort litigation challenging the safety of FDA-regulated products based on fraud-on-the-agency, or state-based tort claims in which fraud is a critical element, unless the FDA has made an antecedent finding that fraud occurred in the process of obtaining (or retaining) approval of a product or label.[45] Although such a finding could follow either an FDA-initiated process or a citizen petition to the agency, she does not discuss the rules that would govern the FDA's fact-finding process in this "primary jurisdiction" situation.[46] It seems likely, however, that such rules would entail considerable delay and other costs that a sound preemption regime should seek to minimize. In March 2008, an equally divided Supreme Court failed to clarify its understanding of how *Buckman* will apply to a state law (in this case, Michigan's) regulatory compliance defense-cum-fraud-on-the-agency exception.[47]

The best reading of *Buckman*'s scope, I suggest, would build on the Court's evident concerns about comparative institutional competence between court and agency, and about the "inherently" and "uniquely" federal interest in having the FDA control the regulatory relationship between the manufacturer and itself under the FDCA.[48] Because the FDA's approval process for drug

43. 531 U.S. 341 (2001).

44. *Id.* at 348-51.

45. Sharkey, *Fraud Caveat*, *supra* note 23; *see also Buckman*, 531 U.S. at 354-55 (Stevens, J., concurring).

46. Sharkey, *Fraud Caveat*, *supra* note 23.

47. Warner-Lambert Co. v. Kent, No. 06-1498, 2008 WL 552875 (U.S. Mar. 3, 2008) (per curiam) (4-4 decision). Because the Court was equally divided, it was obliged to affirm the lower court decision in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), which denied FDA preemption of the Michigan fraud-on-the-agency exception.

48. *See Buckman*, 531 U.S. at 347-48.

safety is more rigorous and comprehensive than the process for medical devices at issue in *Buckman*,[49] one can infer that the Court's concerns about the agency's regulatory primacy and ability to police fraud apply with even greater force to drug safety regulation. A narrower reading of *Buckman*, moreover, would have the Court protecting only the FDA's interest in policing fraud against it, yet the Court seems to speak more broadly to the need for agency discretion in making the necessary expertise-guided, risk-versus-risk tradeoffs among safety, efficacy, prompt consumer access, innovation, and other desiderata.[50] Again, there is simply no reason to think that these concerns would apply only to fraud-on-the-agency claims or to medical device regulation. On the other hand, a broad reading of *Buckman* might invalidate all state laws that provide a fraud exception to preemption, a possibility discussed shortly.

The exception that I favor, then, would be both broader and narrower than the one proposed by Sharkey or that contained in the Michigan statute. It would be broader in two ways. First, it would defeat preemption not only in cases of fraud (i.e., intentional misrepresentation), but also in three other kinds of cases: (1) negligent misrepresentation, (2) innocent misrepresentation, and (3) failure (not amounting to affirmative misrepresentation) to inform the agency about material risk-relevant information in timely fashion.[51] I call these three additional categories "non-fraud disclosure deficits."

The second way I would broaden the exception is that FDA inaction or indecision with respect to any disclosure deficits would not in and of itself bar plaintiffs from proceeding in tort. To be sure, I would, with Sharkey, make an express FDA finding of fraud automatically defeat a claim of preemption,[52] as such a finding would remove the risk, so central to the Court's rationale in *Buckman*, of interference by the tort litigation with the agency's

49. Nagareda, *supra* note 6.

50. *See Buckman*, 531 U.S. at 349-51.

51. Sharkey does note that a narrow reading of *Buckman* would enable plaintiffs to easily circumvent its strictures by pleading failure-to-warn claims based on incomplete disclosures to the FDA, Sharkey, *Fraud Caveat*, *supra* note 23, but she does not directly discuss the fact that non-fraudulent disclosure deficits pose the same threat to sound safety regulation that fraud does.

52. *See id.*

own policing of manufacturer fraud. Under my proposal, however, a preemption claim would also be defeated by an FDA finding of a non-fraud disclosure deficit.

The exception would be narrower in that in order to survive a motion to dismiss, the tort plaintiff would have to meet a pleading standard requiring greater specificity with respect to both the allegations of disclosure deficit and the supporting factual evidence. This pleading standard should be much more demanding than the already heightened standard that the Federal Rules of Civil Procedure currently requires for complaints alleging fraud.[53]

A third change, also building on the work of other preemption scholars, concerns the status of a regulatory compliance defense under state law. As noted earlier, most states do not provide for such a defense where the manufacturer fully complies with FDA (or other agency) regulations, and those states that do—again, Michigan excepted—make compliance only a presumptive defense that the plaintiff can overcome, or make it a defense only to the imposition of punitive damages, which only rarely occurs. Although modifying FDA preemption principles as I propose would block (at least prima facie) many design and warning defect claims in state courts[54] as a matter of federal law under the Supremacy Clause,[55] there is much to be said for also effecting this change as a non-constitutional matter under state law by crafting a regulatory compliance defense-cum-deficit disclosure exception along the lines discussed below. But because *Buckman*'s rationale may bar such a disclosure deficit exception under state law *a fortiori*, federal legislation may be required, a possibility discussed near the end of Part III.

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53. FED. R. CIV. P. 9(b) ("Fraud or Mistake; Conditions of Mind. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Málice, intent, knowledge, and other conditions of a person's mind may be alleged generally."). For interpretations, see United States *ex rel.* Williams v. Martin-Baker Aircraft Co., 389 F.3d 1251, 1256-59 (D.C. Cir. 2004), and United States *ex rel.* Totten v. Bombardier Corp., 286 F.3d 542, 551-52 (D.C. Cir. 2002).

54. That is, subject to plaintiffs' ability to invoke the expanded fraud "disclosure deficit" exception that I propose and thus overcome the defense.

55. U.S. CONST. art. VI, cl. 2. I put it this way because although courts typically justify their preemption decisions as exercises in statutory interpretation, those interpretations are influenced, if not mandated, by the Supremacy Clause. *See* Merrill, *supra* note 22.

The remainder of this Article is divided into three parts, which correspond to these three proposed reforms. Building on the excellent recent scholarship in this vein by professors Sharkey, Merrill, and others, Part I develops several additional institutional-structural arguments for expanding FDA preemption of drug safety and efficacy decisions at the expense of tort law, arguments that I hope will advance these scholars' project of rendering more rational and predictable the legal principles and decision processes that shape determinations for and against FDA preemption. Part II focuses on the so-called "fraud exception" to FDA preemption, proposing a different conception of the proper scope and proof of that exception. In light of the principles and reforms defended in Parts I and II, Part III very briefly makes the case for supplanting state tort law doctrine concerning the effect of regulatory compliance. All three parts reflect my broad reading of the legal policy justification for FDA preemption that the Court advanced in *Buckman*. Although *Buckman* does not itself require this reading, its rationale supports such an interpretation.

I. EXTENDING THE INSTITUTIONAL COMPETENCE ANALYSIS

In new work, Merrill and Sharkey have each underscored the normative importance of comparative institutional analysis to sound preemption decisionmaking in the area of FDA drug safety regulation. Their analyses are convincing, as far as they go, but they neglect certain points of structural comparison that supplement, and in most cases reinforce, their positions.

Merrill notes that recent federal court decisions "involve 'institutional competence writ small,' in the sense that they ask how much weight courts should give to the views of other institutions in resolving preemption controversies."[56] What makes this fact particularly salient, he says, is that preemption decisions primarily turn on "a discretionary judgment about the permissible[57] degree of tension between federal and state law, a question that typically cannot be answered using the tools of

56. Merrill, *supra note 22* (citing Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885, 938 (2003)).

57. I would add "and actual," a wholly empirical question that Merrill would surely agree is crucial and often difficult to answer, particularly for a court. *Cf.* Sharkey, *Institutional Approach*, *supra* note 7 (noting that this question is one about which agencies are particularly competent to answer).

statutory interpretation."[58] Elsewhere, he inveighs against a formalistic doctrine that conceals, or gives short shrift to, "an evaluation of the real-world impact of" allowing state tort law to operate concurrently with FDA regulation.[59] Such an evaluation, he asserts, necessitates a systematic comparison of Congress, agencies, and the courts with respect to certain constitutional, interpretative, and pragmatic variables.[60]

Merrill's pragmatic variables can be combined into one: the technocratic capacity to adduce and analyze legislative facts concerning the tradeoffs between uniformity and diversity in legal standards.[61] While essential, this criterion is significantly incomplete. Moreover, his institutional analysis, while valuable, elides the most decisive comparison of all—between the FDA and state courts and juries in pharmaceutical liability cases. These flaws are analytically interrelated because both his list of variables and his institutional analysis are designed to answer the very same question: which institution at the federal level is best equipped to conduct the preemption analysis? This threshold "who shall decide" question is obviously critical, and his answer—"to rely on courts as the primary institution for resolving preemption controversies, but to augment their representational and pragmatic capacities by drawing upon other institutions, notably the federal agencies"[62]—is convincing as far as it goes, but it does not go far enough. Merrill makes no attempt to answer the ultimate legal policy question in all implied preemption cases: between the federal agency regulation and the state tort law, which is to govern?

Professor Sharkey, on the other hand, directly analyzes and answers both of these questions. On the "who shall decide" issue, she proposes an "agency reference model" in which courts would look to the relevant regulatory agency to supply them with its expert analysis of a variety of factual issues that are, or should be, considered in deciding the ultimate question of preemption *vel non*, as well as legal interpretation issues relating to the meaning of the regulatory statute, the nature of the agency's authority,

58. Merrill, *supra* note 22.
59. *Id.*
60. *Id.*
61. *See id.*
62. *Id.*

consistency of the regulatory action in question with earlier agency policy, and so forth.[63] In particular, Sharkey argues that agencies are well-situated to find and communicate to courts the legislative facts underlying the kind of "context-specific cost-benefit (or risk-risk) analyses" that should inform the optimal uniformity-diversity tradeoff[64]—a crucial factor also emphasized by Merrill.[65] Drawing upon recent instances of agency-court interactions on preemption, in which the Supreme Court has almost invariably adopted the agency's view in products liability cases,[66] Sharkey urges courts to exploit the agency's analytical and policy expertise in a number of ways: such as asking agencies to file amicus briefs, certifying questions to them, and invoking primary jurisdiction.[67] Agency findings and recommendations, she argues, should enjoy only *Skidmore*-type deference—that is, calibrated to the court's assessment of the agency's thoroughness, reasoning, consistency, "and all those factors which give it power to persuade, if lacking power to control"[68]—rather than the stronger *Chevron* deference, which tends to be more outcome-determinative.[69]

With respect to the ultimate preemption question—which institution's law should govern a particular dispute, the agency or state judges and juries in tort cases—Sharkey's comparative analysis, unlike Merrill's, is directly relevant, but incomplete. Comparing agency safety regulation with common law liability, she begins with Professor Steven Shavell's standard law-and-economics analysis of the optimal mix of liability and regulation, focusing on differences in information and administrative costs, the actual liability threat to tortfeasors, and their ability to pay

63. Sharkey, *Institutional Approach*, *supra* note 7.

64. *Id.*

65. Merrill, *supra* note 22.

66. *See* Sharkey, *Institutional Approach*, *supra* note 7 (discussing *Medtronic*, *Geier*, and *Sprietsma*). Sharkey notes that *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005), is the only exception. *Id.*

67. *Id. See also* Sharkey, *Fraud Caveat*, *supra* note 23.

68. Sharkey, *Institutional Approach*, *supra* note 7 (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

69. *Id.* Like Sharkey, Merrill prefers *Skidmore* to *Chevron* deference in the implied preemption context, but instead persuasively proposes "a *sui generis* standard of review that focuses on the agency's assessment of the practical impact of diverse state standards." Merrill, *supra* note 22.

judgments.[70] She then discusses the choice between state regulation via tort law versus federal regulation.[71] Turning to institutional considerations that favor agency preemption generally, she cites expertise and the advantages of a uniform legal standard in a national market.[72] Favoring state common law liability generally, she claims, are the importance of victim compensation and of FDA regulatory failure or under-enforcement.[73] Commonly added to these are the advantages of state law diversity and experimentation, particularly if the costs of this diversity can be confined to a state's own residents.[74]

Sharkey is at some pains not to take a bottom-line position on the ultimate preemption question of which institution's law should govern. Her point, rather, is a more limited one: that courts confronted with this question should employ her agency reference model to assist them in answering it.[75] This is indeed an attractive process model for courts that must decide implied preemption claims where agnosticism on the merits of the ultimate preemption question can best be resolved only after reference to the agency. In the great majority of situations in which preemption is at issue, the agency's regulatory authority is

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70. *See* Sharkey, *Institutional Approach*, *supra* note 7 (citing Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357, 358-64 (1984)).

71. *See id.*

72. *See id.*

73. *See id.* I discuss both of these issues *infra*.

74. This cost confinement is a basic assumption of Professor Stephen Sugarman's interesting critique of Sharkey's pro-preemption analysis. Sharkey's implicit position, he notes, is that there exists a national interest in uniform drug safety regulation that overrides the states' possible interest in adopting diverse tort (or even no-fault) compensation remedies for victims *even though all manufacturers would still have to comply with the uniform FDA standard.* Email from Stephen Sugarman, Professor of Law, University of California, Berkeley School of Law, to Catherine Sharkey, Professor of Law, New York University School of Law (Oct. 24, 2007, 11:45:00 PM) (on file with author). Sharkey, citing with approval Merrill's axiom that "[o]ne person's healthy regional diversity is another's interstate externality," notes that agency expertise about the merits or demerits of diverse state common law in such situations can and should be exploited by courts deciding preemption issues. Email from Catherine Sharkey, Professor of Law, New York University School of Law, to Stephen Sugarman, Professor of Law, University of California, Berkeley School of Law (Oct. 24, 2007, 2:59:37 PM) (on file with author).

75. Sharkey, *Institutional Approach*, *supra* note 7.

neither comprehensive nor aimed at determining optimal risk. In those situations, moreover, the institutional comparison factors, "risk-versus-risk" considerations,[76] and policy tradeoffs may be closely balanced enough that the expert information elicited by the agency reference may turn out to tip the balance on the ultimate preemption decision by the court.[77]

FDA drug safety decisions, however, are significantly different. In this narrow but exceedingly important subset of safety regulation, the FDA exercises an authority that is probably more comprehensive and technocratically rigorous than that exercised by any other federal regulator. Moreover, these decisions reflect what appears to be the agency's best judgment about the optimal tradeoffs of the conflicting goals and considerations that inevitably surround such regulation. It is true, as Sharkey has noted, that the FDA has been somewhat inconsistent in its claims about whether its drug safety standards seek optimal or minimum protection—whether they purport to establish a regulatory "sweet spot" or instead a mere safety floor—and if the former, whether they are preemptive.[78]

Be that as it may, the FDA's current pro-preemption position on this issue is emphatic and crystal clear,[79] with the agency aggressively asserting it in a number of forms and fora.[80] More to

76. *See generally* RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (John D. Graham & Jonathan Baert Wiener eds., 1995) (discussing risk-versus-risk considerations in policy analysis)

77. Sharkey, *Institutional Approach*, *supra* note 7; *see also* Sharkey, *Roberts Court*, *supra* note 18, at 5 ("[T]he products liability preemption inquiry is multidimensional, involving layers of legal and policy issues, beginning with interpretation of the statutory language, but reaching beyond to issues of regulatory policy, federalism, and the level of deference accorded federal agency actions and interpretations."). Sharkey's review of Supreme Court case law identifies many such situations. Sharkey, *Institutional Approach*, *supra* note 7.

78. Sharkey, *Institutional Approach*, *supra* note 7; Sharkey, *Roberts Court*, *supra* note 18, at 7-8.

79. *See* Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1009 (2008) (under *Skidmore* and *Mead*, deference to the FDA's position may be reduced, but not eliminated, by its change of position).

80. Sharkey, *Roberts Court*, *supra* note 18, at 6-8 (regulatory preambles, amicus briefs in court cases, and official statements). The FDA's insistence and new-found consistency, of course, do not necessarily justify its pro-preemption reading of its statutory authority, but courts should take due account of its position, past and present, in deciding the scope of that authority. *See* Sharkey, *Institutional Approach*, *supra* note 7 (arguing for

the point, its claim of optimality in the sense just described—that its decisions reflect its judgment about the appropriate level of safety, all things considered—is amply justified, for the reasons just given. If *any* agency can be said to regulate for optimal safety, then, it is the FDA in its drug safety program.[81] Needless to say, this speaks only to the agency's regulatory *goal*; it in no way implies that the agency actually attains that Goldilocks ideal —to get the safety level "just right"—in any particular case. To be sure, the FDA has made tragic errors in the past and doubtless will make more in the future. Although some of these errors may be avoidable and even negligent, others are instead in the nature of complex decisionmaking under irreducible uncertainty and conflicting goals. The policy-relevant questions, however, are (1) what "error" means where regulatory decisions are fraught with so many difficult risk-versus-risk and other tradeoffs and with science that is so often uncertain and in flux, and (2) whether juries are likely to do better on that score than the agency.

In the FDA drug regulation context, the institutional competence comparison cuts strongly in favor of agency preemption on both counts—especially with respect to pre-market approval of pharmaceutical products and labeling. The post-approval stage, which involves different activities and considerations, made the case for FDA preemption a closer one before the 2007 amendments, which significantly expand FDA authority in the post-approval period.[82] It remains to be seen how this new authority—and the resources that Congress provides for its exercise—alters the FDA's overall regulatory effectiveness. Also relevant to this question is how the disclosure deficit exception to preemption that I present in Part II would actually operate.

Like me, most scholars making the FDA-tort litigation comparison have stressed the agency's technocratic and information-processing advantage.[83] Sharkey emphasizes this as

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Skidmore deference); *see also* Epstein, *supra* note 36, at 3 (given the FDA's comprehensive regulation of drug safety, even its disavowal of preemption should not be determinative).

81. As Nagareda explains, this is not true for some aspects of the FDA's regulation of medical devices. Nagareda, *supra* note 6, at 17-18.

82. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007).

83. *See, e.g.*, *supra* Part I (discussing Merrill and Sharkey).

well in noting the FDA's ability to find and analyze context-specific legislative facts relating to cost-benefit and risk-risk tradeoffs generated by uniform FDA rules.[84] These points, however, overlook deeper structural differences that support FDA preemption even more firmly. The principal structural limitation of FDA regulation, of course, is that it cannot directly compensate victims of unsafe or improperly labeled drugs. For reasons that I explain in the penultimate paragraph of this part, I view this limitation as irrelevant to the preemption question, particularly in light of the potentially important but carefully constrained role for tort litigation that the disclosure deficit exception elaborated in Part II would preserve for cases in which such a deficit substantially undermines agency decisions.

Apart from the issue of compensation, the most important difference between FDA regulation and state tort litigation, of course, is that most common law decisions in pharmaceutical design and warning defect cases are made by, or in the shadow, of juries. Juries have many virtues: lay common sense, institutional independence, knowledge of community standards, an unbiased desire for accuracy and fairness, and others.[85] Unfortunately, however, the ability to process detailed scientific research information and complex risk-risk tradeoffs, and to make or second-guess technocratic decisions about drug design and labeling, is not among them.[86] As the Supreme Court observed in

84. Sharkey, *Institutional Approach*, *supra* note 7. Professor Zipursky observes, correctly, that under the existing system, a jury may have before it a body of risk information that is superior to that which the agency had before it when it made its decision. Email from Benjamin Zipursky, Professor & James H. Quinn Chair, Fordham Law School, to author, Simeon E. Balwin Professor of Law, Yale Law School (Nov. 13, 2007, 5:19:49 PM) (on file with author). He goes on to argue that if we bar juries from deciding such cases (except where a disclosure deficit can be shown), it is because of a liability rule—limiting liability to the state-of-the-art when the disclosures were made —not an institutional competence analysis. *Id.* I disagree. So long as the FDA can require the manufacturer to disclose all material, relevant risk information, both pre- and post-approval, its institutional advantages in technocratic information and analysis remain.

85. The most recent catalogue of strengths of both criminal and civil juries can be found in NEIL VIDMAR & VALERIE P. HANS, AMERICAN JURIES: THE VERDICT (2007). *See also* VERDICT: ASSESSING THE CIVIL JURY SYSTEM (Robert E. Litan ed., 1993).

86. Indeed, savvy lawyers would probably try to use their voir dire to exclude any potential juror who knew anything about these subjects.

its very recent *Riegel v. Medtronic, Inc.* decision, "[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."[87] As a practical matter, it seems most unlikely that even the most able trial lawyers could reproduce in the courtroom the process of FDA decisionmaking that produced its standard; a process that is technically and politically complex, intensively interactive, tradeoff-pervaded and highly protracted. Yet it is hard to see how even the most conscientious and attentive jury can accurately assess the reasonableness (for that is usually the relevant legal standard) of the agency's regulatory product unless it can replicate that process.

Nor is a jury even remotely accountable to political, administrative, or technocratic controls. This built-in lack of accountability is in sharp contrast to a regulatory agency, particularly one whose decisions are as controversial and closely-monitored as those of the FDA in the drug safety area. The jury answers to no one.[88] Indeed, by institutional design its general verdicts are Delphic and inscrutable in the extreme, providing no clues whatsoever to the facts that it found, the content of the legal standards that it actually applied (as distinct from what the judge instructed them to apply), or the reasoning process by which it linked facts and standards to reach its ultimate judgment.[89]

In contrast, the FDA Commissioner is nominated by the President and requires Senate confirmation in a process that is sometimes quite controversial, and a few of their top-level subordinates are political appointees and also subject to dismissal. The FDA, and its regulation of drug safety in particular, are the subjects of constant and often probing oversight by congressional

87. 128 S. Ct. 999, 1008 (2008)

88. There is of course the extremely rare instance when the civil trial judge is prepared to rule that the jury was actuated by prejudice or passion such that no reasonable juror could have reached the verdict that was rendered. Appellate courts, with a narrower standard of review, are even less likely to reverse a jury's verdict.

89. Special verdicts can reduce this inscrutability somewhat by answering specific questions of fact, but courts tend not to use them in tort cases generally. I have no information on how often they are employed in pharmaceutical design and warning defect disputes, but the answer is probably seldom.

staff,[90] industry and public interest groups,[91] the Government Accountability Office,[92] the departmental inspector general,[93] professional associations,[94] specialized and general media,[95]

90. *E.g., The Adequacy of FDA Efforts to Assure the Safety of the Nation's Drug Supply: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007) [hereinafter *FDA Efforts*]; *The Food and Drug Administration's Critical Mission and Challenges for the Future: Hearing Before the H. Comm. on Oversight and Government Reform*, 110th Cong. (2007).

91. *See, e.g., Ephedra: Who is Protecting the American Consumers?: Hearing Before the Oversight of Government Management, Restructuring, and the District of Columbia Subcomm. of the S. Comm. on Governmental Affairs*, 107th Cong. 104-111 (2002) (statement of Sidney M. Wolfe, M.D., Director, Public Health Citizen Health Research Group); Sidney M. Wolfe et al., Petition to the Food and Drug Administration (FDA) Requesting the Ban of Production and Sale of Dietary Supplements Containing Ephedrine Alkaloids (Sept. 5, 2001), http://www.citizen.org/publications/release.cfm?ID=7053.

92. *E.g., Prescription Drugs, Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation: Testimony Before the Permanent Subcomm. on Investigations, S. Comm. on Governmental Affairs*, GAO-04-839T (2004) (statement of Richard M. Stana, Director, Homeland Security and Justice Issues); *Internet Pharmacies, Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices: Testimony Before the Permanent Subcomm. on Investigations, S. Comm. on Governmental Affairs*, GAO-04-888T (2004) (statement of Marcia Crosse, Director, Health Care-Public Health and Military Health Care Issues).

93. *See, e.g.*, Gardiner Harris, *Report Assails F.D.A. Oversight of Clinical Trials*, N.Y. TIMES, Sept. 28, 2007, at A1 (discussing report by inspector general of the Department of Health and Human Services that notes flaws in FDA clinical trials).

94. *See, e.g.*, COUNCIL ON SCIENTIFIC AFFAIRS, AMERICAN MEDICAL ASSOCIATION, ENHANCED PHYSICIAN ACCESS TO FDA DATA (2005), http://www.ama-assn.org/ama/pub/category/15152.html#recent_fda (discussing drug safety problems and recommending enhancements to the drug approval and postmarketing surveillance processes).

95. *See, e.g.*, FDAnews Drug Daily Bulletin, Survey: Most Orthopedic Specialists Want Access to Vioxx, Looser Drug Approval Process (Feb. 9, 2007), http://www.fdanews.com/newsletter/article?articleId=90587&issueId=9836; FDAnews Drug Daily Bulletin, Creation of New Drug 'Regulators' Prompted by Vioxx Verdict (Aug. 29, 2005), http://www.fdanews.com/newsletter/article?articleId=75803&issueId=7977; *In Wake of Vioxx Recall, FDA's Integrity Questioned*, PHARMACEUTICAL CORP. COMPLIANCE REP., Oct. 12, 2004, at 5, http://www.hendlerlaw.com/news/PCCR_2004-10-12.pdf; Diedtra Henderson, *FDA Rejects Vioxx-Like Painkiller*, BOSTON GLOBE, Apr. 28, 2007, at B6; Alex Berenson, *Plaintiffs Find Payday Elusive in Vioxx Suits*, N. Y. TIMES, Aug. 21, 2007, at A1; CNN.com, American Morning (Aug. 22, 2005), http://transcripts.cnn.com/TRANSCRIPTS/0508/22/ltm.04.html (transcript of television broadcast discussing $229 million verdict against Merck over the Vioxx drug).

agency whistleblowers,[96] and other watchdogs.[97] Physicians, prompted by their individual patients, usually learn first of unlabeled side effects post-approval and report them to the FDA and medical journals. This intensive scrutiny often leads to high-profile, well-publicized congressional hearings, including those held in the current Congress by the House Oversight and Government Reform Committee led by its aggressive, censorious chairman, Henry Waxman, in which agency officials are called on the carpet to publicly explain and defend their regulatory actions.[98] Indeed, this political accountability of the FDA is in some tension with its expertise; politics may sometimes override or compromise the technical judgments of the agency's professional staff, as in the case of the morning-after contraceptive pill.[99] Even so, much that the FDA (and other agencies) does, of course, remains undetected by outsiders until after damage is done.[100] Nevertheless—and this is the key analytical point—the

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96. *See, e.g.*, *Morning Edition: Lawmakers Take a Hard Look at FDA, Drugs* (NPR radio broadcast Feb. 14, 2007); *FDA Efforts*, *supra* note 90, at 90-93 (statement of Sen. Chuck Grassley); Theresa Agovino, *Government Whistle-Blower to be Deposed in Vioxx Case*, STAR-LEDGER (Newark, N.J.), Mar. 16, 2006, at 46.

97. *See, e.g.*, Peter Barton Hutt, *Investigations and Reports Respecting FDA Regulation of New Drugs (Part I)*, 33 CLINICAL PHARMACOLOGY & THERAPEUTICS 537 (1983); Peter Barton Hutt, *Investigations and Reports Respecting FDA Regulation of New Drugs (Part II)*, 33 CLINICAL PHARMACOLOGY & THERAPEUTICS 674 (1983).

98. *E.g.*, Walt Bogdanich, *F.D.A. is Unable to Ensure Drugs are Safe, Panel is Told*, N.Y. TIMES, Nov. 2, 2007, at A17 (reporting testimony before Congress regarding FDA's limited program for inspecting foreign drug manufacturers and their products); Harris, *supra* note 93; *Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations for Fiscal Year 2008: Hearing on H.R. 3191/S. 1859 Before a Subcomm. of the S. Comm. on Appropriations*, 110th Cong. 479-92 (2007) (statement of Hon. Andrew Von Eschenbach, Comm'r, Food and Drug Administration); *FDA Efforts*, *supra* note 90, at 207-40 (testimony of Andrew C. Von Eschenbach, M.D., Comm'r, United States Food and Drug Administration).

99. *See, e.g.*, Gardiner Harris, *F.D.A. Gains Accord on Wider Sales of Next-Day Pill*, N.Y. TIMES, Aug. 9, 2006, at A13 ("The [FDA] has delayed a decision on Plan B for three years in a process that critics have said was driven by political considerations.").

100. On criticism of FDA, see Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 20-28 (1973); Gina Kolata, *The F.D.A. Approves a Drug. Then What?*, N.Y. TIMES, Oct. 7, 1997, at F1 (highlighting a leading epidemiologist's criticism of the FDA's reporting system about drug reactions because "most doctors don't know the system

comparison to the jury's non-accountability could hardly be more striking. Indeed, as Professor Sharkey points out, FDA preemption might actually *increase* the agency's political accountability.[101] Absent preemption, it shares responsibility for drug safety regulation with the tort system. This enables the agency to deflect some of the public criticism of drug safety regulation onto plaintiffs' lawyers, judges, and juries.[102]

Another important but seldom-discussed advantage of the FDA (and of agencies more generally) when compared with common law tort litigation is the FDA's vastly superior capacity to learn from its environment and correct its policy mistakes in a timely fashion. The common law proceeds slowly and incrementally, driven by opportunistic legal entrepreneurs who tend to act in largely uncoordinated, unsystematic ways.[103] Given the largely ad hoc nature of this gradual process, the generalization and rationalization of common law become possible only after a significant number of fact-specific adjudications accumulate. Even then, it does not necessarily produce accurate or efficient outcomes.[104]

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exists"). For examples of specific FDA errors that were detected only after the fact, see Bruce Ingersoll, *Amid Lax Regulation, Medical Devices Flood a Vulnerable Market*, WALL ST. J., Mar. 24, 1992, at A1 (discussing Orcolon's approval despite a lead reviewer's "deep misgivings about the product" and its withdrawal after thirty-three patients had to undergo an additional surgical procedure because of complications that risked their vision); Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335, 1350 (1992) ("Tampon [l]abeling for toxic shock syndrome was delayed some twenty months because the FDA chose to rely first on voluntary standards by the industry (although the standards were not universally adopted) instead of issuing a rule requiring the labeling.").

101. Sharkey, *Preemption by Preamble*, *supra* note 17, at 252-53.

102. *See id.* (discussing arguments to this effect by Lars Noah and Peter Huber).

103. Very occasionally, visionary reformers do fashion a more self-consciously strategic and long-term litigation campaign. The litigation strategy that led to *Brown v. Board of Education*, 347 U.S. 483 (1954), is of course the most notorious example. In addition, litigators often think strategically in deciding which cases to settle and which to take to trial. *See, e.g.*, George L Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. LEGAL STUD. 1 (1984); Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. Legal Stud. 257, 257-86 (1974).

104. *Compare* Gillian K. Hadfield, *Bias in the Evolution of Legal Rules*, 80 Geo. L.J. 583 (1992), *with* Priest & Klein, *supra* note 103, *and* Ehrlich & Posner, *supra* note 103.

Moreover, courts tend to decide whatever disputes the litigation process, directed by these legal entrepreneurs, happens to deliver to them at the particular time, and they do so largely in the order in which the cases are filed. This severe constraint affords individual judges little opportunity to take the kind of synoptic view that might enable them to guide the law in a systemically rational direction. When one adds to this the fact that tort adjudication is radically decentralized among thousands of trial judges, loosely coordinated by multiple appellate panels in dozens of decidedly independent jurisdictions, one can see how exiguous the common law's learning capacities are and how limited and sporadic are its opportunities to rectify a wrong turn in the law once a judge happens to detect it. These conditions do not vary much with the quality of litigators or the clairvoyance of judges. Instead, they are deeply structural and fundamentally constitutive of common law adjudication.[105]

Agencies are very different in each of these respects. In principle, and to a considerable degree in practice, agencies can self-consciously shape and signal their policy intentions, learn about the consequences of alternative courses of action both in advance and after the fact, and make adjustments to rectify their mistakes. Because the feedback loop from the regulatory environment is relatively short and responsive, and because they possess the power to issue rules and the instruments to implement them, agencies can—for better or worse—effect change far more quickly and systematically than the common law courts. In these respects, they are essentially regulatory monopolists in their particular domains.[106]

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105. *See, e.g.*, STEPHEN J. CARROLL ET AL., ASBESTOS LITIGATION 128-130 (2005), *available at* http://www.rand.org/pubs/monographs/2005/RAND_MG162.pdf (discussing the compensation, deterennce, and individualized treatment deficiencies in asbestos ligitation); *see also id.* at 127 ("Plaintiffs with the same injuries and economic losses receive widely varying amounts, depending on the skills and incentives of the attorneys representing them, the jurisdictions in which their cases are brought and, perhaps, their own "attractiveness" as potential trial witnesses.").

106. There are a few examples of multiple and overlapping regulators at the federal level, most notably those that regulate banks. *See, e.g.*, Elizabeth F. Brown, *E Pluribus Unum-Out of Many, One: Why the United States Needs a Single Financial Services Agency*, 14 U. MIAMI BUS. L. REV. 1, 26 (2005) ("Over the past sixty years, many commentators have noted the problems created by having multiple state and federal financial regulators and have

Professors Robert Rabin and Richard Nagareda mention "information updating" concerning drug-related risks as a putative benefit of tort litigation.[107] This benefit is especially important to the extent that the FDA fails to effectively monitor post-approval risk information and incorporate that information into its labeling and other regulatory decisions. No doubt there are examples of tort litigation "eliciting information about risk and aberrant conduct," as Rabin puts it;[108] the tobacco litigation, he notes, is probably the best example of plaintiffs' lawyers unearthing this vital information.[109] But as I explained earlier in my discussion of accountability, FDA regulation of drug risks is subject to many monitoring institutions, both specialized and generic, other than tort law. In this specific area, it would be surprising indeed if lay plaintiffs' lawyers originated this information—as distinguished from marshalling and shaping information unearthed by others into more focused, tendentious forms for litigation purposes. According to one analysis, this was indeed the case in the Vioxx and other recent litigations that are often cited by opponents of FDA preemption as instances of FDA regulatory failure.[110]

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called for the consolidation of the regulators at the federal level."); Heidi Mandanis Schooner, *Recent Challenges to the Persistent Dual Banking System*, 41 ST. LOUIS U. L.J. 263, 264 (1996) ("Archaic, arcane, or simply bizarre, the dual banking system—which allows a bank to be chartered and supervised by either federal or state authorities—is here to stay.").

107. Nagareda, *supra* note 6, at 5-6, 22; Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 GEO L.J. 2049, 2068-70 (2000).

108. Rabin, *supra* note 107, at 2068.

109. *Id.* at 2069-70. In support of his position, Rabin cites my own analysis of mass torts. *Id.* at 2069 n.86 (citing Peter H. Schuck, *Mass Torts: An Institutional Evolutionist Perspective*, 80 CORNELL L. REV. 941, 951-53 (1995)). But my analysis concerned mass torts for products or pollution that is not comprehensively regulated for optimal safety. Indeed, Rabin himself notes that even in the case of tobacco, the litigation contributed essentially no new information about the risks of smoking. Robert L. Rabin, *The Third Wave of Tobacco Tort Litigation*, *in* REGULATING TOBACCO 176, 202 (Robert L. Rabin & Stephen D. Sugarman eds., 2001).

110. Anita Bernstein argues that plaintiffs' lawyers have not contributed much new risk information in the Vioxx litigation or indeed since the Dalkon Shield litigation. Bernstein, *supra* note 16, at 1055. Whether Vioxx is an instance of regulatory failure or not is debatable. More than two-thirds of the cases that went to trial found no liability, and the pending settlement agreement, despite its $4.85 billion price tag, is widely viewed both as a vindication of Merck's position and of the high transaction costs of mass tort

The question for our purposes, however, is not whether this lawyering function is socially valuable—it clearly can be—but whether it is more or less redundant of the many other monitoring and accountability institutions that are already performing it, or if not, whether they can be equipped and induced to perform it better than they have in the past. This is ultimately an empirical question, which more case studies would illuminate. The 2007 amendments to the FDCA should improve the FDA's performance in this respect,[111] thus reducing the value of whatever marginal contribution tort litigation has made to this function.

I noted earlier that some courts and commentators like Rabin have emphasized that the FDCA does not provide a compensatory remedy for those injured by defective products and warnings. From this fact, they erroneously conclude that a tort judgment applying different standards of conduct than the FDA either does not constitute a form of regulation, much less one that can be inconsistent with that of the agency, or does regulate but only as a necessary aspect of tort's primary compensatory function. Professor Rabin, for example, argues that the tort system is a necessary complement to FDA regulation because tort can fill the "compensation gap" for injured plaintiffs.[112] But if Congress has authorized the FDA to determine the socially optimal level of drug safety and information, taking all other risk-relevant factors into account, then a properly labeled, duly-approved drug is not in fact defective.[113] If this is so, no jury should be permitted to render a verdict that creates incentives to market that drug and label in a different form. In that case, no wrong has been committed and

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litigation. *See* Alex Berenson, *Merck is Said to Agree to Pay $4.85 Billion for Vioxx Claims*, N.Y. TIMES, Nov. 9, 2007, at A1. On the other side, some juries have assessed large damages against Merck. The most important was a Texas jury verdict in 2005 for $253 million in compensatory and punitive damages. *See* Alex Berenson, *Jury Calls Merck Liable in Death of Man on Vioxx*, N.Y. TIMES, Aug. 20, 2005, at A1.

111. *See supra* note 39.

112. Rabin, *supra* note 107, at 2073. Sharkey refers to this as a "remedial void." Sharkey, *Institutional Approach*, *supra* note 7.

113. As the Court recently put it in a case of an express preemption provision, "the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of [fifty] [s]tates to all innovations." Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1009 (2008)

thus compensation *based on fault principles* is simply inappropriate.[114] Even if one were to conclude that Congress has not yet authorized the FDA to regulate for optimal safety, the analysis in this part strongly suggests that Congress should change (or clarify) the FDCA to do precisely that.

Based on comparative institutional competence grounds, then, I do not share Professor Sharkey's agnosticism as to whether FDA drug safety regulation should preempt state tort litigation[115]—subject to the disclosure deficit exception discussed in Part II—nor do I see much marginal value in adding an agency reference process that (in *this* situation, not in others) would simply increase uncertainty, delay, and cost, while yielding agency views about an ultimate preemption decision that is (and should be) over-determined on these grounds. When agencies set out to regulate, they need to know what, how, and with what effect they can do so, particularly if they are to justify the confidence that Sharkey thinks courts should have in them. Yet the prospect of

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114. In principle, this need not leave uncompensated those consumers who are injured by drugs that fully comply with FDA requirements. If Congress wishes to compensate those harmed by FDA-compliant drugs, it could establish a no-fault compensation system.

Professor Sugarman goes so far as to suggest that a state could use its tort law to impose strict liability on drug manufacturers—thus fulfilling the compensation function—so long as this liability does not alter or interfere with a manufacturer's obligation to comply with the FDA's labeling and other requirements. Email from Stephen Sugarman, Professor of Law, University of California, Berkeley School of Law, to author, Simeon E. Baldwin Professor, Yale Law School (Jan. 7, 2008, 12:39 PM) (on file with author).

I doubt, however, that Sugarman's scheme would—or should—survive under a preemption rule. One simply cannot separate the compensation and regulatory issues without affecting drug manufacturer incentives in ways that are difficult to predict and that involve the highest social stakes. The prospect of having to pay compensation under a strict liability rule, especially one not subject to a state-of-the-art defense, would surely increase the already large uncertainty that surrounds manufacturers' large long-term investments that are necessary in order to develop socially valuable pharmaceutical products. It might also cause risk-averse manufacturers to include more in their labeling than would be optimal for consumers. Professor Merrill also raises a question about the legality of *state*-legislated programs of this kind. Email from Thomas Merrill, Professor of Law, to author, Simeon E. Baldwin Professor, Yale Law School (Nov. 14, 2007) (citing Goodyear Atomic v. Miller, 486 U.S. 174 (1988) (government argued that state workers compensation award would be preempted if tort liability would be preempted)) (on file with author).

115. Sharkey, *Institutional Approach*, *supra* note 7.

state-level common law "regulation" produces precisely the opposite effects. On the other side, claimants, their lawyers, and the state courts need to know the implied preemption rules so that they can wisely allocate their scarce litigation and adjudication resources.

If I am correct about this, then there is much to be gained – in terms of legal clarity, predictability, transparency, and administrative cost—from adopting a categorical implied preemption rule in this area. The rationale for this rule, however, depends on the FDA being fully informed about the risks associated with the drug and its ability to vigorously enforce the law on the basis of that information. This rule and its scope, then, must be subject to a carefully designed "disclosure deficit" exception that can assure that this condition actually exists, an exception to which I now turn. I discuss the enforcement issue in the Conclusion.

II. DESIGNING A DISCLOSURE DEFICIT EXCEPTION TO FDA PREEMPTION

Any federal rule providing for FDA preemption of common law claims of drug warning and design defect must have an exception for situations in which manufacturers or others who are under a legal duty to supply accurate drug risk information to the agency fail to do so. The same is true, *mutatis mutandis*, of state laws providing for a regulatory compliance defense. The basic rationales are, first, that manufacturers and other regulated entities typically have much better and cheaper access to risk information than the FDA in the first instance; second, that the FDA depends on this information for optimal safety regulation; and third, that the regulatory standard might have been different (usually more stringent) had the FDA been so informed. It follows, then, that the law should create strong incentives for entities that seek regulatory benefits, such as pre-marketing or post-marketing approval or immunity, to disclose whatever regulation-relevant risk information they possess (or in some formulations, information that they should have obtained). The "fraud exception," as it is usually called, is designed to create these incentives, while the hyper-heightened pleading standard proposed below is designed to prevent that exception from swallowing the preemption rule.

All scholars who tackle the subjects of implied agency preemption or regulatory compliance favor some version of a state common law or statutory fraud exception.[116] Because the FDA's regulatory approval is negated by a finding—by the agency, or by a court whose finding is binding on the agency—of fraud on the FDA, it would seem that no additional federal law regulatory fraud exception is needed.[117] Nevertheless, Professor Sharkey, who has analyzed this exception most closely and recently, notes that it has been under-theorized,[118] which surprises her (and me) precisely because so much in the FDA preemption debate turns on it.

Perhaps for this reason, the Supreme Court recently took up the question—indecisively, as it turned out—of whether and to what extent the *Buckman* decision, which preempted a stand-alone fraud-on-the-FDA claim (there, involving a medical device, not a drug) because of the federal interest in controlling the policing of fraud against the agency, also preempted the fraud exception in the Michigan statute's otherwise absolute regulatory compliance defense.[119] If the Court takes a broad view of the kinds of exceptions preempted by its earlier *Buckman* rationale, then establishing the kind of "disclosure deficit" exception to preemption that I shall now propose can only be accomplished by federal statute. This possibility is discussed near the end of Part

116. Sharkey, *Fraud Caveat*, *supra* note 23; Nagareda, *supra* note 6, at 46-47 ("[A] showing of . . . fraud should suffice to defeat the preemptive effect that a given FDA assessment of a device or drug otherwise might have on garden-variety actions for product liability."); Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2161-62 (2000) (fraud); Rabin, *supra* note 107, at 2076-79, 2082 (noting the dangers of a complete regulatory compliance defense). Where the regulatory statute prescribes for *express* preemption, as with some medical devices, the preemption will ordinarily be limited by statutory provisions that either provide for a fraud exception, or that impose other civil or criminal sanctions for failure to disclose risk information to the agency. *See* 21 U.S.C. § 332 (2000) (injunctive relief); *id.* § 333(a) (criminal penalties); 21 U.S.C. § 333(g)(1)(A) (Supp. V 2001-2006) (civil penalties); 21 U.S.C. § 334(a)(2)(D) (2000) (seizing the device).

117. *See* 21 U.S.C. § 355(e) (2000) (authorizing withdrawal of approval of a new drug application); *id.* § 360e(e)(l) (authorizing withdrawal of approval of a premarket approval application); *id.* § 360j(g)(5) (authorizing withdrawal of approval of an investigational device exemption).

118. Sharkey, *Fraud Caveat*, *supra* note 23.

119. *See supra* note 47 and accompanying text.

III.

In my view, the rationales for an exception to FDA preemption extend well beyond the instances of intentional misrepresentation that other commentators have found to warrant a fraud exception. These rationales also militate in favor of three additional exceptions from FDA preemption corresponding to the three other kinds of disclosure deficits: (1) negligent misrepresentation, (2) innocent misrepresentation, and (3) failure (not amounting to an affirmative misrepresentation) to inform the agency in a timely fashion about material risk-relevant information. Note that these disclosure deficits would not affect the substantive liability rule (e.g., strict liability, negligence, or some other standard) to which the manufacturer would be held if the tort litigation proceeds. Instead, these deficits are meant to be relevant only to the threshold question of whether such a claim is preempted in the first instance.

These three exceptions would apply so long as the disclosure deficit could materially affect any decisions by the agency or by physicians and consumers whose decisions on risk depend on the accuracy and timeliness of this information. Such decisions would include, among others, the following: (a) those concerning the FDA's initial approval, labeling, and advertising of the product; (b) the FDA's post-approval monitoring of the product in the market; (c) possible changes in the product's labeling and advertising as the FDA learns more about the product's uses and effects; and (d) any off-label uses by physicians and consumers of which the manufacturer knew or should have known had it diligently searched for information about such uses.[120]

The rationale for a broader disclosure deficit exception follows almost logically from the rationale for the existing fraud exception. FDA regulatory preemption of tort law is based on the strong assumption that the quality of the agency's risk-related decisions concerning the drug depends upon the manufacturer's timely disclosure to the FDA of all material risk information—defined as information that could reasonably be expected to affect

120. The FDA is reportedly developing new regulations on how manufacturers should inform doctors and the agency about off-label uses. Anna Wilde Mathews, *FDA and Drug Marketing*, WALL ST. J., Dec. 1, 2007, at A9.

those agency decisions[121]—that the manufacturer, under existing law, should have transmitted to the agency during the approval process and as long as the drug remains on the market. Of course, fraud on the FDA by a manufacturer[122] is the most obvious and egregious violation of this assumption, but the informational assumption underlying the rationale equally fails if the misrepresentation to the agency is negligent or innocent, or if the manufacturer simply fails to disclose the legally-mandated information in circumstances that do not constitute an affirmative misrepresentation. To extend the exception to these three additional categories of non-disclosure would not increase the burden on manufacturers to gather and report risk-related information that they are required to transmit under existing law.[123] Nor would it deprive them of any other defenses to liability that they may possess. The only question is whether their failure to disclose all requisite information, for whatever reason, should vitiate preemption in these situations as well as in instances of fraud. I believe that it should.

A danger exists, however, with respect to all of these exceptions. Under the modern system of notice pleading, it is all too easy to allege fraud, non-fraudulent misrepresentation, or non-disclosure of material facts—and indeed all of them simultaneously. Unless the rules for pleading these torts are

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121. FDA regulations define a statement of material fact as

> [A] representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

21 C.F.R. § 814.3(i) (2007). The term "material fact" also appears elsewhere in the FDA regulations. *E.g.*, *id.* § 314.125(b)(7); *id.* § 314.127(a)(13); *id.* § 314.150(a)(2)(iv) (2007).

122. While the manufacturer is the typical culprit in cases of fraud, other actors may participate in the fraud as well. *See, e.g.*, Wawrzynek v. Statprobe, Inc., No. 05-1342, 2007 WL 3146792, at *1-4 (E.D. Pa. Oct. 25, 2007) (fraud by both the research firm overseeing the clinical trial and the manufacturer); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 343 (2001) (fraud by manufacturer's consulting company).

123. For postmarking reporting requirements, see 21 C.F.R. § 314.81(b)(2) (2007) (annual reports); *id.* § 314.81(b)(1) (field alert reports); *id.* § 314.80 (adverse event reporting); 71 Fed. Reg. 6281 (Feb. 7, 2006) (same).

more demanding than usual, a plaintiff can defeat one of the principal purposes of preemption—avoiding costly litigation under state law in situations in which uniform federal law should apply —simply by alleging fraudulent or non-fraudulent misrepresentation or non-disclosure.[124] Rule 9(b) of the Federal Rules of Civil Procedure recognizes this problem with respect to fraud, requiring that the circumstances allegedly constituting fraud be pleaded "with particularity."[125] But the reasoning in the previous paragraph implies that if this need for particular pleading is true of fraud, it should be equally true of non-fraudulent disclosure deficits.[126] In all of these cases, the central problem is the same: the manufacturer failed to provide the FDA with legally-mandated risk information that was material to its regulatory decision. To deny such a manufacturer a preemption safe harbor that is premised on compliance with legally-mandated disclosure follows logically. It also strengthens the manufacturer's incentives to fully meet its disclosure obligations.[127]

Indeed, this analysis suggests that the pleading standard in such cases should be "hyper-heightened." For example, a plaintiff's mere allegations that the agency misinterpreted the results of existing tests or failed to require or conduct other tests should not suffice. He must show, at the threshold, that he is likely to prove that the agency violated the law in ways that place its presumed expertise with regard to such testing substantially in

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124. In the antitrust context, the Supreme Court has recently emphasized the need for more particularized pleadings. *See* Bell Atl. Co. v. Twombly, 127 S. Ct. 1955, 1964-67 (2007). There is much to be said, however, for heightening pleading requirements in particular areas of litigation by statute or through the process of the Rules Enabling Act, 28 U.S.C. § 2072 (2000), rather than by judicial decision. I am indebted to David Shapiro for this point.

125. FED. R. CIV. P. 9(b); *see also* Nagareda, *supra* note 6, at 52.

126. This pleading rule should apply not only to tort plaintiffs but also to those who petition the FDA to act against alleged fraud or non-fraudulent misrepresentation or non-disclosure. However, this should not alter the very broad, if not complete, discretion that agencies typically enjoy about whether to act upon such petitions. *See, e.g.*, Massachusetts v. EPA, 127 S. Ct. 1438, 1459 (2007) (judicial review of refusals to promulgate rules "is 'extremely limited' and 'highly deferential'" (citing Nat'l Customs Brokers & Forwarders Ass'n of Am. v. United States, 883 F.2d 93, 96 (D.C. Cir. 1989))).

127. Nagareda proposes to augment these incentives with additional information-forcing rules. Nagareda, *supra* note 6, at 42-50.

doubt.[128] Were the plaintiff to satisfy this "hyper-heightened" pleading rule, the burden would then shift to the manufacturer to show that the exception to preemption nonetheless does not apply.

As Sharkey persuasively argues, courts are well-advised to look to the FDA for advice on the factual and policy questions on which their preemption decision should turn.[129] And as the Supreme Court noted in *Buckman*, and as Sharkey demonstrates, the FDA is generally better equipped than the courts to inform and analyze such questions, especially the question of whether a disclosure deficit has occurred.[130] An agency finding one way or the other should be dispositive of the preemption issue: if it finds such a deficit, the tort litigation can proceed.[131] If not, the litigation cannot proceed—unless the plaintiff alleges harm based on something other than an allegation that the agency approved a product or label based on inadequate or incorrect information. If the agency, having notice of the disclosure deficit allegations, fails to make a timely finding one way or the other—perhaps because it perceives more pressing regulatory priorities or because its own investigation of the allegations is still pending—then the situation is different. Once a reasonable period of time for agency investigation has elapsed without an agency determination on the disclosure deficit issue, plaintiffs should be permitted to proceed

128. For example, the Private Securities Litigation Reform Act of 1995, which amended the Securities Exchange Act of 1934, toughened the pleading standard for private securities litigation. *See* Private Securities Litigation Reform Act of 1995, Pub. L. 104-67, 109 Stat. 737, 746-47 (1995). Complaints alleging that the defendant made a false statement of material fact or failed to state a material fact must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1) (2000). Furthermore, the plaintiff must, "with respect to each act or omission[,] . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2) (2000). If these requirements are not met, the complaint will be dismissed. 15 U.S.C. § 78u-4(b)(3)(A) (2000).

129. Sharkey, *Institutional Approach*, *supra* note 7.

130. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S 341, 348-51 (2001) (discussing how allowing state-law fraud-on-the-FDA claims would frustrate the agency's statutory power to punish and deter fraud against it); Sharkey, *Institutional Approach*, *supra* note 7.

131. Such a finding would obviate the need for the hyper-heightened pleading requirement proposed in the previous paragraph.

with their claims, albeit subject to the hyper-heightened pleading standard. Thus, agency inaction or indecision on the issue should leave potential plaintiffs no worse off than they would have been otherwise, such as if the FDA had not taken cognizance of the deficit issue.

Merrill observes that this proposal would encourage manufacturers to seek some sort of early ruling by the FDA that they had complied with all of their disclosure obligations, a ruling that the agency might or might not be prepared to provide at any particular point in time.[132] The industry, he speculates, might press Congress to provide more resources to enable the agency to respond to such requests, which in turn might "reverse some of the current regulatory pathologies, where FDA has very broad authority but insufficient resources." [133] Alternatively, Congress might want to prevent the agency from providing such advance assurances, perhaps on the theory that the absence of such assurances would induce manufacturers to err on the side of greater disclosure rather than less.[134] In either event, the full disclosure issue would be front-and-center, as it should be.

If preemption does apply, the issue of whether the manufacturer satisfied its disclosure obligation should be resolved, at least preliminarily, at the threshold of the litigation on a motion to dismiss or, more likely, on a motion for summary judgment. Where FDA preemption properly applies, defendants should not be obliged to engage in protracted discovery and litigation in order to establish that fact.[135] Unfortunately, this is

132. E-mail from Thomas Merrill, Professor of Law, to author, Simeon E. Baldwin Professor, Yale Law School (Nov. 14, 2007, 11:42:46 AM) (on file with author).

133. *Id.* In commenting on my proposal, Peter Barton Hutt, a former FDA General Counsel, casebook author on FDCA law, and lawyer for drug companies, warns that even a hyper-heightened pleading rule can easily be satisfied by creative plaintiffs lawyers and will leave manufacturers too vulnerable to specious liability claims and that they will respond with more "defensive testing" that will reduce the flow of beneficial drugs. This warning suggests the importance of very careful and tactically-sophisticated drafting of the disclosure deficit exceptions and pleading standard.

134. Because over-disclosure carries its own costs, both to the manufacturer and to the FDA, one would want to balance them against the likely benefits of fortifying the manufacturer's existing incentives to disclose.

135. There is a strong analogy to the desirability of threshold determinations of qualified and absolute immunity defenses in actions seeking to impose liability for damages on individual government officials.

more easily said than done. In practice, invoking an exception triggered by any of these types of disclosure deficits will often require proof of facts likely to be both energetically controverted by the parties and subject to conflicting interpretations.

In order for a court to decide such potentially dispositive facts at the threshold of the litigation, it may have to hear and interpret testimonial evidence and resolve inconsistencies.[136] It may also have to allow some limited discovery pursuant to the more specific allegations required by the proposed pleading standard, or at least require substantial evidence that discovery will likely yield such facts. Only then will it be in a position to determine the availability of the exceptions in such cases and hence the applicability of preemption. Doing so may require the court to conduct a mini-trial on the factual allegations; if the facts are complex, such a trial may not be so "mini." On the other hand, of course, courts routinely conduct such fact-finding when called upon to decide motions for preliminary injunctions and other potentially dispositive threshold issues that require them to resolve questions of fact before a full trial.

III. THE REGULATORY COMPLIANCE DEFENSE UNDER STATE TORT LAW

The discussion so far has been concerned almost entirely with the federal law of preemption. State law has made its appearance here largely with respect to common law claims for design and warning defects, which may or may not be preempted, as a matter of federal law, by reason of FDA drug safety regulation. Professor Sharkey estimates that roughly half of these are being adjudicated as diversity cases in the federal courts,[137] with many of them

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See, e.g., Scott v. Harris, 127 S. Ct. 1769, 1773 n.2 (2007) ("Qualified immunity is 'an *immunity from suit*' rather than a mere defense to liability; and like an absolute immunity, it is effectively lost if a case is erroneously permitted to go to trial.'" (quoting Mitchell v. Forsyth, 472 U.S. 511, 526 (1985)).

136. As Sharkey notes, courts that apply a strong presumption against preemption elide the need to engage in much fact-finding. Email from Catherine Sharkey, Professor of Law, New York University School of Law, to author, Simeon E. Baldwin Professor, Yale Law School (Oct. 9, 2007, 09:18:51 AM) (on file with author).

137. Sharkey, *Federalism in Action*, *supra* note 15, at 1014 n.4 (quoting Thomas H. Cohen, Do Federal and State Courts Differ in How They Handle Civil Trial Litigation: A Portrait of Civil Trials in State and Federal District Courts 18 (2d Annual Conference on Empirical Legal Studies, Paper, 2006),

having been removed from state courts.[138] She finds that federal and state courts differ in their interpretations and applications of preemption doctrine, with the former being more likely to find preemption.[139] Even more interesting is her finding that "state courts, which by and large have previously rejected any absolute regulatory compliance defense . . . are now willing to entertain preemption arguments, even if not at the same level as federal courts' affinity for such claims . . . ."[140] Nevertheless, these changes still leave an unacceptably large amount of uncertainty and conflict in an area in which greater uniformity is vital.[141]

As noted earlier, a complete regulatory compliance defense—the state tort doctrine counterpart of FDA preemption—exists only in Michigan, and even there, its effect on preemption remains uncertain.[142] If my analysis in Part I is correct, however, every other state should adopt the defense, along with the disclosure deficit exception and the hyper-heightened pleading requirement discussed in Part II. Realistically, the probability that the states will adopt it seems low. Moreover, state variation and experimentation, often a virtue in other areas, is decidedly unwelcome in the particular context of comprehensive FDA drug regulation.

This danger of diverse state rules governing these matters, coupled with the superiority of FDA preemption demonstrated in Part II, implies that federal law should mandate FDA preemption under these conditions. This mandate can be accomplished either through courts' case-by-case preemption decisions or by federal statute. Sharkey's analysis, including her critique of the

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available at http://ssrn.com/abstratct=912691.

138. *Id.* at 1015 n.4.

139. *Id.* at 1017-18.

140. *Id.* at 1019.

141. The need for uniform regulation of drug research and safety is likely to increase in the future, as the industry moves in new directions that would be stifled by conflicting regulatory regimes. *See, e.g.*, Andrew Pollak, *Drug Makers Seek Clues to Side Effects in Genes*, N.Y. TIMES, Sept. 27, 2007, at C3 (discussing how pharmaceutical companies formed a new group to develop genetic tests for determining which patients will suffer adverse side effects from drugs in order "to cut costs and increase their success rates in developing medications").

142. The recent Supreme Court case, Warner-Lambert Co., LLC v. Kent, No. 06-1498, 2008 WL 552875 (U.S. Mar. 3, 2008) (per curiam) (4-4 decision), failed to clarify the issue.

traditional "presumption against preemption" as applied to FDA drug regulation,[143] amply demonstrates the ineffectiveness of the case-by-case approach due to the courts' divergent approaches to the issue.[144] Even if this were not so, the protracted process that would be necessary to effectuate convergence, not to mention universal state adoption, argues strongly for a federal statute, crafted along the lines of my proposal in Part II, to cover those situations not already preempted by the reasoning in *Buckman*.[145] Furthermore, even an unmistakably clear holding (or dictum) by the Supreme Court that FDA regulation of drug safety categorically preempts design and warning defect claims might still leave uncertain the precise contours of a disclosure deficit exception.

A final consideration also argues strongly in favor of effecting my proposal by enacting a federal statute. If the Supreme Court eventually holds that its rationale in *Buckman* bars *any* fraud exception—perhaps on the ground that *any* such exception would interfere with the agency's own policing of fraud, interference that *Buckman* insisted on preempting[146]—then the exception proposed in Part II might be seen as invalid *a fortiori* because it would extend the exception beyond fraud to include negligent and innocent disclosure deficits. A new federal statutory foundation for this broader exception to preemption would defeat any constitutional objection to the exception under the Supremacy Clause.

Congress, then, should define the contours of the disclosure deficit exception. Doing so, after all, entails a number of legal policy considerations and tradeoffs that the Court is not well-equipped to make. These considerations include, among others: possible distinctions among different types of disclosure deficits; the role of state tort law in defining those categories; the precise definition of "materiality"; standards of pleading and proof;

143. Sharkey, *Institutional Approach*, *supra* note 7 ("Where the presumption is invoked by courts, an anti-preemption determination is close at hand.").

144. *Id.*. This ineffectiveness is evident in the recent Vermont decision, Levine v. Wyeth , No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006), *cert. granted*, 128 S. Ct. 1118 (2008).

145. *See* discussion of *Buckman*, *supra* text at notes 43-50.

146. The Court will have an opportunity to do so in *Levine*.

limitations periods on actions by claimants and the FDA; the FDA's own role in interpreting and applying the exception; the important practice of off-label uses;[147] procedures for dealing with drugs already on the market whose approvals are found to have been tainted by these deficits; and so forth. Doubtless, Congress would find it politically difficult to perform this task, but it seems much less contentious than in other areas such as tax policy, immigration, and entitlement reform where it must ultimately resolve important conflicting interests that surround pressing public issues.

CONCLUSION

No analysis of FDA preemption should be concluded without some reference to the 800-pound gorilla in the room: what Sharkey calls the "enforcement void" associated with FDA drug safety regulation.[148] Many critics denounce the agency's enforcement activity as lax and inadequate; some go so far as to claim that the regulated industries have "captured" it, often invoking public choice analysis.[149] Some analysts maintain that if anything, the incentives of agency officials actually lead to safety standards that are too high, not too low: politically and psychologically, the argument goes, the personal and political risks *to officials* of allowing a dangerous drug (e.g., Thalidomide) to reach the market are greater than the same risks in the event that a good one is not approved, while society's interests are just the reverse.[150] A recent report by some of the FDA's scientific advisors suggests that the agency's performance, hobbled by a chronic inadequacy of resources relative to its public health

147. *See supra* note 120 and accompanying text. The related problem of off-label promotion also involves complex tradeoffs. For favorable views of off-label uses, see Epstein, *supra* note 36, at 30-31 (off-label uses are desirable supplements to "[t]he sclerotic approval process"); Scott Gottlieb, *Stop the War on Drugs*, WALL ST. J., Dec. 17, 2007, at A21 (off-label promotion facilitates off-label use, which in turn often saves lives).

148. *See* Sharkey, *Institutional Approach*, *supra* note 7. *See also* discussion of the "remedial void" *supra* Part I.

149. *See supra* text accompanying notes 90-98.

150. *E.g.*, PETER BARTON HUTT ET AL., FOOD AND DRUG LAW (3d ed. 2007); Epstein, *supra* note 36, at 4-5 (FDA effectiveness review is costly and delays drug innovation, which ultimately harms consumers as long as the drug is "erroneously kept off the market"); *id.* at 32-33 (arguing that legal regulation impedes product innovation).

responsibilities, continues to warrant serious criticism.[151] Exactly where the balance of competing official incentives lies is a vitally important question, of course, but the crucial question is, "compared to what?"

No one can doubt that the FDA's current enforcement capacities are deficient. Unfortunately, only Congress can remedy these deficiencies by equipping the agency with the information, authority and resources necessary to perform its regulatory tasks better. One hopes that the 2007 amendments, if properly funded and monitored for effectiveness, will significantly improve the quality of the FDA's performance, particularly with respect to safety-relevant information that arises only during the critical post-approval period.[152] And to the extent that these changes still do not provide the agency with enough timely and accurate risk information, the deficit disclosure exception to preemption proposed in Part II should further minimize the probability of regulatory error caused by manufacturers' inadequate transmittal of legally-mandated information.

In any event, there is simply no reason to think that state tort juries that are invited to second-guess the FDA's safety determinations can improve them or produce better outcomes. Part I suggests precisely the opposite. The overriding policy goal of promoting public health by encouraging the private investment necessary to develop optimally safe life- and health-preserving drugs is more likely to be attained by a system in which liability risks depend on preemptive, authoritative decisions made by a single, politically accountable expert agency, rather than by a non-system in which a multitude of lay state court juries wield different and notoriously opaque standards[153] that can be deciphered, if at all, only after a long course of litigation. The proposal advanced in Part II is designed to ensure that the FDA is

151. Peter Barton Hutt, The State of Science at the Food and Drug Administration, *in* FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY B-1, B-1 (2007), http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_02_FDA%20Report%20Appendices%20A-K.pdf; Gardiner Harris, *Advisors Say F.D.A.'s Flaws Puts Lives at Risk*, N.Y. TIMES, Dec. 1, 2007, at A12.

152. *See supra* note 39.

153. *See* discussion regarding general verdicts *supra* Part I.

adequately informed.[154] Only Congress and an aroused and vigilant public can ensure that the agency is adequately funded and highly motivated to pursue effective enforcement in the public interest.

154. The disclosure deficit exception discussed *supra* Part II is designed to assure this condition.