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Why preemption proponents are wrong

Corporate defendants' claim that the effect of state tort actions is equivalent to state positive law has no merit. The reality is that consumer protection can be guaranteed only when tort remedies work in tandem with federal regulation.

BRIAN WOLFMAN

The basic idea of federal preemption is easily stated: It is a constitutionally mandated principle that demands that federal law trumps state law when the two conflict or in the rare instances when a federal law is so comprehensive that there's no role left for state law to fill. But in practice, courts have often had difficulty applying the principle.

For plaintiff lawyers, preemption is an ever-present worry. When your client has been injured by a defective car, truck, medical device, boat, tobacco product, pesticide, or mislabeled drug, or has been victimized by a bank or other lending institution, the defendant will probably assert that federal law preempts your client's state law damages claim. You can expect this argument no matter how weak the federal regulatory scheme or how attenuated the connection between that scheme and the harms your client suffered or the state law duties under which your client seeks a remedy.¹

But defendants' and tort "reformers'" pro-preemption arguments do not reflect current preemption doctrine as established by the courts. A common—and false—argument for preemption, for example, is that state tort law necessarily interferes with federal regulatory objectives.

Moreover, preemption of state tort law is a bad idea. Immunizing the makers of products that cause injury simply

because, for instance, these products have been approved for marketing by a federal agency harms both the injured people and society generally.

An unsound theory

The theoretical basis that defendants offer for preemption of state tort law is not firmly established in preemption doctrine. I don't mean the detailed comparison between a particular federal regulatory regime and the state tort claims asserted in a particular case. There, as the case law shows, the devil is in the details.² I am referring to defendants' efforts to equate the effect of tort law—of

seeking damages on the ground that the plaintiff's injuries were caused by the device's defective design or inadequate labeling is also preempted.

In other words, is the effect of positive law (in this case, a state's positive law requirement that a product not be marketed) the same as a jury's damages verdict (in this case, a state's award of damages based on a design defect)? This is an important question because defendants have relied heavily on the argument that positive law and common law damages exert the *same* regulatory effect and that when positive law is preempted, common law should be as well.

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state law damages actions—with positive state regulation.

For example, assume that a federal agency has approved the marketing of a particular medical device as it is currently designed, manufactured, and labeled and that a state's ban on the marketing of this device would be preempted on the ground that it would conflict with federal law. The question, then, is whether a state law tort suit

Does the Supreme Court buy into this equivalence between positive state regulation and a jury's award of damages? To put it mildly, the Court has been unpredictable.

Its first statement on this topic was in the labor law context, in *San Diego Building Trades Council v. Garmon*.³ *Garmon* involved a business's attempt to prevent union picketing by bringing a suit under California law seeking an in-

junction and damages. In an early stage of the litigation, the Supreme Court ruled that the injunctive relief was preempted by the National Labor Relations Act.⁴ The Court also rejected the attempt to impose damages under California law:

[State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy. Even the states' salutary effort

The Supreme Court has said it is 'perfectly rational' for Congress to preempt state positive law but not common law claims, which 'perform an important remedial role in compensating accident victims.'

to redress private wrongs or grant compensation for past harm cannot be exerted to regulate activities that are potentially subject to the exclusive federal regulatory scheme.⁵

Garmon was not a products liability case, and federal labor laws, unlike most federal statutes that regulate consumer products and services, authorize monetary remedies. *Garmon* thus presented a different situation from the medical device example above because neither the relevant federal regulatory statute nor any other federal law provides a means to compensate people harmed by medical devices.⁶

Nevertheless, it is easy to see why preemption-seeking defendants rely so heavily on *Garmon*. Its exclusive focus on tort damages as a regulatory, rather than a compensatory, tool is useful to defendants seeking to equate positive law with tort law.

But *Garmon* arose in a context quite different from modern tort law, and even after *Garmon*, the prevailing assumption in the courts was that regulatory standards and state compensation schemes occupied separate spheres.⁷ Indeed, until the 1990s, the Supreme Court had never held a state law tort claim preempted by federal regulation, at least not where federal law itself did not provide a right of action for damages.

In 1992, the Court seemed to change course. A plurality opinion in the famous tobacco liability case, *Cipollone v. Liggett Group, Inc.*, relied on the language from *Garmon* quoted above and concluded that the Public Health Cigarette Smoking Act of 1969, which requires specific warnings on cigarette packages, preempted some, but not all, tort claims based on a failure to warn about the dangers of smoking.⁸

This section of the *Cipollone* decision was premised in part on particular

language of the 1969 act that purportedly pointed in the direction of preemption of common law duties.⁹ But it also relied on *Garmon*'s claim that damages liability can have, and is intended to have, the same effect on the defendant's future conduct as would positive state regulation. Since then, defendants in products liability and similar cases have relied on this language from *Garmon* and *Cipollone* ad nauseam, in an effort to show that state tort law and state positive law have the same regulatory effect—that is, that they are inherently the same.

But not so fast. In the majority portion of the *Cipollone* decision—which addressed the preemptive effect of an earlier version of the cigarette-labeling law (the 1965 Federal Cigarette Labeling and Advertising Act)—just a few paragraphs above the endorsement of *Garmon*, the same justice who wrote the plurality opinion, Justice John Paul Stevens, said something quite different: that the 1965 act, because of its particular wording, preempts “only positive enactments by legislatures or administrative agencies that mandate particular warning labels” and “not . . . common law damages actions.”¹⁰ The Court held that although the 1965 act preempted state positive law labeling requirements, it did not preempt any state damages actions, *even those premised on a failure*

to warn.

In responding to the tobacco industry's arguments that the 1965 act preempted state law damages claims based on the industry's failure to warn, the Court seemed to reject the *Garmon* viewpoint as a general, overarching justification for preemption: “[T]here is no general, inherent conflict between federal preemption of state warning requirements and the continued vitality of state common law damages actions.”¹¹

The internal tension in *Cipollone* carried over to a 1996 medical device preemption case, *Medtronic v. Lohr*.¹² A plurality opinion, again authored by Justice Stevens, suggested that a rational Congress could (and did) treat state common law damages actions differently from positive state law,¹³ while the dissenters and one concurring justice generally equated the two.¹⁴

Divining congressional intent

Although the Supreme Court's confusion on this score runs deep, it is important to mention three rulings from the Court that directly challenge the premise that positive law and damages liability are the same for preemption purposes. First, in *Goodyear Atomic Corp. v. Miller*, the Court considered whether an Ohio administrative agency could, consistent with federal preemption principles, award additional workers' compensation benefits based on violations of state safety standards at a federally owned, privately operated nuclear production facility.¹⁵

The Court held that the additional award was not preempted. Acknowledging that state positive law safety requirements might be preempted, the Court viewed damages liability as fundamentally different:

Congress' reluctance to allow direct state regulation of federal projects says little about whether Congress was likewise concerned with the incidental regulatory effects arising from the enforcement of a workers' compensation law, like Ohio's, that provides an additional award when the injury is caused by the breach of a safety regulation. The effects of direct regulation on the operation of federal projects are significantly more intrusive than the

incidental regulatory effects of such an additional award provision. [The] appellant may choose to disregard Ohio safety regulations and simply pay an additional workers' compensation award if an employee's injury is caused by a safety violation. We believe Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.¹⁶

The last sentence, which suggests that Congress had thought about the differences between “incidental regulatory pressure” and “direct regulatory authority,” seems a misstatement. Like most federal regulatory statutes—even those that expressly preempt state law—the statutes relevant in *Goodyear Atomic* had said nothing about preemption of state law monetary liability. In reality, the Court was saying that positive law and damages liability do not exert the same regulatory effect and that a reasonable Congress, if it had thought about the question, would not have equated the two in confronting the issue presented by the case.

Nor can the *Garmon* formulation be squared with two more-recent Supreme Court forays into tort preemption. In *Sprietsma v. Mercury Marine*, which considered a preemption argument based on the Federal Boat Safety Act (FBSA), a young woman died tragically when she fell overboard and was struck by a boat's propeller blades.¹⁷ One of the questions the case presented was whether a state common law claim premised on a boat manufacturer's failure to install a propeller guard was preempted by the FBSA's express preemption provision—which, according to the manufacturer, preempted all positive law and common law regarding boat safety.

The Court rejected that argument. It noted that it is “perfectly rational” for Congress to preempt state positive law but not “common law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims.”¹⁸

This statement is important because, generally, even when the Court has refused to find tort claims preempted and has challenged the notion that tort law exerts the same regulatory effect as pos-

itive law, it has not expressly touted tort law's remedial function. And tort law's ability to compensate the injured is one way that tort law and positive administrative law requirements differ fundamentally.

Finally, in *Bates v. Dow Agrosciences*, a 2005 case about whether the Federal Insecticide, Fungicide, and Rodenticide Act preempts state tort claims, the Court overruled the pro-preemption position of nearly every federal circuit and about 30 state appellate courts.¹⁹

The Court confronted an express preemption provision that preempts state law “requirements” when they differ from, or add to, federal regulatory requirements.²⁰ In holding that most (and possibly all) of the plaintiff's claims were not preempted, the Court explained that a positive law “requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision, is not a requirement.”²¹ The Court was making the point that positive regulation has a much more direct effect on conduct than does a damages award.

Why are these cases important? Because if the basic theoretical justification for preemption—equating state positive law and state tort law—is not really a part of the legal landscape, then defendants have only two things on

protector of its citizens' health and safety.²³

In short, once the overarching justification for tort preemption is gone, preemption proponents must come up with some other, more case-specific, justification. They no longer have a knockout punch.

A typical express preemption provision goes something like this: Preemption occurs where a state law “requirement” conflicts with a federal positive law “requirement.”²⁴ That language, standing alone, doesn't tell the courts much about whether state tort law is or is not preempted. If anything, because the federal law “requirement” is indisputably a positive regulatory requirement, it makes sense to think of the state law “requirement” as being one of positive law as well.²⁵

And these ambiguous provisions sit smack-dab in the middle of statutes enacted in the 1960s and 1970s to *improve* consumer safety and health or financial security, such as the Medical Device Amendments or the National Traffic and Motor Vehicle Safety Act, to name but two. And those statutes contain not a word—not a single word—suggesting that what Congress was really doing was enacting massive tort “reform” more expansive than the express tort “reform” statutes that Congress has been repeat-

To the extent that tort law exerts regulatory effect on a drug maker, it does so only after repeated suits, settlements, and findings of liability; even then the cause-and-effect relationship is rarely clear.

which to hang their hats: highly ambiguous express preemption provisions created by Congresses that were striving to *increase* protections for consumers, or, even less plausibly, claims of implied preemption arising from the interstices of federal law.²²

Neither of these assertions should fare well if the courts consistently apply the presumption against preemption of state law, which is said to apply with particular force in tort cases because of the state's traditional role as the prime

edly unwilling to enact over the last 20 years.²⁶

Let's take one possible illustration of such a claim's implausibility. Is it possible that the Medical Device Amendments to the Food, Drug, and Cosmetic Act²⁷—sponsored by Sen. Edward Kennedy (D-Mass.) and passed in 1976 by an overwhelmingly Democratic post-Watergate Congress in response to medical device tragedies such as the Dalkon Shield saga²⁸—were intended to eliminate the right to recover under state

law for injuries caused by defective FDA-approved medical devices? Some people may believe that tort preemption is a good thing, but they can't seriously believe that it arises from an enactment like the Medical Device Amendments.

As Kennedy bluntly put it, "The legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer that pays with his health and life for medical device malfunctions."²⁹

Even those inside the FDA have raised serious questions about the agency's ability to achieve its mission. FDA employees have expressed alarm at the improper pressure they felt to approve drugs.

A practical question

The doctrinal playing field regarding preemption is therefore wide open. The next question, then, is a practical one: Does equating positive law with tort law work as a practical matter? In other words, does the equation make empirical sense? That's an easy one, and the answer is no.

As a matter of regulatory impact, it is a huge leap from the proposition that tort law is meant to (and does to some degree) have a regulatory effect, to the proposition that its impact is equivalent to direct, positive law regulation.

When the FDA, for instance, wants to get a food, drug, or device off the market, it can do so swiftly. It can actually seize products, like David Kessler did with misbranded orange juice when he first became FDA commissioner.³⁰ It can deny regulatory approval; it can impose advertising restrictions; it can demand data. The Food, Drug, and Cosmetic Act gives industries the right to oppose agency action, but as a practical matter, the agency generally can exert its positive law priorities with great force.

Of course, agencies often do not exercise their full regulatory authority because of indifference, insufficient resources, lack of political will, or "capture" by the regulated industry.³¹ But federal agencies, if they wish to do so, have the ability to quickly alter the con-

duct of the regulated industry.

Contrast that direct regulatory power with the tort system. Large industry players generally react slowly, and sometimes not at all, to liability pressures. Most instances of liability are absorbed without a change in the manufacturer's conduct, or at least the kind of change that a regulator could bring about swiftly. As the District of Columbia Circuit has recognized, the imposition of damages liability does not legally compel the

defendant to alter its future conduct.³²

To the extent that tort law exerts a regulatory effect on a drug manufacturer, it does so only after repeated suits, settlements, and findings of liability—and even then the cause-and-effect relationship is rarely clear. In many instances, even after an onslaught of lawsuits, the manufacturer holds out for a long time—or forever. The Supreme Court put this well in *Goodyear Atomic*, when it said that "the effects of direct regulation on the operation of federal projects are significantly more intrusive than the incidental regulatory effects of such an additional award provision."³³

Of course, there is some symbiosis here. The regulatory system exerts pressures on the tort system and vice versa, both exert financial and political pressure on politicians and industry, and both are capable of publicizing information that would otherwise stay locked away in corporate file cabinets. But that doesn't alter the basic truth: There is no reason to build a body of legal literature and judicial doctrine on the equivalency between tort and direct regulation when that equivalency is not remotely accurate.

Compensatory role

Against this background, there are two reasons why tort preemption is generally a bad idea. First, the tort system

has a nonregulatory component—compensation—that is virtually never a component of the U.S. administrative law system. To put it another way, federal agencies that regulate virtually never compensate.

Unfortunately, much modern preemption doctrine and many legal academics, intrigued by the theoretical regulatory effect of tort as a means of social control, have not focused on the compensatory component. Yet the principal purpose of tort law—particularly in a world where, at least in theory, the agencies are already accomplishing their regulatory function—is compensation.

Compensation is what distinguishes the tort system from the modern regulatory state. That is not to say that the creation and perpetuation of tort duties are not intended to have an effect on future conduct. They are. But, at the very least, regulatory control *and* compensation are major goals of tort law. That being so, why should the compensation principle give way to the regulatory principle when there is a perceived "regulatory" conflict between tort law and the administrative state? And why shouldn't the plaintiff's interest in compensation prevail, particularly given the current political reality, in which federal law provides neither comprehensive health care nor accident insurance?

Given these political deficiencies and the relatively weak regulatory effect of tort, the compensation principle should trump the regulation principle, at least in the absence of the most direct types of conflict between federal law and state law (for instance, where federal law forbade boat propeller guards, and the state law tort claim was premised on a duty to provide one,³⁴ or where federal law prohibited air bags, and the state law tort claim was premised on a duty to require them³⁵). In this regard, one conception of strict products liability—in which the law acknowledges that even socially beneficial products can cause grave harm and allows those products on the market but compensates those who are injured—is perfectly consistent with a regulatory system that seeks, but can never fully achieve, optimal health and safety benefits.³⁶

The regulatory system is not intended to prevent all harm, nor could it—and this is the second reason why preemption is generally a bad idea. Regulation is meant to balance risks and benefits (with the knowledge that injuries will occur) in a highly imperfect system, where regulators depend almost exclusively on profit-motivated sellers to submit all available, relevant data—data that changes over time, as new information emerges after a product is marketed to the public.

Even if we assume that tort law exerts *some* regulatory pressure—and I do—why wouldn't we want it to do so? The Supreme Court itself has seemed to answer that question affirmatively, understanding both that tort law does not exert the same regulatory effect as positive law *and* that it can apply useful pressure where the regulatory system fails to achieve its full purposes.³⁷

A present-day example helps illustrate the serious concerns raised by a system that would tolerate both tort preemption and regulatory failure. In a regulatory preamble accompanying a new FDA rule concerning drug labeling, the agency has claimed that its labeling rules preempt state tort claims based on a drug manufacturer's failure to warn.³⁸

In other words, the agency maintains that the principal type of state law damages claim raised by people injured by drugs has been silently obliterated by federal law—silently, because no federal statute or regulation remotely suggests such a result. As a legal matter, the FDA's view seems like a stretch for a host of reasons, not the least of which is that when Congress was considering the legislation that became the Food, Drug, and Cosmetic Act in 1938—the legislation that authorizes the FDA to issue labeling rules in the first place—it “rejected a provision in a draft of the original (FDCA) providing a federal cause of action for damages because ‘a common law right of action [already] exists.’”³⁹ As my colleague Allison Zieve and I have elsewhere explained, the FDA's preemption position has no legal support and is not entitled to judicial deference.⁴⁰

My point for present purposes is not to undermine the FDA's legal claim to

preemption, but to show why preemption would do violence to public safety and to the agency's mission. To put it mildly, the FDA's preemption plea is ill-timed. Recently, two independent government reports have described the dangerous shortcomings in FDA oversight of drug safety.

First, in a report issued in March 2006, the Government Accountability Office concluded that the

FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues. The process has been limited by a lack of clarity about how decisions are made and about organizational roles, insufficient oversight by management, and data constraints.⁴¹

And more recently, a National Academies Institute of Medicine report, prepared at the FDA's request, found that the drug safety system is impaired by “serious resource constraints that weaken the quality and quantity of the science that is brought to bear on drug safety; an organizational culture in [the FDA] that is not optimally functional; and unclear and insufficient regulatory authorities particularly with respect to enforcement.”⁴²

The Supreme Court recognizes that tort law does not exert the same regulatory effect as a positive law and can apply useful pressure where the regulatory system fails to achieve its full purposes.

Even those inside the agency have raised serious questions about the FDA's ability to achieve its mission. In two recent surveys, FDA employees expressed alarm at the improper pressure they felt to approve new drugs.

In one survey, released by the Union of Concerned Scientists last summer, 60 percent of FDA employees who responded knew of situations “where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal, or modification of FDA determinations or actions.”⁴³ Eighteen percent agreed that “I have been asked, for nonscientific reasons, to inap-

propriately exclude or alter technical information or my conclusions in an FDA scientific document.”⁴⁴

Similarly, in a 2003 survey by the FDA's parent agency, the Department of Health and Human Services, 18 percent of FDA physicians and scientists who responded reported pressure to recommend that drugs be approved, even when they had reservations about the drugs' safety, effectiveness, or quality, and 66 percent lacked confidence that the agency “adequately monitors the safety of prescription drugs once they are on the market.”⁴⁵

Rezulin, Lotronex, Celebrex, Vioxx, Zolof, Prozac, and Accutane are among the many drugs that have required post-approval labeling changes to add or strengthen warnings. Several were removed from the market entirely.

The labeling changes were due, at least in part, to information and pressure derived from the tort system. As a 2002 medical journal article noted, “Many serious [adverse drug reactions] are discovered only after a drug has been on the market for years. Only half of newly discovered serious [adverse drug reactions] are detected and documented in the *Physicians' Desk Reference* [the

doctors' drug-labeling bible] within seven years after drug approval.”⁴⁶

With all that said, do we really want to override the tort system? Do we really want a system where imperfect regulatory agencies, all too often influenced by the regulated industries, must do the job on their own, while those who are injured have no means of compensation? To ask those questions is to answer them.

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Notes

1. For a discussion of strategies for defeating a preemption defense based on identifying differences between the purpose of the relevant federal regulatory scheme and the purpose of the relevant state common law, see Brian Wolfman & Douglas L. Stevick, *Preempting the Preemption Defense*, TRIAL 54 (July 1998).

2. See e.g. *Bates v. Dow Agrosciences*, 544 U.S. 431, 437-42 (2005); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-80 (1996) (plurality).

3. 359 U.S. 236 (1959).

4. *Id.* at 238.

5. *Id.* at 247.

6. See Medical Device Amendments to the Food, Drug, and Cosmetic Act, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified chiefly at 21 U.S.C. §§360c-360k (2000)).

7. See e.g. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251-53 (1984); *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1176-78 & n. 2 (5th Cir. 1988); *Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908, 911-13 (5th Cir. 1987); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1539-43 (D.C. Cir. 1984); *Feldman v. Lederle Laboratories*, 479 A.2d 374, 390-91 (N.J. 1984).

8. 505 U.S. 504, 521 (1992) (quoting *Garmon*, 359 U.S. at 247).

9. *Id.*

10. *Id.* at 519.

11. *Id.* at 518.

12. 518 U.S. 470.

13. *Id.* at 486-89.

14. *Id.* at 504-05 (Breyer, J., concurring), 510 (O'Connor, J., Rehnquist, C.J., Scalia, J., & Thomas, J., concurring in part and dissenting in part).

15. 486 U.S. 174 (1988).

16. *Id.* at 185-86.

17. 537 U.S. 51 (2002).

18. *Id.* at 64. The Court also rejected the manufacturer's argument that the plaintiff's common law claim was impliedly preempted by the Coast Guard's supposed safety-based opposition to propeller guards or by the FBSA more generally. *Id.* at 64-70.

19. 544 U.S. 431, 441 (2005).

20. 7 U.S.C. §136v(b) (2000).

21. *Bates*, 544 U.S. at 445.

22. See e.g. *Medtronic*, 518 U.S. at 487 (plurality).

23. *Id.* at 485.

24. See e.g. 7 U.S.C. §136v(b) (2000) (pesticides); 21 U.S.C. §360k(a) (2000) (medical devices).

25. See e.g. *Medtronic*, 518 U.S. at 489 (plurality) (21 U.S.C. §360k "refers to 'requirements' many times throughout its text. In each instance, the word is linked with language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law

by judges and juries. . .[.] suggesting that the preempted 'requirements' established or continued by states also refer primarily to positive enactments of state law.").

26. See e.g. Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 940-42 & nn. 185-89 (1994).

27. Pub. L. No. 94-295, 90 Stat. 539 (1976).

28. See e.g. *Medtronic*, 518 U.S. at 475-76 (plurality); Adler & Mann, *supra* n. 26, at 912 & n. 84.

29. 121 Cong. Rec. 10688 (1975); see generally Food & Drug Law Inst., *An Analytical Legislative History of the Medical Device Amendments of 1976* (Daniel F. O'Keefe Jr. & Robert A. Spiegel eds., 1976).

30. Warren E. Leary, *Citing Labels, U.S. Seizes Orange Juice*, N.Y. Times A18 (Apr. 25, 1991).

31. For a comprehensive review of these problems at an agency particularly indifferent to its safety mission, the Federal Motor Carrier Safety Administration, see Stephen Labaton, *As Trucking Rules Are Eased, a Debate on Safety Grows*, N.Y. Times A1 (Dec. 3, 2006), <http://select.nytimes.com/search/restricted/article?res=F50F15FC345A0C708CDDAB0994DE404482> (fee required) (accessed Feb. 5, 2007).

32. See e.g. *Ferebee*, 736 F.2d at 1541.

33. 486 U.S. at 185.

34. *Sprietsma*, 537 U.S. 51.

35. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

36. See William Lloyd Prosser et al., *Prosser & Keeton on Torts* 536-37, 692-93 (4th ed., West 1984); Clarence Morris, *Morris on Torts* 240-41 (2d ed., Foundation Press 1980).

37. See e.g. *Bates*, 544 U.S. at 451 (quoting *Ferebee*, 736 F.2d at 1541-42).

38. 71 Fed. Reg. 3922, 3933-3936 (Jan. 24, 2006).

39. Adler & Mann, *supra* note 26, at 924 & n. 130.

40. Allison M. Zieve & Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law: Why It Is Wrong and Warrants No Deference*, 21 Toxics Law Rep. 516 (2006) & 34 Prod. Safety & Liab. Rep. 308 (2006). See also Louis M. Bograd, *Taking on Big Pharma—and the FDA*, on page 30 of this issue.

41. U.S. Govt. Accountability Off., *Improvement Needed in FDA's Postmarket Decisionmaking and Oversight Process, Highlights* GAO-06-402 (Mar. 2006), www.gao.gov/new.items/d06402.pdf (accessed Feb. 5, 2007).

42. Inst. of Med., *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, S-4 (Sept. 22, 2006), <http://iom.edu/?id=37339> (accessed Feb. 5, 2007).

43. Union of Concerned Scientists, *Voices of Scientists at the FDA: Protecting Public Health Depends on Independent Science* (2006), www.ucsusa.org/assets/documents/scientific_integ-

[rity/FDA-Survey-Brochure.pdf](http://www.fda.gov/oc/2007/02/05/FDA-Survey-Brochure.pdf) (accessed Feb. 5, 2007).

44. *Id.*

45. U.S. Dept. of Health & Human Servs., Off. of Inspector Gen., *FDA's Review Process for New Drug Applications—A Management Review* 12, 19 (Mar. 2003), www.oig.hhs.gov/oei/reports/oei-01-01-00590.pdf (accessed Feb. 5, 2007).

46. Karen E. Lasser et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (2002).