

**WHAT TORT THEORY TELLS US
ABOUT FEDERAL PREEMPTION:
THE TRAGIC SAGA OF
*WYETH V. LEVINE***

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I.
INTRODUCTION: THE STATE OF CURRENT
PREEMPTION LAW

Most of the papers in this conference volume grapple with whether the venerable federal preemption principle will block private tort rights of action based on state common law principles. Federal preemption derives from the Supremacy Clause, which stipulates that federal statutes, and the regulations adopted pursuant to them, trump any state law.¹ Two recent Supreme Court decisions, *Riegel v. Medtronic, Inc.*² and, especially, *Wyeth v. Levine*,³ now shape this debate. Taken together, these cases stand for two propositions. First, the doctrine of express preemption is alive and well in the Supreme Court; if Congress wants to block state tort actions against defendants that have complied with federal law, all it has to do is give the word. Second, while Congress has not spoken to the matter, recent decisions of the Supreme Court make it exceedingly difficult for defendants to persuade any court, federal or state, to preempt ordinary tort law actions under theories of either field or conflict preemption.⁴ Although the final verdict is not in, I am ruefully confident that implied preemption in drug duty-to-warn cases

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1. U.S. CONST. art. VI, cl. 2 (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).

2. 552 U.S. 312 (2008).

3. 129 S. Ct. 1187 (2009).

4. *See, e.g.*, *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 452–53 (2005); *see also infra* text accompanying notes 154–63.

has, at best, a cloudy future after *Wyeth*—a point that becomes clear with an analysis of *Colacicco v. Apotex Inc.*⁵

It is no accident that both *Riegel* and *Wyeth* arose out of the interaction between the Food and Drug Administration (FDA) and state tort law. *Riegel* held that the Medical Device Amendments of 1976⁶ preempted a state law products liability case brought against a manufacturer whose device had gone through the FDA's pre-market approval process.⁷ This command precluded the application of state law.⁸

In *Wyeth*, in contrast, the Supreme Court held that a plaintiff could bring a duty-to-warn case under state law relating to Phenergan, an antihistamine marketed continuously since 1955 for the treatment of nausea.⁹ Like all drugs made and marketed in the United States, Phenergan was accompanied by detailed warnings and instructions approved by the FDA.¹⁰ But unlike the Medical Devices Act in *Riegel*, the Food and Drug law contains no explicit preemption provision for drugs,¹¹ and indeed appears to contain a provision that limits preemption in cases where there is a "direct and positive conflict" between the federal statute and any state law.¹² That provision was read by Judge Sloviter in *Colacicco* as calling for only a conflict analysis of preemption.¹³ But the force of

5. 521 F.3d 253 (3rd Cir. 2008), *vacated*, 129 S. Ct. 1578, 1578–79 (2009) (remanding for further consideration in light of *Wyeth*, 129 S. Ct. 1187).

6. See Medical Device Amendments of 1976, 21 U.S.C. § 360k (2006) ("[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."). For a perceptive account of the difficulties in construing the forms of state regulation that are allowed under this provision, see Mark Herrmann, David Booth Alden & Bradley W. Harrison, *The Meaning of the Parallel Requirements Exception Under Lohr and Riegel*, 65 N.Y.U. ANN. SURV. AM. L. 545 (2010).

7. See *Riegel*, 552 U.S. at 322–23.

8. *Id.* at 324–25.

9. *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009).

10. *Id.* at 1195.

11. *Id.* at 1193–94, 1196.

12. See Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) ("Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law.").

13. See *Colacicco v. Apotex Inc.*, 521 F.3d 253, 262 n.8 (3d Cir. 2008) ("Of course, the plain language of this provision states that the Amendments do not preempt state law in the absence of a conflict. Thus, to the extent that this provi-

that conclusion is muted when, only one page earlier, she quotes established Supreme Court case law that rejects any effort to regard three basic categories of preemption as “rigidly distinct.” “[F]ield pre-emption may be understood as a species of conflict preemption: A state law that falls within a pre-empted field conflicts with Congress’[s] intent (either express or plainly implied) to exclude state regulation.”¹⁴

If that is correct, the analysis of preemption under the food and drug laws collapses back into the elaborate body of Supreme Court rules applicable to implied preemption cases—which all date back to the watershed case of *Rice v. Santa Fe Elevator Corp.*,¹⁵ which established a presumption against preemption:

Congress legislated here [on the matter of warehouse receipts] in a field which the States have traditionally occupied. So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. Such a purpose may be evidenced in several ways. The scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it. Or the Act of Congress may touch 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. Likewise, the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose. Or the state policy may produce a result inconsistent with the objective of the federal statute.¹⁶

sion affects our analysis, it merely states that conflict preemption applies. In other words, this ‘express preemption’ provision simply leads us to a conflict preemption analysis, which may be applied independently of an express preemption analysis.”).

14. *Id.* at 261 n.6 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990)); see also *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000) (“We see no grounds, then, for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case.”).

15. 331 U.S. 218 (1947).

16. *Id.* at 230 (citations omitted). For different views on preemption, see, for example, Ernest Young, *Federal Preemption and State Autonomy*, in *FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS* 249, 250 (Richard A. Epstein & Michael S. Greve eds., 2007). See also Richard A. Epstein & Michael S. Greve, *Introduction: Preemption in Context*, in *FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS* 1 (Richard A. Epstein & Michael S. Greve eds., 2007); Richard A. Epstein & Michael S. Greve, *Conclusion: Preemption Doctrine and its Limits*, in *FEDERAL*

I have long believed that field preemption was the proper approach in light of the comprehensive control that the FDA exercises in issuing warnings about the dangerous side effects and counter-indications for the use of any drug.¹⁷ Efforts to impose more stringent warnings are best understood as efforts to interdict a set of uses that the FDA has either expressly or impliedly authorized in approving the particular warnings or instructions. The FDA, for all its flaws,¹⁸ does have one advantage over a system of tort liability: It makes its judgments on the overall effects of drug use, not on the particulars of individual cases where the question of proper warning is compromised in a number of ways.

The ex post tort system makes it difficult to disentangle decisions on the adequacy of a warning from those on causation. All warnings have to be issued before any particular use is made. To test the adequacy of a general warning in light of the peculiar circumstances in an individual case puts far too much emphasis on the responses of a particular physician or patient when what is needed is evidence of how the warnings play out in general. It runs a strong risk of inconsistent verdicts both within and across jurisdictions. The ex post tort approach allows plaintiffs' lawyers to attack and demoralize FDA scientists in a public forum. It ignores the fact that the FDA keeps too many drugs off the market. Finally, the social losses from untreated diseases, however real, are rarely laid at the FDA's doorstep. In sum, to the extent that a plaintiff's case relies solely on the inadequacy of the FDA-approved warning, it should be categorically preempted.

That preemption logic does not extend with equal force to those decisions about product promotion that take place *after* the FDA process has run its course. Suits brought against companies for activities beyond labeling are not covered by this institutional argument. Accordingly, cases in which it is alleged that drug companies engaged in fraudulent marketing practices and over-promotion after the release of drugs raise different questions than those in which a drug company is alleged to have fallen short in its obliga-

PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 309 (Richard A. Epstein & Michael S. Greve eds., 2007).

17. See Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 Nw. U. L. Rev. 463 (2009).

18. See Richard A. Epstein, *Against Permittitis: Why Voluntary Organizations Should Regulate the Use of Cancer Drugs*, 94 MINN. L. REV. 1, 35–40 (2009).

tions to report adverse incidents to the FDA after the drug is in the marketplace.¹⁹

The correct substantive position should therefore be to prevent all state law tort attacks. This position should be followed whether or not one agrees that the FDA is a poor gatekeeper. It should be followed by those who want to strengthen FDA oversight of warnings as well as by those, like myself, who would limit the FDA's power to keep drugs off the market once they have passed Phase 1 clinical trials—which are relatively inexpensive affairs designed to test basic toxicity.²⁰ Put differently, one can concede that the FDA plays a vital role in patient safety but still think that all duty-to-warn cases should be preempted when drug manufacturers comply with existing warnings.

This effort to separate judgments about preemption from judgments about the proper operation of the FDA is, however, not the current trend. It is a sign of the troubled status of implied preemption that Seth Waxman, who argued the case for Wyeth, specifically abandoned his reliance on the field preemption theory on appeal.²¹ Sadly, his preferred line of conflict preemption lost out as well.²² The Food and Drug Administration Amendments Act of 2007 (FDAAA)²³ changed the landscape significantly by allowing drug companies to update their warnings prior to FDA approval.²⁴ So Waxman's alternative position might well make sense for new drugs about which valuable information is often acquired from use, except that Phenergan has been used in the same way for decades, ruling out the need for updating. The FDAAA has altered drug policy for the worse, allowing plaintiffs to challenge drug warnings at any time. So long as a stricter warning can be imagined, it may well be for juries to decide whether it should be issued.

19. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.) (allowing the FDA to withdraw approval of any drug if its manufacturer fails to submit the required periodic reports that notify the FDA of adverse drug events and any other new information that might influence the choice of drug labeling). Drug manufacturers must revise their warnings as soon as they obtain reasonable evidence of a serious hazard with drug use. See *id.*

20. See Epstein, *supra* note 18, at 19–20.

21. *Wyeth v. Levine*, 129 S. Ct. 1187, 1192 (2009).

22. See *id.* at 1204.

23. Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.).

24. See *id.* at § 901(a)(4)(B), 121 Stat. at 924.

The approach of piling on tort remedies is counterproductive.²⁵ The implicit premise of this approach, urged most insistently by David Kessler and David Vladeck, is that tort law has to stand ready to pick up where the dilatory efforts of the FDA have left off.²⁶ But this is an oversimplification of the basic situation. The FDA is in a position to commit two equal and opposite sins. In some instances, it lets dangerous non-prescription drugs on the market too quickly.²⁷ More ominously, it often keeps drugs off the market for too long, preventing anyone from using them.²⁸ The threat of tort liability does not correct this second type of error. Rather, tort liability compounds the problem of the FDA's excessive caution. Unfortunately, Justice Stevens's majority opinion in *Wyeth* contains no mention of these offsetting considerations, raised explicitly in a brief filed on behalf of five distinguished economists, each well versed in the subject.²⁹

Catherine Sharkey and Robert Rabin present an intermediate position, which would give preemptive force to those regulations that the relevant enforcement agencies believe require it.³⁰ Unfortunately, Justice Stevens did not show much sympathy for that position either. Finally, by examining the relative institutional capacities of regulators and courts,³¹ Peter Schuck has sought to find the "sweet spot" between an implied preemption doctrine that occupies a field and one that allows all tort actions as a matter of course. His view of the subject—lying midway between Rabin's and Sharkey's on the one hand, and mine on the other—is that the

25. See, e.g., Epstein, *supra* note 17, at 470; Epstein, *supra* note 18, at 18 (noting that drug companies often delay making new, unapproved drugs available for fear of tort liability).

26. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 491–95 (2008). Justice Stevens explicitly relied on their article in *Wyeth*, 129 S. Ct. at 1203 n.12. For my futile response to their article, see Epstein, *supra* note 17, at 468–73.

27. See, e.g., Holly M. Spencer, *The RX-to-OTC Switch of Claritin, Allegra, and Zyrtec: An Unprecedented FDA Response to Petitioners and the Protection of Public Health*, 51 AM. U. L. REV. 999, 1000–01, 1030 (2002).

28. See, e.g., Ronald T. Libby, *Policy Analysis: Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers*, CATO INSTITUTE, June 16, 2005, available at <http://www.cato.org/pubs/pas/pa545.pdf>.

29. Brief of John E. Calfee et al. as Amici Curiae Supporting Petitioner, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

30. See Robert L. Rabin, *Territorial Claims in the Domain of Accidental Harm: Conflicting Conceptions of Tort Preemption*, 74 BROOK. L. REV. 987, 1000–02 (2009); Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 415, 437 (2008).

31. See Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73, 82 (2008).

passage of the FDAAA, which expanded the FDA's capacity to monitor drugs post-approval, should further tilt the scale to the pro-preemption side of the ledger.³² More regulation reduces the need for tort actions that cover the same field. Written before the Supreme Court handed down *Wyeth*, Schuck's view now also seems to have been rejected.

My reading of *Wyeth* is that it largely settles the preemption debate against preemption: Except in rare situations, my prediction is that the only protection drug companies can expect from tort litigation is through congressional action. Justice Stevens slapped down the 2006 effort by the Bush-era FDA to block tort actions³³ as a clear abuse of administrative discretion, including want of any notice-and-comment proceeding.³⁴ For the purpose of this paper, however, I wish to focus on a second strand of Justice Stevens's position, chiding the FDA for abandoning its "longstanding position against the preemptive force of FDA warnings without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence."³⁵ This line echoed the concern of Congress when it enacted the Food, Drug and Cosmetic Act (FDCA) seventy years ago, deliberately preserving state law damages claims.³⁶

In this paper I hope to offer some explanation as to why both these sentiments misapprehend the relationship between state tort law and federal preemption. The common wisdom that the FDA did not urge preemption until its ill-fated 2006 administrative preamble is beyond dispute.³⁷ But I will approach the preemption question from the opposite direction by asking whether the original attitude toward preemption should survive in light of the enormous

32. *See id.* at 83.

33. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3967 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

34. *See* *Wyeth v. Levine*, 129 S. Ct. 1187, 1200–01, 1203–04 (2009).

35. *Id.* at 1201.

36. Brief of Amici Curiae Members of Congress in Support of Respondent at 3, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (“[W]hen Congress enacted the FDCA 70 years ago, it deliberately preserved state-law damages claims. Since that time, Congress has consistently understood that federal law does not preempt state-law failure-to-warn claims with respect to drugs approved by the FDA. This understanding has been fortified by settled practice under the statute. For decades, innumerable state-law actions involving FDA-approved pharmaceuticals have been prosecuted to final judgment or settlement.”).

37. *See* Victor Schwartz et al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising*, 32 HARV. J.L. & PUB. POL'Y 334, 385 (2009).

changes that occurred during this formative period of tort law prior to its vast expansion after the passage of the Second Restatement of Torts. Put simply, context matters. Preemption makes perfect sense against the backdrop of tort law as it was formulated in 1939, right after the 1938 FDCA added requirements dealing with safety,³⁸ through the 1962 Kefauver-Harris Amendments that conferred on the FDA the power to examine the effectiveness of questionable drugs.³⁹ This article reinterprets the peaceful coexistence between tort law and the FDA as a function of the narrow and sensible content of the earlier tort law, which has been undermined by substantive state law developments over the last forty years.

Even the most ardent defender of field preemption would find *nothing* in the tort law before 1965 that could ever collide with the commands of the FDA. To show this, the next section traces the evolution of both duty-to-warn and design-defect products liability cases. The huge expansion of state products liability law immediately followed the adoption of the Second Restatement of Torts in 1965, with its famous, but modest, strict liability provision in Section 402A.⁴⁰ This expansion has put strains on the law that are powerfully exhibited by the facts in *Wyeth* and other modern cases, including *Colacicco*. Section I of this paper shows the absence of conflicts between tort law and FDA policy prior to 1965. Section II explains why modern tort law placed the two on a collision course in cases like *Wyeth*. Section III explains how the distortions in Vermont tort law (which governed in *Wyeth*) pose real threats to the operation of the federal system and require a rejection of the position of the *Wyeth* majority decision of Justice Stevens. Section IV explores the post-*Wyeth* landscape through the lens of *Colacicco*.

II.

PRE-1965 PRODUCTS LIABILITY LAW⁴¹

Products liability law began in restrictive fashion with the 1842 English decision in *Winterbottom v. Wright*,⁴² which arose out of an

38. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938).

39. See Drug Amendments of 1962, Pub. L. No. 87-781, § 102(d)-(e), 76 Stat. 780, 781-82 (1962) (codified as amended in scattered sections of 21 U.S.C.).

40. RESTATEMENT (SECOND) OF TORTS § 402A (1965) (introducing strict liability regime).

41. I have given a longer treatment of these issues in RICHARD A. EPSTEIN, MODERN PRODUCTS LIABILITY LAW 9-35 (1980) [hereinafter Epstein, MODERN PRODUCTS LIABILITY LAW]. I have also addressed many of these issues in 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. 1 (2006).

42. 152 Eng. Rep. 402 (1842).

action brought by an injured driver of a defective coach against the coach repairman. There was no direct contractual relationship between the plaintiff and the defendant, and the lack of privity blocked the action without regard to any causal relationship between the defect introduced by defendant's repairs and the injury to the plaintiff.

In reality, the outcome was not quite as strange as the common denunciations—Prosser described the decision as “a fishbone in the throat of the law”⁴³—might suggest. However, Prosser's arguments are manifestly incorrect. First, he contends that “nothing is more foreseeable than that [goods] will be resold to a consumer, or, if they are dangerously defective that he will be injured by them.”⁴⁴ But the resale of goods with possible defects is equally foreseeable to a plaintiff, so the question is what allocation of risk minimizes total accident costs when each party can foresee errors by the other. Foresight there may be, but its relationship to liability is left unexplained. His second argument is little more than a rephrase of the first: “[H]e has so dealt with the goods that they are likely to come into the hands of another, and to do harm if they are defective.”⁴⁵ This suppresses reference to the mechanism of causation and the knowledge of intermediate parties and product users, both of which could well matter. A complete analysis should ask whether the plaintiff might have an action against his employer for his failure to supply a safe place of work, and what should happen if the defendant had been released from potential liability under his contract with the Postmaster General. *Winterbottom* could be read as an effort to give priority of place to downstream control or to freedom of contract principles. But both points were generally ignored in the subsequent evolution of the doctrine.

Be that as it may, it was quite clear that the privity defense had fully evaporated by the time of the 1938 FDCA. The key landmarks are well known, but the Act's overreliance on foresight has always escaped the criticism it deserves. This critique rests on two related themes. The first theme is that intentional harms by concealment or deliberately mislabeling can be a source of liability. The second is that parties have a differential capacity to avoid risk. In all cases, the conduct of both the plaintiff and third parties matters.

43. W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 96 (5th ed. 1984).

44. *Id.*

45. *Id.*

Both of these themes are evident in *Thomas v. Winchester*,⁴⁶ which carved out the first exception to the privity limitation for unreasonably dangerous products. In modern terminology, *Thomas* was a mislabeling case where a druggist sold the poison belladonna in a bottle that was labeled as extract of dandelion, a harmless substance. The issue of negligence seems trivial, for no careful person would confuse the two substances. But any supposed causal complications were eliminated because the plaintiff had taken the belladonna from its original container in reliance on the label. Liability followed because no one thought that she would have taken the drug if she had known the true state of affairs.

This pattern of bad defendant/good plaintiff carried over into the twentieth century. In *Kuelling v. Roderick Lean Manufacturing Co.*,⁴⁷ the plaintiff was injured when he hitched to his team of horses a defective roller he had acquired from a dealer who purchased it from the defendant. The defendant knew the wood was defective and concealed the defect with putty. Neither the plaintiff nor the dealer was aware of the defect. This is *worse* than *Thomas v. Winchester*, even if the poison was inherently dangerous and the roller imminently dangerous because badly made. The modern analogy to *Kuelling* would be deliberately putting poison in a container that supposedly contained medicine.

*MacPherson v. Buick Motor Co.*⁴⁸ is commonly read to mark the demise of the privity defense. It held that plaintiffs could sue automobile manufacturers in negligence if the wheels were made of defective wood that caused damage in ordinary use.⁴⁹ The description offered by Judge Cardozo simply stated that “while the plaintiff was in the car, [the wheel] suddenly collapsed” because it was made of defective wood.⁵⁰ From this description, there may be a coherent principle that allows for, but limits, the scope of products liability. The product was defective in its original position, the defect was latent, and the plaintiff and all third parties had used it in normal and proper condition. To be sure, this case is more difficult than *Kuelling* where the active concealment of the defect turned the case into one of asymmetrical information. It is easy to impose liability on the party with knowledge of the risk; but, in *MacPherson*, the shift to negligence rests on a (defensible) judgment that the defendant is in a better position to avoid the risk through

46. 6 N.Y. 397 (1852).

47. 75 N.E. 1098 (N.Y. 1905).

48. 111 N.E. 1050 (N.Y. 1916).

49. *See id.* at 1053.

50. *Id.* at 1051.

various techniques of quality control (including systems of inspection).

Yet there are two gaps in Cardozo's opinion, one of fact and the other of law. On the former, a careful study by Professor Henderson exploded the myth that this wheel suddenly broke without explanation. Rather, this Buick car, which had been used to haul concrete, had its wooden wheel break when the plaintiff, while driving thirty miles per hour, sought to turn after sinking into four inches of gravel.⁵¹ That level of downstream misuse was so acute that this plaintiff would have had a hard time winning before a jury even under today's law.

The second gap is conceptual. Cardozo's opinion has an odd juxtaposition of narrow and broad justifications. He explains that: "We are dealing now with the liability of the manufacturer of the finished product, who puts it on the market to be used without inspection by his customers. If he is negligent where danger is to be foreseen, a liability will follow."⁵² The first sentence is quite narrow and follows the pattern of harms caused by latent defects in products subject to ordinary use. The asymmetry between the parties that justifies liability is the greater capacity to avoid harm through inspection, which the customer need not do precisely because the manufacturer has done it. The second sentence turns on foresight, and the potential scope of liability that could be much broader when that notion is, as happened, wrenched out of its narrow context. But foresight is a useless tool in all these cases: If the defendant can foresee danger from defects, so too can the plaintiff. If the defendant can foresee product misuse by the plaintiff, the plaintiff can see subpar product manufacturing by the defendant. The issue is not what can be foreseen. The issue is what steps each party should be expected to take so that when they act together losses are minimized. On that score, the individual plaintiff could have superior access to information because he has knowledge of both the product and the context in which it is being used—a fact which looms large in many cases.

This issue of downstream knowledge looms large in the next major case, *Escola v. Coca Cola Bottling Co.*⁵³ In his famous concurrence, Justice Traynor indicated that he would have applied strict

51. James Henderson, Jr., *MacPherson v. Buick Motor Company: Simplifying the Facts While Reshaping the Law*, in *TORTS STORIES* 45–46 (Robert L. Rabin & Stephen D. Sugarman eds., 2003).

52. *MacPherson*, 111 N.E. at 1053.

53. *Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436 (Cal. 1944).

liability when an exploding Coca Cola bottle injured the plaintiff.⁵⁴ Once again, the majority's statement of the facts makes it appear that the explosion "just happened," but the prospects for downstream misuse were manifold: The record revealed that the distributor had placed the bottles behind the counter for thirty-six hours before the plaintiff picked them up, only to have one explode in her hand. Her coworker testified that she had not banged the bottle.⁵⁵ We do not know, of course, whether the testimony was true or rehearsed. But even if that testimony were 100 percent accurate, the downstream risks are not eliminated. In other explosion cases, the bottle could be mishandled during distribution, which could create liability, although likely in negligence. Or an explosion could result from a sharp tap on the edge of a sound bottle that has been left to sit in the sun. If the distributor had failed to exercise reasonable care, liability could follow under *res ipsa loquitur* if it could be shown that the bottle was safe when it reached the distributor and promptly exploded when unloaded. That theory of liability (even if the distributor was the same party as the manufacturer) would have rendered irrelevant Traynor's disquisition on why strict liability is appropriate for manufacturers.⁵⁶ Likewise, if there was product misuse by the end user—and there were alleged fraud rings for these bottle cases at the time—Justice Traynor would have rightly denied recovery because the product did not cause damage in its "normal and proper" use.⁵⁷

What is most important about the case is not the broad statement of "public interest" rationales, but the narrow content of the strict liability rule: "The manufacturer's liability should, of course, be defined in terms of the safety of the product in its normal and proper use, and should not extend to injuries that cannot be traced to the product as it reached the market."⁵⁸ *Escola* thus makes explicit two limitations on tort liability that were also present in Cardozo's *MacPherson* decision. First, the product must be in its original condition, which, by implication, means that no third party altered the product. Second, the product must have been used in its normal and proper way; the original manufacturer whose prod-

54. *See id.* at 440 (Traynor, J., concurring).

55. *Id.* at 437–38 (Gibson, C.J.).

56. *See id.* at 440–44 (Traynor, J., concurring).

57. I cannot trace down the oral references to this effect that I heard years ago in California, but the prospects can never be dismissed. For the detailed exposure of the fraud rings that undermined the California workers' compensation law, see Gary T. Schwartz, *Waste, Fraud and Abuse in Workers' Compensation: The Recent California Experience*, 52 MD. L. REV. 983, 987–92 (1993).

58. *Escola*, 150 P.2d at 444 (Traynor, J., concurring).

uct was safe in its original condition drops out of the case once a misuse has taken place.

Interestingly, while Justice Traynor offers reasons why strict liability provides a simpler and more powerful rationale than negligence, he does not utter a syllable to explain either of the two limitations he adds. It is, however, possible to supply the missing rationale, but only by dispensing with the foresight reasoning. A sensible social welfare function in torts cases starts with the awareness that there is sequential control over a dangerous instrumentality, where each person handles it out of the sight of others. The parties can, through intermediaries, adjust their price to reflect the risk. The task, therefore, is to find an efficient but general way to describe what each party is entitled to expect of the other. The usual language of “reasonable expectations” is often attacked as circular, and thus unequal to the task in this area as in others.⁵⁹ As the argument goes, the only way one can use reasonable expectations to determine what the law is, is to first know the law.

In fact, that facile argument is incorrect. The right way to approach the problem is to ask, in this sequential game, which steps taken by both parties will minimize social loss—here defined as the sum of accident costs and their prevention, including the costs of litigation. Reasonable expectations set out a pattern whereby if both sides comply, no accidents will happen. Traffic rules do the same thing, for no intersection collisions will occur if all parties follow the rules of the road. The hard issues arise when one side deviates and some other party (the plaintiff or a third person) has to decide without notice what to do in response. In a highway accident, the party who has the last clear chance, i.e., knows of the peril, must take prudent steps to react to the new burst of relevant information.⁶⁰ The harder question is whether he can recover for the costs of those precautions in the absence of injury.⁶¹ In the

59. One example is the use of reasonable expectations in Fourth Amendment law. See, e.g., *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1035 (1992) (Kennedy, J., concurring); *Katz v. United States*, 389 U.S. 347, 358–59 (1967). I have tackled this issue in Richard A. Epstein, *Privacy, Publication, and the First Amendment: The Dangers of First Amendment Exceptionalism*, 52 *STAN. L. REV.* 1003 (2000), and Richard A. Epstein, *Lucas v. South Carolina Coastal Council: A Tangled Web of Expectations*, 45 *STAN. L. REV.* 1369 (1993).

60. See, e.g., *RESTATEMENT (SECOND) OF TORTS* §§ 479–80 (1965); Donald Wittman, *Optimal Pricing of Sequential Inputs: Last Clear Chance, Mitigation of Damages, and Related Doctrines in the Law*, 10 *J. LEGAL STUD.* 65, 78–82 (1981).

61. See Susan Rose-Ackerman, *Dikes, Dams, and Vicious Hogs: Entitlement and Efficiency in Tort Law*, 18 *J. LEGAL STUD.* 25, 26 (1989) (advocating for a rule that allows for the recovery of costs taken to avoid actionable harm).

road case, it means that one driver has to get out of the way if the other crosses over into his lane. In the products liability context, it means that a consumer who knows that there are worms in a candy bar cannot eat it and then sue for damages⁶²—a decision that coincidentally came down in 1962, the year of the Kefauver Harris amendments.

The impact of the early innovations in products liability law was to treat the two parties as though they were in direct contact with each other. Some measure of the cautious attitude regarding these developments is gleaned from *Pease v. Sinclair Refining Co.*,⁶³ decided in 1939. The plaintiff was a science teacher injured in an explosion that occurred when he placed a substantial amount of sodium in water, causing the loss of an eye and serious burns. The plaintiff knew well the dangers of mixing sodium with water, but he put the concoction together because the water was from a bottle marked kerosene. The defendant oil company had marked it as such in order to allow its shipment through the mails. The plaintiff relied on the label and did not smell the bottle. After an extensive trial, the jury found the defendant guilty of negligence and the plaintiff free of contributory negligence.⁶⁴ As a sign of the times, it took an appellate decision by Chief Judge Clark to establish that it was proper to leave the questions of both negligence and contributory negligence to the jury.

What is striking is how easy the case should have been for the plaintiff. The defendant misled the plaintiff, who had a right to rely on the label. That deliberate misrepresentation did not lose its sting because the defendant clearly had no intention to harm the plaintiff. It was quite enough that it disarmed the plaintiff's well-honed instincts for safety. Today, liability is too certain for a parallel case to get within miles of a jury, except perhaps for punitive damages for reckless disregard of safety.⁶⁵ It takes little imagination to ask what would have happened if the fluid which had been mislabeled to facilitate shipping was supposed to be used as a drug for medical treatment.

62. See *Kassouf v. Lee Bros.*, 26 Cal. Rptr. 276, 278–79 (Dist. Ct. App. 1962) (using assumption of risk to achieve that result).

63. 104 F.2d 183 (2d Cir. 1939).

64. See *id.* at 184–85.

65. For a modern view on punitive damages, see *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416–28 (2003) (reviewing constitutional requirements for punitive damages).

The issue in *Pease* regarded a danger that was latent on one side and patent on the other. *Campo v. Scofield*⁶⁶ encompassed the exact opposite pattern of risk, one that was open and obvious to the product user. The facts were simple enough: The plaintiff caught his hand in the revolving rollers of an “onion topper,” where they were badly mangled. Judge Fuld stressed that the obviousness of the defect put the user in a position to decide how best to use it: “[I]f the machine is without any latent defect, and if its functioning creates no danger or peril that is not known to the user, then the manufacturer has satisfied the law’s demand.”⁶⁷ Note that this defense blocks not only the duty-to-warn claim—why impose a duty to tell someone what he already knows—but also the design defect cause of action. The logic of the position is that full information allows downstream parties to decide whether, and if so how, to use the product in question. The threat of personal injury to the user, and the prospect of workers’ compensation payments for the employer, will lead to a selection of equipment suitable for its intended purposes. The clear logic behind this decision is that the downstream users are in a position to customize any equipment in ways that meet their respective demands. And once they do, the equipment is no longer in its original condition, so that liability for the manufacturer ceases on the ground that the “[t]hing used was not the thing sold.”⁶⁸ Supply full information and the logic flips over from *Pease* to *Campo*. Information allows the party that possesses it to organize the efforts that reconcile the conflicting demands of output and safety. And the temptation to redesign equipment to fight the last war is ruled out on categorical grounds because the defendant gets summary judgment on both warning and design theories of liability.

This attitude toward risk was reflected in the “open and obvious” defense in design defect cases. In *Evans v. General Motors*,⁶⁹ the decedent was killed when his GM car was broadsided. The court refused to allow a negligence case based on a crashworthiness theory by pointedly refusing to extend liability “despite the manufacturer’s ability to foresee the possibility” of collision.⁷⁰ Once again, the transfer of full information properly precluded the plaintiff from moving back along the chain of distribution. Joint causation

66. 95 N.E.2d 802 (N.Y. 1950).

67. *Id.* at 804.

68. *See* *Young v. Aeroil Prods. Co.*, 248 F.2d 185, 190 (9th Cir. 1957).

69. 359 F.2d 822 (7th Cir. 1966).

70. *Id.* at 825.

theories of liability for successive liability, so critical in *Wyeth*, were not used in these full information settings.⁷¹

These cases give an accurate description of the state of the law at the time of the Second Restatement of Torts in 1965.⁷² So long as liability was confined to latent hazards, the preemption issues of later times are just not implicated. But the once-solid distinction between patent and latent defects was crumbling. A famous passage in the Fowler Harper and Fleming James treatise argued strongly against the open and obvious rule, claiming that obviousness should count as only one factor in a general negligence equation.⁷³ They did not think of their work as particularly revolutionary, but by taking a huge category of cases from the land of defendant summary judgments into hotly contested jury trials, it surely was.

This widespread academic ferment led some manufacturers to do what they had never contemplated before. Sensing they would be held responsible for losses that were better controlled at the downstream level, they started to insert contractual provisions where tort law had started to turn wobbly, including of course the limited liability provisions at issue in *Henningsen v. Bloomfield Motors*.⁷⁴ But this tactic failed under both contract and tort law. Disclaimers of warranties were effectively banned under the Uniform Commercial Code,⁷⁵ and their role was sharply limited in much-celebrated cases that dealt with implied warranties⁷⁶ or strict liabil-

71. There could clearly be some argument as to whether these cases merit the description "full information." The use of the term "open and obvious" was intended to make liability turn on what was publicly known so as to avoid the risk of perjured defenses of the sort that denied the existence of that knowledge. In fact, the single most important feature about automobile safety, weight, is well known. To require perfect awareness of all that follows from an open and obvious condition clearly makes it impossible to accept any argument of that sort.

72. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

73. See 2 FOWLER V. HARPER & FLEMING JAMES, JR., THE LAW OF TORTS § 28.5 (1956) ("[T]he bottom does not logically drop out of a negligence case against the maker when it is shown that the purchaser knew of the dangerous condition.").

74. *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 74 (N.J. 1960) (finding disclaimers unconscionable in implied warranty case brought by nonpurchasers of the product).

75. See, e.g., U.C.C. § 2-318 (1995) (stating that a "seller may not exclude or limit the operation of this Section"); U.C.C. § 2-719(3) (holding that a limitation on "consequential damages for injury to the person in the case of consumer goods is prima facie unconscionable," without indicating any way in which that presumption could be rebutted).

76. See *Henningsen*, 161 A.2d at 74.

ity in tort.⁷⁷ At this point, contractual correction of judicial errors was no longer possible. The judges who failed to appreciate the importance of downstream conduct effectively froze the law in the wrong place for the wrong reasons.

The Second Restatement is better viewed as a consolidation of earlier trends than the adumbration of the impending transformation of the law.⁷⁸ In its original formulation, the movement to strict liability did not dislodge any of the constraints on downstream conduct that Judge Traynor thought were an integral part of his strict liability rule.⁷⁹ The definition of “product defect” makes it clear that the strict liability rule “applies only where the product is, at the time it leaves the seller’s hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him.”⁸⁰ On the flip side, the doctrines of contributory negligence and assumption of risk hold that:

Contributory negligence of the plaintiff is not a defense when such negligence consists merely in the failure to discover the defect in the product, or to guard against the possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense⁸¹

At this point, the one question that matters is whether any form of liability that was contemplated either in negligence or strict liability could pose the slightest threat to the way pharmaceutical companies made or marketed their products under these early rules. The answer has to be an emphatic “no.” It therefore made perfect sense for many statutes to have a clause that saved common law causes of action—and why not, when such actions clearly reach only issues that fly beneath the radar of these statutory schemes?

Cases of mislabeling and defective preparation are open and shut as to liability today and nothing about the ill-fated 2006 FDA preamble was meant to alter what has become a hard and fast rule. Deviate from the standards of purity or make a mistake in labeling and your goose is cooked. Meet standards on purity and labeling

77. *See, e.g.*, *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963) (approving the “refusal [of the law] to permit the manufacturer to define the scope of its own responsibility for defective products” by contract).

78. For a review of the narrowness of its rules, see Epstein, *MODERN PRODUCTS LIABILITY LAW*, *supra* note 41, at 57–67.

79. *See supra* text accompanying note 58.

80. RESTATEMENT (SECOND) OF TORTS § 402A cmt. g (1965).

81. *Id.* cmt. n.

and you are home free. The responsibility now moves downstream to subsequent actors. Rightly understood, the simple explanation for the state of play between the regulatory system of 1939 and the tort system of that date is that they do not come into conflict. To say that there was peaceful coexistence between the two is correct, but only in a highly restricted sense. The critical but modest aspirations of the early tort law assured that never a conflict, never an overlap, never an occupation of a field could arise. It therefore made perfectly good sense to insert in federal statutes provisions creating express preemption on the one hand and common law savings clauses on the other. For example, the National Traffic and Motor Vehicle Safety Act of 1966⁸² contained both an express preemption clause⁸³ and a savings clause providing that “[c]ompliance with” a federal safety standard “does not exempt any person from any liability under common law.”⁸⁴

Just two years later, tort liability experienced a vast expansion in the series of crashworthiness cases initiated by *Larsen v. General Motors Corp.*⁸⁵ In the pre-*Larsen* environment, it is incorrect to say that the question of preemption did arise and that it was resolved in favor of allowing the private right of action. In the post-*Larsen* environment, however, the conflict became acute. This was shown in the case of *Geier v. American Honda Motor Company*,⁸⁶ where Justice Breyer, over a Justice Stevens dissent, allowed for federal preemption after exhaustively reviewing the complex negotiations that led to a postponement of the introduction of air bags into passenger vehicles.⁸⁷ In effect, his views of preemption did not block any common law product liability actions of the sort maintained before 1965, of which *Geier* was surely not one. Justice Breyer treated *Geier* as a case of conflict preemption, but it could have been decided as easily as a case where tort liability frustrated a coherent federal scheme or where the active intervention of the Department of

82. Pub. L. No. 89-563, 80 Stat. 718 (1966) (repealed 1994).

83. § 103(d), 80 Stat. at 718, 719 (“Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment, any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.”).

84. § 108(c), 80 Stat. at 718, 723.

85. 391 F.2d 495 (8th Cir. 1968).

86. 529 U.S. 861 (2000).

87. *See id.* at 874–81.

Transportation occupied the field.⁸⁸ In any event, *Geier* represents the type of case that could not have survived summary judgment before the advent of the crashworthiness cases. In closing, I know of no litigated case in the pre-1965 period in which the court should have found preemption under any of the three established doctrines.

III. PRODUCTS LIABILITY LAW IN ITS MODERN VOICE

The shift in the basic thrust of products liability came in the immediate aftermath of the Second Restatement. Most critically, the massive expansion of tort liability in products liability cases had little to do with the strict liability innovations of Section 402A. Strict liability provisions proved relevant in the cases where they were hardly needed, namely those dealing with manufacturing defects built into the product before it leaves the manufacturer's hands.⁸⁹ The manufacturer's complete control over the fabrication process, including the capacity to impose quality control standards and inspections, makes it wise to dispense with the use of a negligence inquiry, which even in the pre-1965 period was hurried along by a generous dollop of *res ipsa loquitur*.⁹⁰

Yet the design and warning cases present entirely different issues precisely because the passing down of full information no longer created a shield against liability. The decision to expand liability did not, of course, undercut the traditional product liability cases for latent defects that caused harm in ordinary use. Those cases became so easy (and with good quality control, so rare) that they quickly disappeared, as it became truly hopeless to contest liability. But the pre-1965 pressure to push responsibility down the chain of distribution toward the user came to a halt with the abrogation of the open and obvious rule.

The change was first felt in the design defect area when the courts quickly moved away from the position that concentrated

88. *See id.* at 873–74 (discussing the ways in which various models of preemption might apply).

89. *See, e.g., Moore v. Jewel Tea Co.*, 253 N.E.2d 636, 647 (Ill. App. Ct. 1969) (requiring plaintiff to prove that her injury resulted from a condition of the product which was unreasonably dangerous and which existed at the time the product left the manufacturer's control).

90. *See Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436, 440 (Cal. 1944) (Gibson, C.J.) (affirming the judgment below in reliance on the *res ipsa loquitur* formulation, which applied once it was clear that the downstream users did not alter the product).

solely on latent defects by adopting the Harper and James view⁹¹ that even if a condition was open and obvious to the user, some duty could exist on the part of the manufacturer to guard against it. *Micallef v. Miehle Co.*⁹² unceremoniously overruled *Campo* by treating all accidents arising from the use of machine tools as raising hard questions of joint causation. The downstream parties may have incurred some responsibility, but the initial supplier of the product remained a “substantial factor” in the mix even if foolish things were done downstream.⁹³

Similarly, theories of joint causation in the crashworthiness area displaced the downward pressure of the open and obvious rule. Thus, in the watershed case of *Larsen*,⁹⁴ the decisive question now was what design features the defendant had to install to deal with the anticipated misbehavior of the plaintiff,⁹⁵ which could include driving drunk at over one hundred miles per hour.⁹⁶ Once again, any foreseeable injury was sufficient to trigger the manufacturer’s duty, while the knowledge of the condition of the vehicle by the driver necessarily became a secondary issue. And once again the expansion of liability came under the negligence rubric, given that the manufacturer was “under a duty to use reasonable care in the design of its vehicle to avoid subjecting the user to an unreasonable risk of injury in the event of a collision.”⁹⁷ Sharp boundary conditions and joint causation displaced the relatively sharp separation of responsibilities under the open and obvious rule.

The new developments did not necessarily displace the older tests that tied liability to the reasonable expectations of product users. Indeed, the critical decision in *Barker v. Lull Engineering Company*,⁹⁸ expressly preserved a reasonable expectations strand of product liability when it articulated this two-pronged test for product liability:

[W]e have concluded from this review that a product is defective in design either (1) if the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if, in light

91. See HARPER & JAMES, *supra* note 73.

92. 348 N.E.2d 571, 573 (N.Y. 1976) (“The time has come to depart from the patent danger rule enunciated in *Campo v. Scofield* . . .”).

93. See *id.* at 575.

94. *Larsen v. General Motors Corp.*, 391 F.2d 495 (8th Cir. 1968).

95. See *id.* at 501.

96. See *LeBouef v. Goodyear Tire & Rubber Co.*, 623 F.2d 985, 989 (5th Cir. 1980).

97. *Larsen*, 391 F.2d at 502.

98. 573 P.2d 443 (Cal. 1978).

of the relevant factors discussed below, the benefits of the challenged design do not outweigh the risk of danger inherent in such design. In addition, we explain how the burden of proof with respect to the latter “risk-benefit” standard should be allocated.⁹⁹

The first prong of this test keeps alive, in somewhat expanded form, the noncontroversial approach to product liability cases dealing with latent defects. But the second prong opens up vast new vistas of liability (which the *Barker* court might not have fully appreciated) that notably undermine the old approach to sequential conduct in full information settings.

Specifically, *Barker* involved a high-lift loader designed for work on level ground. The product manuals stated explicitly that it should not be used on uneven terrain, where more complex equipment was required. The plaintiff, a substitute driver with limited experience in using such equipment, was hurt when he fell from the loader. The regular driver was smart enough to call in sick. The plaintiff’s case rested on the claim that the loader should have been designed in ways that would prevent this injury, such as including outriggers to provide greater lateral stability.¹⁰⁰ The original jury refused to find for the plaintiff, and the case was remanded on the ground that the instructions did not take into account the manufacturer’s need to guard against foreseeable misuse, even when the risks in question were obvious to all concerned.¹⁰¹

Barker’s entire framework resulted in a vast misalignment of legal responsibility because the real breakdown in the system occurred at the worksite level where liability, perhaps under workers’ compensation, should apportion the loss. The employer had full information as to the limits of the machine, and the plaintiff may have had it as well. If he did not, we know who was in the better position to communicate the needed information to the worker. But to require this loader—and by implication, every loader—to be designed for uneven terrains, would make it impossible to adopt efficient segmentation of worksite equipment. The decision imposes a heavy tax on anyone who makes a cheaper loader that is proper in most situations simply because they can be misused in settings where they are unsafe. The price will increase, use will dry up, and older equipment will remain in service longer than it should.

99. *Id.* at 446.

100. *See id.* at 447–48.

101. *See id.* at 449.

To reach this misguided result, Judge Tobriner had to deny the exclusive application of the reasonable expectations test, under which the efficient solution requires each party to do its part. To do so, he appealed to an influential article by John Wade that insisted a consumer expectations test could never set the exclusive standard for liability: "In many situations . . . the consumer would not know what to expect, because he would have no idea of how safe the product could be made."¹⁰² But Wade asked the wrong question. The issue for the consumer or product user is not what else is on the market, but rather what steps to take in deciding when and how to use the equipment at hand. By that standard, there was no information gap in *Barker*, where it was painfully apparent that the loader was not designed for use on rugged terrain. Of course, additional design features found in other loaders could have been added, but only in ways that would render the loader less useful.

At this point, the twin sins of the expanded scope of products liability law become clear. First, because reasonable expectations do not do the entire job, the jury is allowed, with the benefit of hindsight, to conduct its own cost-benefit analysis of the product design. The temptation to overrate the risk that did occur, as opposed to those that might have occurred in other settings, is manifest, and it increases the prospect of inconsistent jury decisions in response to alternative hazards. Second, that judgment on product design is not made on the expectation that the product user will make normal and proper use as under the *Escola* formulation. Instead the rule is that the design must also cover cases where the product is used in an "intended and reasonably foreseeable manner,"¹⁰³ which includes all sorts of misuses against which it is possible to guard, but only at a cost. The effect of this rule is to impose a tax on the prudent to protect the foolish. No longer is it permissible to narrow the scope of use to make the equipment more efficient for its intended function. Downstream managers and professionals are now being treated as though they will misbehave, which only increases their incentives to do so.¹⁰⁴ The dangers of departing from a full information model, under which the sole duty is to let downstream users know what is expected of them, conditional on the product manufacturer delivering what he has prom-

102. *Id.* at 454 (citing John Wade, *On the Nature of Strict Tort Liability for Products*, 44 *Miss. L.J.* 825, 829 (1973)).

103. *See, e.g., Barker*, 573 P.2d at 443.

104. *See* Richard A. Epstein, *Products Liability as an Insurance Market*, 14 *J. LEGAL STUD.* 645, 653-54 (1985).

ised to do, are manifest. The dominant theme is to substitute inefficient upstream precautions for efficient downstream ones, and the seeds are planted for *Wyeth v. Levine*.

The revolution behind these post-1965 design defect cases is matched by a parallel revolution in the duty-to-warn cases that is directly relevant to pharmaceutical cases. A fair reading of the pre-1965 cases is that, as in *Pease v. Sinclair*, once the product was properly identified, additional obligations to warn were modest.¹⁰⁵ Poisons had to be labeled as such, but the labeling of most medicines rarely, if ever, generated any form of potential liability. The simplest explanation is two-fold. For widely disseminated generic products, finding information is relatively easy. And in any event, with respect to prescription drugs, the patient can rely on the professional knowledge of the physician to steer clear of trouble on pain of possible malpractice liability. Clearly this picture has some element of tension in it because many dangers from the use of medicine are not discoverable by ordinary inspection. Therefore, there would be no objection to statutes requiring certain products to be labeled before sale, which was also the case in the pre-1965 period.¹⁰⁶ Explicit warnings, provided in advance, could be required for the sale of drugs to close any remaining information gap. There was some modest expansion of warning liability in the Second Restatement, bridging the gap between old and new: "Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required."¹⁰⁷ But even that cautious sentiment does not translate into the huge expansion of duty-to-warn liability against manufacturers, which, under modern law, uses a fine-toothed comb to go through every nook and cranny of ever-long warnings.

In a fashion that was largely unanticipated, the law soon spilled over beyond the narrow confines of the Second Restatement. Early landmarks in this transformation were the 1968 case of *Davis v. Wyeth Laboratories*,¹⁰⁸ followed by *Reyes v. Wyeth Laboratories*,¹⁰⁹ which took the position that there was a duty to disclose a less than one-in-a-million chance that a polio vaccine could cause polio.¹¹⁰ One

105. See *supra* text accompanying notes 63–65.

106. See, e.g., *Osborne v. McMasters*, 41 N.W. 543, 543 (Minn. 1889) (requiring a label that said "poison").

107. RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965).

108. 399 F.2d 121 (9th Cir. 1968).

109. 498 F.2d 1264 (5th Cir. 1974).

110. See *Davis*, 399 F.2d at 124 (quoting a report from the Surgeon General: "The level of this risk can only be approximated but clearly is within range of less than I [sic] case per million doses. Since the cases have been concentrated among

possibility in both these cases was to insist that the duty to warn rested with the party who administered the drugs in the first instance—a pharmacist in *Davis*¹¹¹ and a registered nurse in *Reyes*¹¹²—neither of whom passed specific information onto their respective plaintiffs.

In a sense, it was easy to find liability since the vaccines were administered without any warning to the patient. The issue of the warning's adequacy did not have to be assessed. But the stress on upstream control of the warning process comes at a real cost. The risks in question are generic, so other sources of information are available about them. And it is risky business to insist on the disclosure of a downside risk without being sure that the far greater risk of getting polio from a wild strain is disclosed as well. As a simple matter of fact, the odds were overwhelming that the wild strain, and not the vaccine, caused the injury in light of the epidemic of polio at that time.¹¹³ The net effect of judicial intervention here is to raise the price of vaccines and reduce the likelihood of their dissemination.¹¹⁴ And even when full attention is paid to the issue of information transfer, the task of informing a widely disparate set of persons is quite formidable because there is always the opportunity for slippage in translation. Special conditions of individual plaintiffs could be overlooked; language and literacy barriers could easily exist. Finally, a conscientious doctor or nurse could use a bit of encouragement that would effectively negate the warning in full. These are all issues that are better handled downstream than by a manufacturing company that can ill-afford to monitor a process that it cannot effectively control.

The key issue in many cases, however, arises when the desired warning from the manufacturer is transferred to the recipient of the drug or vaccine. Just what should that warning say? In line with higher levels of judicial oversight, the hairsplitting begins over whether they should be regarded as adequate for the occasion.

adults the risk to this group is greater; whereas, the risk to children is exceedingly slight or practically nonexistent.”). The duty to warn was also explicitly recognized. *Id.* at 126.

111. *See id.* at 123.

112. *See Reyes*, 498 F.2d at 1270.

113. *See id.* at 1290.

114. For an estimate of the cost with respect to whooping cough vaccine, see Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 288 (1985) (noting that the whooping cough vaccine causes twenty-five cases of serious, long-term brain damage each year, while it saves 413 lives). There is with these numbers no need for ex post compensation for injuries. The huge reduction in total losses should supply compensation enough.

Overly chill-inducing warnings that “paralytic disease following the ingestion of live polio virus has been reported in individuals” can be found inadequate because they do not say that this outcome is to be expected.¹¹⁵ There is a catch-22 here. It is wrong to make those statements when the evidence does not support them. But let the jury decide that the evidence cuts the other way, and it will then deem these false statements as true, imposing liability on the strength of its own misperceptions. In consequence, the vaccine cases can usher in a destructive pattern of strategic behavior that cannot be deployed against drug manufacturers when the downstream player is the only person who bears the risk of liability: A plaintiff can settle with the doctor or other responsible intermediary and use his or her testimony to land the larger fish, the drug manufacturer. This is precisely what happened in *Wyeth v. Levine*.¹¹⁶

This trend extends beyond vaccines to other medical contexts. Perhaps the most famous (or notorious) case of this sort is *MacDonald v. Ortho Pharmaceutical Corporation*,¹¹⁷ which held that juries could find a drug company liable under a duty-to-warn theory for alleged injuries caused by birth control pills.¹¹⁸ In *MacDonald*, unlike in *Davis* and *Reyes*, no one doubted that the drug caused the twenty-six year-old woman’s stroke. The issue was whether the warning could be adequate if it did not contain the word “stroke,” even if it did warn that “[t]he most serious known side effect is abnormal blood clotting which can be fatal.”¹¹⁹ The question of the warning’s adequacy was left to the jury as was the causation question, or, more specifically, the question of how likely it would be that someone who knew that a drug could be fatal would nevertheless decide to take the drug (to avoid some alternative peril) because she did not know that the fatal injuries could be caused by a stroke. The marginal impact of the missing information has to be judged against the background information already known. In this case, it is not credible to think that this additional piece of information could alter behavior. Yet even given the tiny omission in this warning, causation in drug duty-to-warn cases will always be a jury

115. *Givens v. Lederle*, 556 F.2d 1341, 1343 (5th Cir. 1977); *see also id.* at 1345.

116. 129 S. Ct. 1187, 1191 (2009). The dangers of the odd dynamics of settlement negotiations have been well known and are clearly set out in Justice Stevens’s opinion in *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 212–13 (1994) (noting how under the credit rule the more responsible defendant can escape by paying less).

117. 475 N.E.2d 65 (Mass. 1985).

118. *See id.* at 71.

119. *Id.* at 66.

question. The error costs of false positives are thus very high indeed.

MacDonald also made clear that the drug company could not escape liability because the plaintiff was in the care of a physician who had all the relevant knowledge about her condition and the drug in question.¹²⁰ The downstream-only option was explicitly rejected in favor of a joint causation model that allowed the plaintiff to simultaneously sue the drug company under a duty-to-warn theory as well as the physician under a negligence theory by including the physician's failure to meet the requirements of an informed consent rule.¹²¹ Not surprisingly, by this time, the issue of federal preemption did surface, because the FDA had approved the warning in question. That additional warning meant that any gap in information had been addressed in the first instance by the FDA warning. But far from letting that warning stabilize the overall situation, "the FDA commissioner specifically noted that the boundaries of civil tort liability for failure to warn are controlled by applicable State law."¹²²

IV. WYETH V. LEVINE, AT LAST

We are now in a position to put all the pieces together to see how the great transformation in tort law creates a genuine tension with the objectives of the food and drug laws. In duty-to-warn cases, such as *Wyeth*, liability depends on the rejection of the full information model; the unwillingness to accept technological specialization at different stages of the production process; the adoption of extensive theories of joint causation; the disregard of downstream abuse; the ineffectiveness of disclaimers and contractual limitations; and the use of collusive settlements between plaintiffs and downstream actors. None of these elements was in play before the tort revolution of the late 1960s. In the modern environment, federal preemption becomes the last line of defense against the combined weight of all of these factors. The key point is that none of the favorable state law doctrines could be invoked unless the plaintiff could first claim that the FDA warning was inadequate. Yet just that possibility was blocked by the FDA preamble, which "interprets the act to establish both a 'floor' and a 'ceiling'" in all duty-to-warn

120. *See id.* at 69.

121. *See id.* at 138–39, 139 n.13.

122. *Id.* at 70 (citing 43 Fed. Reg. 4214 (1978)).

cases.¹²³ Once the FDA began treating its warning as setting both maximums and minimums, it blocked liability at the outset; none of the other changes in state product liability law mattered. Yet once that barrier is overcome, the combined force of all the new state law doctrines comes into play.

To understand how the state law doctrinal transformations work in unison, start with Levine's complaint, alleging that the defendant's warning was inadequate. In the words of Justice Stevens:

Although Phenergan's labeling warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, Levine alleged that it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug's therapeutic benefits.¹²⁴

The choice of methods in this case depends on this cost-benefit analysis.

The FDA concluded that a two-tiered strategy was correct. The first-line treatment was the IV-drip method, which should be used in most cases. But where the pain was acute and the system did not work, resort to the second-line treatment might be appropriate on the ground that the additional benefits might justify the riskier method, at least if all appropriate precautions were taken. It should be evident that each step in the use of the IV-push method relies on optimal downstream actions, both in the evaluation of the risk and the execution of the riskier IV-push procedure. The FDA, whose warnings were tied to the sale and distribution of the drug, could not make the individualized judgment. Downstream cooperation was essential, and allowing for recovery in the face of the occasional, if inevitable, downstream misuse by medical professionals wrecked the coordination. There is no way for good doctors to get sound information on product use if the warnings are designed to prevent abuse by incompetent ones. Warning the doctor to take extreme care makes perfectly good sense as a matter of overall system design, and this is precisely what the Wyeth warning did when it specified the quantity limitations on drug levels, the preferred mode of application, the warning signs of danger, and the extreme

123. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2006).

124. *Wyeth v. Levine*, 129 S. Ct. 1187, 1192 (2009).

level of care required.¹²⁵ I cannot think of anything that it should have done differently.

But Levine sought to make an end-run around this system. In a world of free jury discretion, the question of *whether* to use a procedure is always in play along with *how* to use the procedure. So Levine's key tactic was to attack the risk-segmentation strategy by insisting that Wyeth should have warned against any use of the IV-push method. In her view, the bottom line was that Wyeth was negligent because it had not "earnestly attempted" to strengthen the warning against any use of the IV-push method, and because the evidence had shown that the risk of gangrene "can be almost entirely eliminated through the use of the IV-drip."¹²⁶ Levine took the same line in her interview, alluding to how the company might have put profits before welfare in choosing not to issue that warning:

Pharmalot: What's your view of Wyeth and its actions?

Levine: They should've taken responsibility for changing the label It's not a bad drug. It's a good drug, for what it is. But I'd much rather throw up than lose my arm. I think they should've come out and said that, under no circumstances

125. *Id.* at 1192 n.1. The warning for "Inadvertent Intra-arterial Injection" stated:

Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Phenergan Injection, usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs. . . . Aspiration of dark blood does not preclude intra-arterial needle placement, because blood is discolored upon contact with Phenergan Injection. Use of syringes with rigid plungers or of small bore needles might obscure typical arterial backflow if this is relied upon alone. When used intravenously, Phenergan Injection should be given in a concentration no greater than 25 mg per mL and at a rate not to exceed 25 mg per minute. When administering any irritant drug intravenously, it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily. In the event that a patient complains of pain during intended intravenous injection of Phenergan Injection, the injection should be stopped immediately to provide for evaluation of possible arterial placement or perivascular extravasation.

Id.

126. *Id.* at 1192.

should the drug be administered under push IV. They didn't protect me and ensure my safety . . . They have strong economic incentives and, sometimes, those things take precedent . . . They say the FDA is their first line of defense, but if a drug company recognizes there's something that could hurt the public, they have an obligation to do something.¹²⁷

Her belated demand for a stiffer warning or categorical exclusion, however, ignores the benefit side of the cost-benefit equation. In particular, it assesses the ex ante use of the IV-push method on the strength of the ex post outcome in the one case that went awry.

The upstream side of the equation looks impenetrable for Wyeth. The last thing any jury should be allowed to do is to decide, after the fact, that instructions on the use of the IV-push method under any circumstances count as negligence per se. What is a drug company supposed to do if one jury finds that Wyeth warnings were accurate and thus denies liability, when a second jury regards the failure not to insist on banning the IV-push method as negligent? In the case where IV-push might have worked when the IV drip failed, is it negligent not to have instructed on its use? Is it possible to write and revise labels to give respect to two, or more, inconsistent judgments?

It is also unclear what the FDA should have done in response to the warning. Its chosen course of action was to insist that the Black Box warning¹²⁸ be used to highlight the risks of the IV-push system.¹²⁹ But there are real costs associated with the use of Black Box warnings. They can over-deter patients from accepting treatments whose benefits outweigh their costs. They also can deter physicians from using the Black Box treatment for fear of malpractice

127. Ed Silverman, *Preemption and Amputation: Diana Fights Wyeth*, *Pharmalot.com* (Feb. 20, 2008), <http://www.pharmalot.com/2008/02/preemption-and-amputation-diana-fights-wyeth/>.

128. According to the *Federal Register*:

Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. . . . The box must contain, in uppercase letters, a heading inside the box that includes the word "WARNING" and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the "Contraindications" or "Warnings and Precautions" section

21 C.F.R. § 201.57(c)(1) (2001).

129. See Press Release, U.S. Food and Drug Administration, FDA Requires Boxed Warning for Promethazine Hydrochloride Injection (Sept. 16, 2009), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182498.htm>.

liability with the same effects. To require a Black Box warning in response to the outcome of a single jury verdict in Vermont shows how dubious jury verdicts can reorient national policy for the worse.

The powerful influence of common law decisions creates gratuitous expense and uncertainty that feed their way back into the cycle of drug development, testing, and marketing. Properly understood, the entire duty-to-warn apparatus has become a tax on drugs, which, in some instances, may drive both old and new products off the market and, in most instances, will increase drug cost and reduce the levels of beneficial patient use. Yet any liability disclaimer for bad uses is dead in the water in the post-1965 period.¹³⁰ There is no set of warnings that could remove the risk of liability after *Wyeth* and convey the message that IV-push has a net patient benefit in some cases.

The outcome looks only worse when we look at downstream behavior. Justice Alito's dissent notes that the plaintiff's suit was originally against the physician, Dr. John Matthew, his assistant Jessica Fisch, and the local hospital.¹³¹ Justice Alito also reports that the two individual defendants settled with the plaintiff and testified against Wyeth on her behalf,¹³² but he does not comment on the obvious risk of a collusive settlement.¹³³ Justice Alito also noted that two medical defendants offered profuse apologies for their negligence, perhaps in order to increase their credibility before the jury.¹³⁴ Most instructively, he states that:

[H]er medical practitioners testified that they used IV-push in order to help her "in a swift and timely way" when she showed up at the hospital for the second time in one day complaining of "intractable" migraines, "terrible pain," inability to "bear light or sound," sleeplessness, hours-long spasms of "retching" and "vomiting," and when "every possible" alternative treatment had "failed."¹³⁵

130. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 18 (1997) ("Disclaimers and limitations of remedies by product sellers or other distributors, or waivers by product purchasers, and other similar contractual exculpations, oral or written, do not bar or reduce otherwise valid products liability claims against sellers or other distributors of new products for harm to persons.").

131. *Wyeth*, 129 S. Ct. at 1218 n.3 (Alito, J., dissenting).

132. *Id.*

133. *Cf. Booth v. Mary Carter Paint Co.*, 202 So. 2d 8, 8 (Fla. Dist. Ct. App. 1967). For critical commentary, see Lisa Bernstein & Daniel Klerman, *An Economic Analysis of Mary Carter Settlement Agreements*, 83 GEO. L.J. 2215 (1995).

134. *Wyeth*, 129 S. Ct. at 1218 (Alito, J., dissenting).

135. *Id.* at 1226 (Alito, J., dissenting).

That version of the facts jibes perfectly with Levine's. In an interview about her case, she gave the following account:

Pharmalot: But in 2000, you went to the hospital and Phenergan was administered. What happened?

Levine: I have a history of these migraines and, normally, I can manage them, but on occasion, they could be excruciating and debilitating, and I'd get hauled off to the emergency room. Normally, I'd get Demerol for the pain and then Phenergan, because the Demerol would make me nauseous. And it would be intramuscular administration, which was normally a shot in the butt. This time, they gave me a push IV and that's what caused the problem. When I woke up, I was still in pain.¹³⁶

Which way does her testimony cut? The evidence shows that Levine's case was serious, one for which neither the FDA nor Wyeth should rule the IV-push method out of bounds. It proves that the physician and his assistant knew which cases needed only the first-line approach and which cases called for the second-line approach, which, if properly executed, might have provided much needed palliation. This account of the facts makes it clear that Dr. Matthew and Ms. Fisch were not negligent in ordering the IV-push given their prior failure with the less aggressive technique. Justice Stevens, however, studiously declined to mention what their negligent actions and omissions were. He notes twice that the warnings specified that Phenergan "should be given in a concentration no greater than 25 mg/ml and at a rate not to exceed 25 mg/minute."¹³⁷ But he did not say that it was the admitted failure to follow those precise instructions that prompted their profuse apologies.

And Levine did no better when she recounted the case. She mentioned that she got the IV-push but did not utter a word about the misconduct of Matthew and Fisch. That information was, of course, included in Wyeth's brief, which reads as follows:

Although Phenergan's labeling specified a dosage range for nausea of 12.5 to 25 mg, Fisch gave respondent a 50 mg dose—double the labeled amount. Moreover, Fisch administered the entire 50 mg double dose without pausing, despite respondent's complaints of pain—pain she later described as "one of the most intense pains that [she] had ever felt" to that point—

136. Silverman, *supra* note 127.

137. 129 S. Ct. at 1192 n.1.

even though the labeling instructed that IV injection should stop immediately if the patient complains of pain.¹³⁸

It is also worth noting that an injection into an artery produces a wholly different response than an injection into a vein. Arterial pressure is roughly 100 mm (of mercury)¹³⁹ while that of venal pressure is usually, approximately a tenth that amount.¹⁴⁰ An arterial injection typically produces spurting of blood, which sometimes is strong enough to dislodge a needle. Neither of these happens with an intravenous injection. Here, the responsibility to monitor the downstream risk of arterial injection lay exclusively with Ms. Fisch. If there is a claim for negligent supervision, it lies against Dr. Mathews. Wyeth should be nowhere in the mix. At bottom, the only risks that came to pass in obvious fashion at the downstream level were the ones that the Wyeth warnings and instructions had specifically taken into account. To put it mildly, the deviation from the stated warnings “increased the risk or hazard” of the injury suffered far beyond what would have happened if the correct procedures had been followed. And the use of a theory of joint causation in these circumstances can only be described as a grotesque extension of sound tort theory, which is not made any more palatable by its constant use.

It is unassailable as a matter of law that successive actions of negligence render both defendants responsible.¹⁴¹ That is true where one defendant digs a hole that the other does not see before he falls in. But it should not hold where the first person has filled a hole into which the second decides to jump head first. Unfortunately, once the full information model is rejected, the theory of joint causation gobbles up all sorts of defendants who should be categorically insulated from liability.

These massive doctrinal errors are now compounded by settlements that build off the underlying tort doctrine. Settlements generate little complexity in two-party situations. But strategic settlements between two parties are capable of creating real negative externalities against any third person not party to the agreement. Whether the third person will be hurt depends critically on

138. Brief of Petitioner Wyeth at 20, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (citations omitted).

139. See RODNEY RHOADES & RICHARD PFLANZER, *HUMAN PHYSIOLOGY* 590–91 (4th ed. 2003).

140. See *id.* at 606–07 (“The pressure in the venules and small veins is only about 10 mm Hg.”).

141. See, e.g., *Atherton v. Devine*, 602 P.2d 634, 636 (Okla. 1979) (original wrongdoer not excused by negligence of treating physician).

how the initial settlement between the plaintiff and the first defendant(s) affects the potential liability of the remaining nonsettling defendant. Everyone agrees that once a given defendant has settled with the plaintiff he is protected from a cross-claim by a nonsettling defendant. Without that protection, no settlements will take place. But the question remains: What effect does the first settlement have on the subsequent litigation of the claims against the nonsettling defendants?

One rule, called the “proportionate share” or “carve-out” rule, holds that the plaintiff who settles with one defendant loses the entire portion of the loss attributable to that claimant. Under this rule, if the physician and assistant’s apportionment of liability is ninety percent, then ninety percent of the claim is gone whether they settle for a lot or a little. The plaintiff knows she can only recover ten percent of the total loss against the remaining defendant. This rule is used in admiralty in order to avoid strategic settlements, as ably explained in Justice Stevens’s earlier opinion in *McDermott, Inc. v. AmCLYDE*.¹⁴²

But Vermont does not follow the carve-out rule.¹⁴³ Instead, it follows the *pro tanto* rule, which gives the second defendant a credit against final judgment equal to the amount paid out by the settling defendant. Under this rule, the risks of strategic bargaining are manifest, for it is widely understood that the bulk of responsibility for compensation could be placed on the wrong defendant, which is why Justice Stevens wisely opted for the proportionate share rule in admiralty cases.¹⁴⁴

To make the difference explicit, suppose that we decide (charitably for Matthew and Fisch) that these defendants were ninety percent responsible for the \$7,400,000 settlement. If they settled for, say, \$500,000 under the Vermont rule, Wyeth is left with \$6,900,000 in damages. But if the proportionate share disappears, the opportunity for game-playing by early settlement vanishes, and the plaintiff can get only \$740,000 from Wyeth regardless of the order in which the suits against the separate defendants resolved. The credit rule thus leaves Wyeth at the mercy of the downstream players. When the dust settles, Wyeth gets slapped with the bulk of the damages, every bit of which should be paid by downstream actors.

142. 511 U.S. 202, 215–16 (1994).

143. See *Wyeth*, 129 S. Ct. at 1193 (noting Vermont’s use of the credit rule).

144. For an explanation, see *McDermott*, 511 U.S. at 217; *Am. Motorcycle Ass’n v. Super. Ct.*, 578 P.2d 899, 919–20 (Cal. 1978) (Clark, J. dissenting).

V.
BEYOND WYETH

There is little doubt that *Wyeth* poses major obstacles for preemption defenses in duty-to-warn cases brought against drug manufacturers. On its facts, *Wyeth* is an uncommon case because of the infrequency with which downstream physicians and physician assistants will be as grossly negligent as Dr. Mathews and Ms. Fisch. But the same rules on field and conflict preemption also apply to the many cases in which drugs are alleged to cause harm wholly without regard to the palpable negligence of those who administer them. The litmus test is as follows: A detailed warning will preempt only if the FDA precisely addresses potential risks in a manner that Sharkey and Rabin support.¹⁴⁵

This issue is raised by cases involving suicides committed by depressed persons, previously medicated by selective serotonin reuptake inhibitors, or SSRIs. For example, in *Colacicco v. Apotex Inc.*,¹⁴⁶ the decedent Lois Colacicco, age fifty-five, had been put on Paxil, a generic SSRI, and committed suicide less than one month later. At the time of her death, the Paxil labeling included a specific warning about the possibility of suicide attempts.¹⁴⁷ In a companion case, a patient was prescribed Zoloft for anxiety and depression, and committed suicide a week later. The label for Zoloft also explicitly warned of suicide.¹⁴⁸

In *Colacicco*, Judge Sloviter offered an extensive demonstration of FDA oversight that relied on its Psychopharmacological Drugs Advisory Committee. The Committee rejected the need for additional warnings on SSRIs, and in 1991, 1992, and 1997, the agency had rejected citizen petitions to either take Prozac (an SSRI) off the market or require additional warnings.¹⁴⁹ Judge Sloviter was cor-

145. See Rabin, *supra* note 30; Sharkey, *supra* note 30.

146. 521 F.3d 253 (3d Cir. 2008).

147. See *id.* at 256 (noting that the "Precautions" section of the label included the following language: "*Suicide*: The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for PAXIL should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose . . .").

148. See *id.* at 257 (noting that the precautionary language for Zoloft included the following: "*Suicide*—The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Zoloft (sertraline) should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.").

149. See *Colacicco*, 521 F.3d at 269.

rect to conclude that “[t]he FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.”¹⁵⁰ This makes sense. Virtually everyone who takes an SSRI is drawn from a suicide-prone portion of the population. No doubt some people on these drugs will commit suicide, but there is always an argument as to whether that desperate act was a function of the prior condition alone, the drug alone, or some combination of the above. Any effort to sort out that form of causation in an individual case is bound to fail.

It is, however, no surprise that the vast majority of deaths that occur after one goes on SSRIs results in lawsuits. This will continue to happen unless the preemption defense is rock solid. It is impossible to decide in a single case whether a person who commits suicide after a week or a month, as in these cases, did so because the drug had not yet had time to work, was not going to work at all, or pushed someone over the edge. That causation question is fair game in all cases, and is, under current law, the type of issue on which summary judgment against the plaintiff will not be granted, no matter the statistics on the rate of suicides for those who do and do not take an SSRI.¹⁵¹

What matters is not the etiology of the individual case but rather the overall distribution of suicides. We know from the recent aggregate data that the decision to place the Black Box warning on Prozac reduced its use for the reasons stated above¹⁵² and may have also caused some increase in suicides in young populations.¹⁵³ The usual—and correct—caution about the interpretation of data means that the correlations could well turn out to be

150. *Id.*

151. *See supra* text accompanying notes 120–21 (noting that causation is a question for the jury).

152. *See supra* text accompanying notes 128128–29.

153. See Robert D. Gibbons et al., *The Relationship Between Antidepressant Prescription Rates and Rate of Early Adolescent Suicide*, 163 AM. J. PSYCHIATRY 1898 (Nov. 2006), which reports as follows:

RESULTS: After adjustment for sex, race, income, access to mental health care, and county-to-county variability in suicide rates, higher SSRI prescription rates were associated with lower suicide rates in children and adolescents.

CONCLUSIONS: The aggregate nature of these observational data precludes a direct causal interpretation of the results. More SSRI prescriptions are associated with lower suicide rates in children and may reflect antidepressant efficacy, treatment compliance, better quality mental health care, and low toxicity in the event of a suicide attempt by overdose.

Id. at 1898.

positive at which point we can fully expect psychiatrists to take the necessary corrective action in the interests of their patients.

What becomes clear is that no legal regime is truly sustainable if matters as complex as this are trusted to juries to make of the evidence what they please. It is critical in this context to remember that each and every jury trial in these suicide cases has to conclude both that the drug caused, alone or in combination, the suicide and that the existence of a stronger warning would have made a difference, given that the warning in question is strong already. If a jury is seventy percent confident on each issue, the likelihood that the plaintiff has made out all elements of his or her case is still below fifty percent. Most cases of this sort will not come close to meeting the standard of a preponderance of the evidence for the entire case. The upshot is that the huge expense of defending these cases will lead to a shrinkage in the use of SSRIs, which, if appropriate, should be taken for medical reasons, not for a fear of liability gone amok.

The entire jury process represents yet another instance of how it is possible to spend a fortune in litigation only to achieve an inferior outcome to that which could be reached by using a field preemption theory to block all these suits in their inception. But that result, as Judge Sloviter notes, cannot be “seriously” pursued today.¹⁵⁴ Given that juridical reality, she conducts no independent analysis as to the soundness of her rules. Nor, it appears, will the Supreme Court, which summarily returned the case to the Third Circuit.¹⁵⁵ Originally, the two district courts split on the preemption question, and it is of course possible that the same result will arise on remand.¹⁵⁶ But as to the warnings, there is little that distinguishes Prozac from Phenergan except the mechanism of causation, which is far more complicated for the former drug than for the latter. So on balance, even I would be forced, against my better judgment, to refuse to find preemption in *Colacicco* after *Wyeth*; the doctrine is all but dead in these cases.

VI.

CONCLUSION: PREEMPTION AT LAST

Linking up all these disparate pieces reveals two essential propositions. The first goes to the historical arc of the tort law and its

154. *Colacicco*, 521 F.3d at 262.

155. See *Colacicco v. Apotex Inc.*, 129 S. Ct. 1578, 1578–79 (2009) (remanding for further consideration in light of *Wyeth*).

156. See *Colacicco*, 521 F.3d at 256–57.

relationship to federal preemption. It is simply incorrect to think that the relatively limited and sensible doctrines of the pre-1965 period gave rise to any occasion requiring the preemption issues seen today. Tension arose only after two prominent developments in product liability laws. First, courts' refusal to honor contractual limitations on liability opened up the possibility of tort liability, generating excessive deterrence—if parties had contracted as to the ideal risk allocation, ignoring such agreements constituted a deviation from optimal deterrence. Second was the decision, as a matter of state law, to treat FDA warnings as adequate with respect to drug risks. At this point, where tort liability is generally available but a federal agency has sent a different message by approving warnings, all the pressure falls on the doctrine of implied preemption. Unfortunately, Justice Stevens's profound misunderstanding of the historical evolution of tort law prompted him to adopt the mischievous substantive position articulated by Kessler and Vladeck, which wrongly assumes that the only failures of the FDA are to let too many new drugs onto the market with warnings too weak for the occasion, with no failures in the opposite direction.¹⁵⁷ If there was ever a reason to apply the doctrine of "changed circumstances" in understanding the relationship between litigation and the administrative state, this was it. Why federal preemption should ignore that profound sea change for the worse is never explained.

For whatever it is worth, *Riegel* presents the same pattern of downstream disregard of explicit warnings and instructions that *Wyeth* did. The defendant physician used the defendant's angioplasty device at pressures higher than those for which it was rated.¹⁵⁸ It could well have been that the treating physicians made a correct downstream judgment that exceptional circumstances called for exceptional treatment in disregard of the explicit warnings and instructions. Such a deviation from standard practice is, of course, not negligence per se, given just this possibility.¹⁵⁹ Right now, legislation is before Congress to remove the explicit bar to preemption in medical device cases,¹⁶⁰ so that *Riegel* could go the same way as *Wyeth*, even though the reverse result is sorely needed. But the use

157. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1203 n.12 (2009) (citing Kessler & Vladeck, *supra* note 26).

158. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008).

159. See RESTATEMENT (SECOND) OF TORTS § 288A (1965); RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 12 (Proposed Final Draft No. 1, 2005).

160. See Medical Device Safety Act of 2009, S. 540, H.R. 1346, 111th Cong. § 2 (2009) (amending Section 521 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360K, by adding the following language: "Nothing in this section shall be

of tort law in modern circumstances makes it harder to be sure that safe and effective drugs can be delivered to the public at large.

The judicial failure to understand the historical arc of the law of torts leads to a second set of unsound judgments on matters of institutional competence—the second proposition. There is nothing that erratic and expensive juries can do to make accurate scientific judgments that will allow people to plan their conduct in advance. Stability of expectations is indispensable in marketing dangerous compounds, and, for all its manifest failings, the FDA is better at this task than juries. So even if one utterly rejects market solutions to drug liability, there is still no reason to embrace the looming no-preemption regime in drug cases.

Congress's stated purpose in establishing the FDA, as taken from the 1962 amendments to the FDCA, was to "assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority"¹⁶¹ How, institutionally, does this square with a system that allows juries to override systematic decisions by a risk-averse agency without having to say a word on their behalf? If the state of Vermont wanted to impose a \$1,000 fine on Wyeth for using its Phenergan label, its action would surely be preempted. But a \$6 million tort judgment that offers none of the procedural protections of the administrative state is said to pose no threat to the integrity of the federal system.

In sum, the imposition of past liability and the threat of future liability pose a serious threat to the continued viability of what Diana Levine called a "good" drug. Yet Justice Stevens appears to be oblivious to the institutional chaos that his decisions introduce. Thus in *Bates v. Dow Agrosciences, LLC*,¹⁶² he held against preemption, stating:

A 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. The proper inquiry calls for an examination of the elements of the common-law duty at issue . . . it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action.¹⁶³

construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.").

161. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in various sections of 21 U.S.C.).

162. 544 U.S. 431 (2005).

163. *Id.* at 445.

His naively optimistic account assumes that all that can be expected in response to a major liability shock is a label change. But as the Bendectin saga of the 1980s shows, sometimes warning changes will not do the work, and drugs are pulled from the market.¹⁶⁴ That is not likely to happen with Phenergan because staggering incompetence inside the hospital is not likely to be a common occurrence. The makers of Bendectin did not have that protection because the birth defects were said—incorrectly—to arise from the prescribed usages of the product.¹⁶⁵ Yet the massive disruption that even a single trial causes to a blameless product makes the pro-preemption conclusion entirely appropriate. Unless and until someone writes a warning that can provide conscientious drug makers with a safe harbor, the entire system will have less to do with warning patients than with second-guessing drug warnings in courts.

Justice Stevens's decision to belittle conflict preemption in *Wyeth*, after the passage of the FDAAA, is indefensible.¹⁶⁶ There was no new information that indicated that the older understandings were defective. To the contrary, *Wyeth* reveals facts that show how unwise it is to adopt a per se rule against IV-push. This entire episode reaffirms the wisdom of the pre-1965 products liability tort law, which, if adopted, would allow the confused doctrine of federal preemption to fade into the woodwork. But this is a second-best world, in which state law has to be taken as a given, warts and all. Any federal preemption must be evaluated against the tort law as it is, not as it was once or should be. By that standard, *Wyeth* was decided wrongly—egregiously so.

164. For an account of the demise of Bendectin, see *Lynch v. Merrell-National Labs., Inc.*, 830 F.2d 1190, 1194 (1st Cir. 1987) (noting a decline in usage from one million new therapy starts in 1979 to zero in 1984).

165. See *id.* (noting no change in the incidence of birth defects following the removal of Bendectin from the market).

166. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1195–96 (2009).

