

FDA Regulatory Compliance Reconsidered

Carl Tobias

Follow this and additional works at: <http://scholarship.law.cornell.edu/clr>

 Part of the [Law Commons](#)

Recommended Citation

Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 Cornell L. Rev. 1003 (2008)
Available at: <http://scholarship.law.cornell.edu/clr/vol93/iss5/13>

This Article is brought to you for free and open access by the Journals at Scholarship@Cornell Law: A Digital Repository. It has been accepted for inclusion in Cornell Law Review by an authorized administrator of Scholarship@Cornell Law: A Digital Repository. For more information, please contact jmp8@cornell.edu.

FDA REGULATORY COMPLIANCE RECONSIDERED

Carl Tobias†

INTRODUCTION	1004
I. AN INTRODUCTORY WORD, MAINLY CONCERNING SCOPE ...	1004
II. FDA REGULATION'S ORIGINS AND DEVELOPMENT	1007
III. ANALYSIS OF REGULATORY COMPLIANCE'S RELEVANCE	1010
A. The Relevance Traditionally Accorded Regulatory Compliance	1010
1. <i>Early History</i>	1010
a. <i>Products Liability</i>	1010
b. <i>Regulatory Compliance</i>	1013
2. <i>Subsequent History</i>	1017
a. <i>Doctrine</i>	1017
b. <i>Justifications</i>	1019
c. <i>Application</i>	1024
B. Increased Relevance of Regulatory Compliance	1025
1. <i>Doctrine</i>	1025
2. <i>Justifications</i>	1027
3. <i>Application</i>	1030
IV. COST-BENEFIT ANALYSIS OF AN FDA REGULATORY COMPLIANCE DEFENSE	1031
A. Introduction	1031
B. Disadvantages	1031
C. Benefits	1033
D. Resolution	1034
V. SUGGESTIONS FOR THE FUTURE	1034
A. An Introductory Word	1034
B. Preferable Approaches	1035
C. Qualified Regulatory Compliance Defense	1037
D. FDA Reform	1037
CONCLUSION	1038

† Williams Professor, University of Richmond School of Law. I wish to thank Paul Catanese, Mary Davis, Michael Green, Scott Jones, James T. O'Reilly, and Noah Sachs for valuable suggestions, Beth Garrett and Tammy Longest for processing this Article, and Russell Williams for generous, continuing support. Errors that remain are mine.

INTRODUCTION

Many observers consider the Food and Drug Administration (FDA) vital for the protection of consumer health and safety. One hundred years ago, Congress established the entity that would become the FDA and authorized it to regulate foods and drugs, critical responsibilities that the agency has long discharged carefully. Throughout the past century, the FDA's regulatory power has expanded systematically, albeit gradually, while legislatures and courts in the fifty American jurisdictions broadened liability exposure for manufacturers that sold defective products that injured consumers. Observers have recently criticized the agency for overseeing pharmaceuticals too leniently, even as states increasingly narrowed manufacturers' liability exposure. For instance, numerous jurisdictions have elevated burdens of proof and circumscribed damage awards.

Substantially less clear is the relationship between FDA regulation and the products liability cause of action. Conventional wisdom holds that agency mandates and common law suits occupy distinct, albeit intersecting, universes. Comparatively few legislative and judicial bodies in the states assign great relevance to defendants' conformity with regulation, and only a small number expressly apply a "regulatory compliance defense." However, scrutiny reveals that more jurisdictions address conformity in ways that profoundly, yet subtly, affect the cause of action. Because compliance and the defense have significant effects on personal injury litigation, they require evaluation, which this Article undertakes.

Part I provides an overview of this Article's scope. Part II then descriptively analyzes the origins and expansion of FDA regulation. Part III details the weight legislatures and courts have traditionally accorded compliance and the increasing relevance that both assign to the concept, ascertaining that a growing number of states make conformity a factor that limits defendants' liability exposure. Part IV next reviews whether the disadvantages of this phenomenon outweigh the benefits and finds that they do. This Article concludes by proffering suggestions that recognize the compelling societal value of drugs, the importance of uniform manufacturer regulation, and the acute need for the essentially individualized patient consideration that common law suits afford.

I

AN INTRODUCTORY WORD, MAINLY CONCERNING SCOPE

The historical background of the regulatory compliance defense merits rather extensive assessment to help clarify the ambiguities that suffuse its beginnings, development, conceptualization, recognition, and application. The defense's relatively uncertain origins are in-

formative, as are discrepancies in how jurisdictions characterized and enforced the idea.

The growth of the defense epitomizes broader, contemporary products liability trends that have increasingly restricted manufacturers' exposure. Truncated statutes of limitations, accentuated proof burdens, narrowed liability theories, and confined damage awards are illustrative. Especially striking is some jurisdictions' requirement that consumers allegedly injured by defective prescription pharmaceuticals show that the manufacturer's negligence caused harm.¹ This Article alludes to some of the topics that I have enumerated; however, most of these considerations implicate the defense generally and thus exceed the scope of this discussion. The ways in which numerous states restrict damages can be instructive, yet ultimately explain few propositions that liability fails to illuminate.² Medical devices concomitantly warrant abbreviated treatment here, even though their FDA regulation and liability exposure for defects resemble pharmaceuticals.³ Litigation under consumer fraud and protection acts needs analogous consideration.

This Article correspondingly deemphasizes a few modern precepts that relate to the defense. The first is the learned intermediary rule, which effectively insulates from liability for failure to warn those sellers whose FDA-approved labels correctly advise prescribing physicians.⁴ This Article examines the learned intermediary rule as one significant concomitant of the defense in warning litigation. Another is preemption, which commentators aptly describe as a "close cousin"⁵ of the defense, but this approach involves the question,

¹ The states rejected strict liability in tort, which is generally easier for injured consumers to prove. *See, e.g.*, *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) ("[A] drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability . . ."); *see also* *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991) (same). *See generally* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1998) (prescribing negligence liability for manufacturers of defective prescription drugs and medical devices).

² *See infra* note 161.

³ *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (providing for the safety of medical devices); *see also* Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2123 (2000); *infra* note 19.

⁴ *See, e.g.*, *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 914 (W. Va. 2007) (describing, and refusing to adopt, the traditional learned intermediary rule); *Perez v. Wyeth Labs Inc.*, 734 A.2d 1245, 1254-55 (N.J. 1999) (describing the same rule); *see also* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d) & cmt. d; DAN B. DOBBS, *THE LAW OF TORTS* § 365, at 1010-12 (2000); 2 DAVID G. OWEN, M. STUART MADDEN & MARY J. DAVIS, *MADDEN & OWEN ON PRODUCTS LIABILITY* § 22:9, at 566-68 (3d ed. 2000); *infra* notes 128-40 and text accompanying notes 204-05.

⁵ DAVID G. OWEN, *PRODUCTS LIABILITY* § 14.3, at 886 (2005). Justice Ruth Bader Ginsburg articulates a regulatory compliance defense by recognizing that a "medical device manufacturer may be entitled to interpose a regulatory compliance defense based on the

under the Supremacy⁶ and Commerce Clauses,⁷ of when a federal requirement overrides state products law with which it appears to conflict.⁸ Preemption deserves minimal analysis here because it has received discussion elsewhere, including other Articles in this symposium.⁹

This Article's focus is, thus, an FDA regulatory compliance defense under strict liability and negligence tort rubrics, and in particular liability for defective warnings, rather than under implied or express warranty theories.¹⁰ The Article stresses drug regulation; FDA comprehensiveness, expertise, and stringency and the varying ways that pharmaceuticals affect individual patients highlight crucial aspects of the defense and comprise the best case for its application.¹¹

FDA's approval of the premarket application," while she proffers the defense as one justification for rejecting the notion that medical-device premarket approval preempts state tort law. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1013, 1020 (2008) (Ginsburg, J., dissenting).

⁶ U.S. CONST. art. VI, cl. 2.

⁷ *Id.* art. I, § 8, cl. 3.

⁸ See generally *Riegel*, 128 S. Ct. 999 (balloon catheters); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (pacemakers); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (cigarettes); DOBBS, *supra* note 4, § 373, at 1033–37 (explaining how federal law preempts state tort law); LAURENCE TRIBE, *AMERICAN CONSTITUTIONAL LAW* § 6-28, at 1172–79 (3d ed. 2000) (describing the history and statutory interpretation of the preemption doctrine); Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 907–24 (1996) (discussing the history and modern use of preemption); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2053–60 (2000) (describing how federal law may preempt state regulations and tort liability rules).

⁹ See James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics & a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, pt. XIII (2008); Catherine T. Struve, *Greater and Lesser Powers of Tort Reform: The Primary Jurisdiction Doctrine and State-Law Claims Concerning FDA-Approved Products*, 93 CORNELL L. REV. 1039, 192–206 & nn.7–22 (2008). For sources discussing preemption outside of this symposium, see, for example, OWEN, *supra* note 5, § 14.4, at 895–920; Catherine M. Sharkey, *Preemption By Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007) (describing an increasing trend of federal preemption of state law). I do not analyze the government contractor defense, which allows defendants that manufacture products under a federal government contract to avoid liability in certain situations, because it is a "more distant cousin" of the regulatory compliance defense. OWEN, *supra* note 5, § 14.3, at 881–86; see also *Boyle v. United Techs. Corp.*, 487 U.S. 500, 511–12 (1988) (holding state law displaced under the government contractor defense).

¹⁰ Warning defects merit precedence because courts rarely deem FDA-approved drugs defectively designed. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f (1998). A few states treat warranty similarly to strict liability. See, e.g., *Sensenbrenner v. Rust, Orling & Neale, Architects, Inc.*, 374 S.E.2d 55, 58 (Va. 1988).

¹¹ See Richard C. Ausness, *The Case for a "Strong" Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1239–57 (1996) (describing the rationale and operation of the regulatory compliance defense and the best-case idea); Noah, *supra* note 8, at 926–60 (discussing justifications for the regulatory compliance defense and the best-case idea); cf. Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 501–07 (1997) (assessing the possible effects of a regulatory compliance defense); Rabin, *supra* note 8, at 2074–78 (same). See generally OWEN, *supra* note 5, § 14.3, at 892–94 (arguing that FDA approval should not immunize drug manufacturers from liability).

Yet this Article also explores how other agencies regulate other products and how courts and legislatures articulate the defense for them. Those questions inform comprehension of FDA regulation and application of the defense. The Article will review statutory *and* case developments because legislative entities have assumed considerable responsibility for adopting the defense, primarily under the “tort reform” label at the behest of manufacturers and insurers.

Finally, certain ambiguities complicate appreciation of the defense. One is the notion’s genesis. Many jurisdictions fail to recognize the precept explicitly, while a number that apparently invoke the concept assign different relevance to evidence of conformity when ascertaining whether manufacturers were negligent or purveyed defective goods.¹² Therefore, the term “regulatory compliance defense” applies only to tort schemes in which the manufacturer completely avoids liability for selling purportedly defective items, rather than the relatively limited, different weight that a number of states accord conformity.

II

FDA REGULATION’S ORIGINS AND DEVELOPMENT

Numerous authors have chronicled the beginnings and expansion of FDA regulation.¹³ However, some treatment is appropriate to increase understanding of the comprehensive duties the agency fulfills—through control of research, development, approval, marketing, and distribution of pharmaceuticals and other goods—as well as the interplay between FDA regulation and products liability.

In 1906, Congress enacted the Federal Food and Drug Act as a response to growing concerns, principally over food safety,¹⁴ that were depicted most tellingly in accounts like *The Jungle* by Upton Sinclair.¹⁵ This law created the entity that would become the FDA and authorized it to regulate food and drugs.¹⁶ Thereafter, Congress passed the New Drug Amendments of 1938, which increased FDA power and revamped the new drug approval system.¹⁷ In 1962, Congress prescribed major amendments that updated and broadened FDA

¹² See OWEN, *supra* note 5, § 14.3, at 888–91 (describing differing approaches to the regulatory compliance notion).

¹³ See, e.g., RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 109–12 (2006). See generally Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753 (1996) (describing the history of statutes and policies enlarging the FDA’s jurisdiction).

¹⁴ Merrill, *supra* note 13, at 1758.

¹⁵ See UPTON SINCLAIR, *THE JUNGLE* (1906).

¹⁶ See Act of June 30, 1906, ch. 3915, 34 Stat. 768.

¹⁷ See Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938); Merrill, *supra* note 13, at 1797–1801.

responsibility for food and drugs.¹⁸ In 1976, lawmakers passed the Medical Device Amendments, which granted the FDA expansive authority over the mechanisms and resembles somewhat its drug regulatory power.¹⁹ During 1997 and 2000, Congress instituted substantial amendments that enhanced FDA control of and authority over imported pharmaceuticals.²⁰

A commissioner appointed by the President heads the FDA, which relies mainly on career specialists who possess expertise in medicine, science, technology, and public policy.²¹ The agency concomitantly depends on expert advisory committees that render opinions on new drug applications and related issues.²² Congress delegated to the agency responsibility for balancing pharmaceutical risks and therapeutic advantages in the new drug approval process, which mandates that the FDA regulate pharmaceutical safety and effectiveness as well as drug labels.²³ Like most similar agencies in the European Union and other technologically advanced nations, the FDA has received much criticism and has experienced scandals.²⁴

These concerns notwithstanding, the agency's technical demands, review procedures, and scientific quality make U.S. pharmaceutical regulation one of the world's most stringent regimes, ensuring that "the American drug supply continues to be among the safest in the world."²⁵ For instance, broad FDA power to mandate thorough research and experimentation—including in vitro, in vivo, and clinical testing—and good manufacturing practices before it approves the labeling, marketing, and sale of new drugs, in addition to the agency's postapproval requirements and other expansive authority, mean that FDA regulation is strict and generally protects consumers from defective pharmaceuticals. Indeed, many observers have

¹⁸ See Drug Amendments of 1962, Pub. L. No. 87-781, tit. 1, 76 Stat. 780, 780-92. See generally SAM PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS (1974) (discussing the impact of the 1962 Amendments).

¹⁹ See Merrill, *supra* note 13, at 1806-09. Medical devices and their regulation are important, but the FDA has regulated devices more recently and less pervasively than drugs, as to which regulation and products liability are representative. Thus, this Article stresses them and deemphasizes medical devices. See *supra* note 3 and accompanying text.

²⁰ See Act of Oct. 28, 2000, Pub. L. No. 106-387, §§ 745-746, 114 Stat. 1549, 1549A-35 to -41; Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 406, 111 Stat. 2296, 2369-70.

²¹ See 21 U.S.C. § 393(d)(1) (2000).

²² See Rabin, *supra* note 8, at 2075.

²³ See 21 U.S.C. § 393(d)(1).

²⁴ See, e.g., Robert Pear & Andrew Pollack, *Leader of the F.D.A. Steps Down After a Short, Turbulent Tenure*, N.Y. TIMES, Sept. 24, 2005, at A1; Jared A. Favole & Corey Boles, *Lawmakers Fault FDA on Heparin*, WALL ST. J., Apr. 30, 2008, at A2.

²⁵ FDA's Foreign Drug Inspection Program: Hearings Before House Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 110th Cong. 15 (2007) (statement of Andrew von Eschenbach, FDA Comm'r), available at http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.110107.vonEschenbach-testimony.pdf; see also *supra* note 11.

long contended that the new drug approval regime is excessive and unduly cumbersome, protracted, and cautious, and that it sometimes stymies and prevents expeditious marketing of pharmaceuticals that could save lives and decrease pain.²⁶

Even staunch advocates of FDA regulation, harsh critics of strict liability, and avid champions of the defense acknowledge numerous concerns implicating the agency. Some claim that the FDA is overly politicized and solicitous of large pharmaceutical manufacturers while not sufficiently responsive to legislative mandates and drug consumers and that it improved the reporting scheme for post-approval adverse events too slowly, has committed occasional errors, and is risk averse.²⁷ Moreover, FDA regulation can be so narrow and particular that it fails to capture activities at the margins, while controls that address science and technology become outdated faster.²⁸ Limited resources and authority may prevent the FDA from being an effective arbiter of optimal, rather than minimal, safety.²⁹ The agency does not comprehensively address important contemporary realities of marketing, such as drug manufacturer advertising directly to consumers, or of the American health care system, in which patients have reduced access to the doctors who prescribe their pharmaceuticals.³⁰ For example, the FDA may approve a new drug before it receives thorough experimental data proving the drug is safe and efficacious because the agency depends substantially on manufacturer information and is pressured to certify pharmaceuticals quickly, while the FDA might elevate broader societal health goals over individual patients' needs.³¹ Recent threats to product, food, and drug supplies emanating from imports have generally fueled these criticisms of agency safety regula-

²⁶ See, e.g., EPSTEIN, *supra* note 13, at 119–26; W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1442–49 (1994).

²⁷ See, e.g., Teresa Moran Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1153–61 (1988); Peter Schuck, *A Cure for What Ails the FDA*, AM. LAWYER, June 26, 2007, available at <http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1182503155456>.

²⁸ See, e.g., DOBBS, *supra* note 4, § 224, at 573; OWEN, *supra* note 5, § 14.3, at 887.

²⁹ See, e.g., OWEN, *supra* note 5, § 14.3, at 890. *But see* Noah, *supra* note 8, at 965.

³⁰ See, e.g., Julie Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 N. ENG. J. MED. 673, 677–80 (2007) (studying recent direct-to-consumer advertising and the FDA's tepid response to it); Gary Taubes, *Do We Really Know What Makes Us Healthy?*, N.Y. TIMES, Sept. 23, 2007, § 6 (Magazine), at 52. See generally *infra* notes 131–40 and accompanying text (describing judges' justifications for restricting the scope of the learned intermediary rule and how the FDA does not comprehensively address important contemporary realities of marketing). For a general description of how drug companies market pharmaceuticals directly to consumers, see EPSTEIN, *supra* note 13, at 161–64.

³¹ See, e.g., DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., THE FOOD AND DRUG ADMINISTRATION'S OVERSIGHT OF CLINICAL TRIALS 22–24 (2007) (recommending improvements to FDA research monitoring); *infra* notes 119–20 and accompanying text.

tion.³² In 2007, lawmakers passed bipartisan reform legislation addressing a number of issues, especially deficient agency power and resources.³³

III

ANALYSIS OF REGULATORY COMPLIANCE'S RELEVANCE

A. The Relevance Traditionally Accorded Regulatory Compliance

1. *Early History*

The early history of the regulatory compliance defense and products liability warrants scant review here because the first judicial decisions addressing the concept rarely implicated products liability, applied the doctrine to the FDA, or recognized an explicit defense, and because numerous scholars have already canvassed the background.³⁴ However, the FDA was one of the initial agencies that Congress authorized to regulate safety, and much confusion surrounds the defense.³⁵ Thus, careful scrutiny might increase appreciation of the FDA and elucidate the regulatory compliance defense.

a. *Products Liability*

Although *Winterbottom v. Wright*,³⁶ an 1842 English case, was the major source of liability for injuries caused by defective products in the United States, the traditional rationales underlying strict liability for abnormally dangerous activities, especially blasting, seemingly had importance.³⁷ Certain judges and scholars find that American courts misinterpreted *Winterbottom* to require privity of contract with a defective product seller before injured parties could recover.³⁸ This view precluded liability except for articles that judges found inherently or

³² See David Barboza, *Scandal and Suicide in China: A Dark Side of Toys*, N.Y. TIMES, Aug. 23, 2007, at C1; Eric Lipton, *Safety Agency Faces Scrutiny Amid Changes*, N.Y. TIMES, Sept. 2, 2007, at A1; Renae Merle, *Food Scrutiny Varies Widely in Split System of Inspection*, WASH. POST, Aug. 5, 2007, at A1.

³³ See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823; Gardiner Harris, *Senate Takes Up Bill to Change Drug Agency Operations*, N.Y. TIMES, May 1, 2007, at A1; Sarah Rubinstein et al., *Congress Expands FDA Oversight on Drug Safety*, WALL ST. J., Sept. 21, 2007, at A12.

³⁴ See, e.g., OWEN, *supra* note 5, § 14.3, at 886-95; Rabin, *supra* note 8, at 2049-53 (describing early judicial articulation of the regulatory compliance defense).

³⁵ Andrew E. Costa, *Negligence Per Se Theories in Pharmaceutical & Medical Device Litigation*, 57 ME. L. REV. 51, 88-89 (2005); Noah, *supra* note 8, at 964-67.

³⁶ (1842) 152 Eng. Rep. 402 (Exch. P.).

³⁷ See DOBBS, *supra* note 4, §§ 346-351, at 950-68 (describing the development of American strict liability doctrine).

³⁸ See *infra* notes 40-41, 44-45, 48; see also Frances H. Bohlen, *The Basis of Affirmative Obligations in the Law of Torts*, 53 AM. L. REG. 273, 337 (1905); Fleming James, Jr., *Products Liability*, 34 TEX. L. REV. 44, 44 & n.4 (1955).

imminently dangerous.³⁹ Throughout the remainder of the nineteenth century, American jurisdictions essentially denied products liability relief to harmed individuals who were not in privity with the manufacturer.

This situation dramatically changed in the early 1900s. The New York Court of Appeals removed the privity barrier to negligence claims with its 1916 ruling in *MacPherson v. Buick Motor Co.*⁴⁰ The Washington Supreme Court analogously lifted the bar for implied warranty claims over adulterated food in the 1913 case of *Mazzetti v. Armour & Co.*⁴¹ That same court also recognized an express warranty products liability cause of action in its 1932 *Baxter v. Ford Motor Co.* decision.⁴² Implied warranty liability only gradually expanded from foods to drugs to products for intimate bodily use, like shampoo, from 1913 until 1960.⁴³

In 1960, the New Jersey Supreme Court decided *Henningsen v. Bloomfield Motors, Inc.*,⁴⁴ ushering in the contemporary products liability era.⁴⁵ The justices recognized an implied warranty cause of action for selling a defective motor vehicle,⁴⁶ and it seemed that this ruling, together with applicable Uniform Commercial Code sections addressing physical harm caused by defective goods, would chart the future

³⁹ See, e.g., *Huset v. J.I. Case Threshing Mach. Co.*, 120 F. 865 (8th Cir. 1903) (threshing machine); *Thomas v. Winchester*, 6 N.Y. 397 (1852) (medicine). See generally OWEN, *supra* note 5, §§ 1.2–1.3, at 20–34, § 9.1, at 562–63 (describing the evolution of strict liability before U.S. courts); Cornelius W. Gillam, *Products Liability in a Nutshell*, 37 OR. L. REV. 119, 153–55 (1958) (discussing various ways to avoid the privity requirement).

⁴⁰ 111 N.E. 1050 (N.Y. 1916). See generally James A. Henderson, *MacPherson v. Buick Motor Company: Simplifying the Facts While Reshaping the Law*, in TORTS STORIES 41 (Robert L. Rabin & Stephen D. Sugarman eds., 2003) (describing the factual background of *MacPherson* and explaining how those facts were determinative in the court's opinion); Walter Probert, *Applied Jurisprudence: A Case Study in MacPherson v. Buick and Its Precedents*, 21 U.C. DAVIS L. REV. 789 (1988) (examining how the New York Court of Appeals interpreted its precedents in *MacPherson*).

⁴¹ 135 P. 633 (Wash. 1913). See generally William Prosser, *The Assault on the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1106–10 (1960) (describing jurisdictions' decisions permitting consumers to bring suits against food manufacturers without privity).

⁴² 12 P.2d 409 (Wash. 1932); *accord* *Rogers v. Toni Home Permanent Co.*, 147 N.E. 2d 612 (Ohio 1958) (removing the privity requirement when a manufacturer offers an express warranty); see OWEN, *supra* note 5, § 3.4, at 137–38 (describing the *Baxter* court's holding).

⁴³ See, e.g., *Mazetti*, 135 P. at 636 (holding a food manufacturer subject to an implied warranty of merchantability); Prosser, *supra* note 41, at 1104–14 (describing how courts expanded strict liability to a variety of products).

⁴⁴ 161 A.2d 69 (N.J. 1960).

⁴⁵ See DOBBS, *supra* note 4, § 353, at 974; OWEN, *supra* note 5, § 1.3, at 23.

⁴⁶ *Henningsen*, 161 A.2d at 84. The implied warranty cause of action is a hybrid of contract and tort law. See Mark Geistfeld, *Escola v. Coca Cola Bottling Co.: Strict Products Liability Unbound*, in TORTS STORIES, *supra* note 40, at 229, 230 (arguing that Justice Traynor's *Escola* concurrence helped “free” products liability from contractual restrictions).

application of products liability.⁴⁷ However, California became the first jurisdiction to employ strict liability in tort for defective articles with the 1963 *Greenman v. Yuba Power Products* case,⁴⁸ and the American Law Institute (ALI) promulgated Section 402A of the 1965 *Restatement (Second) of Torts*, which designated this as the appropriate products liability theory.⁴⁹

The cause of action rapidly swept the nation so that by 1980, virtually all jurisdictions had adopted strict liability, most through court opinions.⁵⁰ Courts identified numerous justifications for adopting the theory. These include the belief that manufacturers are better able to control risks and spread losses, that negligence is too difficult to prove, and that strict liability encourages manufacturers to exercise greater care and has a deterrent effect.⁵¹ Regarding pharmaceuticals, strict liability theory acknowledges that drugs have inherent risks but can also save lives and ameliorate health concerns.⁵² Thus, many states allow manufacturers to sell pharmaceuticals without incurring liability if the company adequately warns the consumer or physician.⁵³ Courts may then impose liability if a manufacturer fails to provide these warnings.⁵⁴

⁴⁷ See U.C.C. § 2-314(2)(c) (1958) (an implied warranty of merchantability includes the requirement that goods must be "fit for the ordinary purposes for which such goods are used").

⁴⁸ 377 P.2d 897, 901 (Cal. 1963); see *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 438-39 (Cal. 1944) (Traynor, J., concurring) (suggesting that the defendant be held strictly liable for defects that occurred while the product was within the defendant's control); G. EDWARD WHITE, *TORT LAW IN AMERICA: AN INTELLECTUAL HISTORY 198-200* (2d ed. 2003) (describing the underlying *Escola* rationale in terms of risk allocation); Geistfeld, *supra* note 46, at 230 (remarking that Justice Traynor's *Escola* concurrence "helped set in motion the forces that would lead to the widespread adoption of strict products liability"); William Prosser, *The Fall of the Citadel*, 50 MINN. L. REV. 791, 793-94 (1966).

⁴⁹ RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965) ("One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling the product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.").

⁵⁰ See W. PAGE KEETON ET AL., *PROSSER AND KEETON ON THE LAW OF TORTS* § 98, at 694 (5th ed. 1984) (observing that Section 402A of the Second Restatement adopting strict liability "swept the country . . . until at the present writing [in 1984] nearly all states have adopted some version of it"); WHITE, *supra* note 48, at 244-48 (describing the "unexpected persistence" of strict liability from 1980-2000) (citations omitted).

⁵¹ See KEETON ET AL., *supra* note 50, § 98, at 692-93.

⁵² See Rabin, *supra* note 8, at 2076 (arguing that additional tort liability would ensure that manufacturers compensate consumers for injury because regulatory compliance focuses only on safety).

⁵³ See *Brown v. Superior Court*, 751 P.2d 470, 477-78 (Cal. 1988); *supra* notes 10-11 and accompanying text.

⁵⁴ See *Green & Shultz*, *supra* note 3, at 2121 (analyzing warnings and arguing that the consumer expectations test overdeters manufacturers of pharmaceuticals); *supra* notes 10-11 and accompanying text; cf. *Brown*, 751 P. 2d at 477-78 (holding that if the manufac-

Around 1980, state legislatures began to codify products doctrine, mainly because of apparent concerns regarding the breadth of liability, in ways that narrowed defendants' exposure.⁵⁵ These measures ordinarily governed statutes of limitations, proof burdens, theories of recovery, and damages.⁵⁶ The statutes, however, frequently neglected to address the issue of regulatory conformity.⁵⁷

b. *Regulatory Compliance*

State legislatures and courts traditionally accorded manufacturers' compliance with agency regulation minimal or no weight.⁵⁸ Practically all legislative entities left to courts the articulation of considerable substantive tort law,⁵⁹ including products liability and the relevance of conformity with agency regulation and FDA commands.⁶⁰ Judges in turn enunciated the doctrinal rules applied through case development by articulating the common law.

Multiple sources contributed to the origination and growth of the regulatory compliance defense. Professor Rabin and others assert that the 1892 U.S. Supreme Court decision in *Grand Trunk Railway Co. v. Ives*⁶¹ was the first authoritative pronouncement on the defense.⁶² The railroad defendant asserted that compliance with regulatory mandates should be determinative of whether it had exercised sufficient care.⁶³ The Court disagreed, holding that "neither the legislature nor railroad commissioners can arbitrarily determine in advance what shall constitute ordinary care . . . [for] a railroad company at a crossing, in every particular case which may afterwards arise[.] . . . [E]ach case must stand upon its own merits, and be decided upon its own facts and circumstances."⁶⁴

Professor Rabin suggests that some might view Justice Oliver Wendell Holmes's "cryptic" opinion in *Baltimore & Ohio Railroad Co. v.*

turer has provided the physician with adequate warnings and the physician has communicated the warnings to the patient, the patient has no cause of action).

⁵⁵ See, e.g., *infra* notes 158–61 and accompanying text.

⁵⁶ See, e.g., *infra* notes 158–61 and accompanying text.

⁵⁷ See, e.g., *infra* notes 158–61 and accompanying text.

⁵⁸ See Noah, *supra* note 8, at 964–65 (arguing that courts' traditional disregard of a party's regulatory compliance is outdated).

⁵⁹ See, e.g., *Grand Trunk Ry. Co. of Can. v. Ives*, 144 U.S. 408, 427 (1892) (providing a clear example of the Supreme Court's rejection of the regulatory compliance defense); see also *Pokora v. Wabash Ry. Co.*, 292 U.S. 98, 105 (1934) (providing a second example of judicial involvement because of the Supreme Court's warning of the "need for caution in framing standards or behavior that amount to rules of law").

⁶⁰ See, e.g., *Pokora*, 292 U.S. at 105; *Ives*, 144 U.S. at 427.

⁶¹ 144 U.S. 408.

⁶² Rabin, *supra* note 8, at 2050; see also *Ives*, 144 U.S. at 427 (holding that a party may have to "do much more than is required by positive enactment").

⁶³ *Ives*, 144 U.S. at 416–17.

⁶⁴ *Id.* at 427.

*Goodman*⁶⁵ as articulating the regulatory compliance defense.⁶⁶ Justice Holmes espoused the judge-made rule of law that one who approaches an unmarked grade crossing must look, listen, stop, exit the vehicle, and reconnoiter before proceeding.⁶⁷ However, Professor Rabin also finds that Justice Benjamin Cardozo's 1934 *Pokora v. Wabash Railway Co.* opinion limited the effect of *Goodman*, as the Justice admonished judges to be cautious when "framing standards of behavior that amount to rules of law" in confronting diverse factual situations.⁶⁸

Another potential, but less clear, source for the defense was apparently the related idea of "negligence per se" or "negligence as a matter of law," which can expose a person who violates a statute or regulation to liability.⁶⁹ This notion allows judges to derive tort standards from applicable criminal laws, provided that the litigant seeking to benefit from the rule shows that he or she is within the class the law protects, the danger is the harm contemplated by the statute, and that articulating the rule would reflect sound public policy.⁷⁰ The class, hazard, and policy strictures that litigants invoking this doctrine must satisfy and the legal effect of nonconformity with such a rule—whether it is negligence per se, a rebuttable presumption of negligence, or merely some evidence of negligence—resemble the dynamics of the regulatory compliance defense.⁷¹ For instance, when treating the regulatory compliance defense, courts often state that the risk entailed needs to be the danger that the agency control specifically addresses,⁷² which is like the hazard factor, while judges correlate

⁶⁵ 275 U.S. 66 (1927).

⁶⁶ Rabin, *supra* note 8, at 2049.

⁶⁷ See *Goodman*, 275 U.S. at 69–70. A specific rule, if followed, may be viewed as the precursor to a party's later regulatory defense.

⁶⁸ 292 U.S. 98, 105 (1934); see Rabin, *supra* note 8, at 2049–50. With rare exceptions, the Supreme Court did not resolve products cases after the mid-twentieth century. See, e.g., *E. River S.S. Corp. v. Transamerica Delaval, Inc.*, 476 U.S. 858, 874–76 (1986) (holding that economic injury is not a cognizable products liability cause of action in admiralty).

⁶⁹ See, e.g., *Martin v. Herzog*, 126 N.E. 814, 814–15 (N.Y. 1920) (holding intestate's failure to use his lights during the night to be per se contributory negligence because a state statute prescribed the use of lights); *Osborne v. McMasters*, 41 N.W. 543, 543 (Minn. 1889) ("[W]here a statute or municipal ordinance imposes . . . a specific duty for the protection or benefit of others, [a person who] neglects to perform that duty is liable . . ."); *Dobbs*, *supra* note 4, §§ 133–142, at 311–34 (describing techniques for interpreting how statutes apply to tort issues).

⁷⁰ See, e.g., *Perry v. S.N.*, 973 S.W.2d 301, 307 (Tex. 1998) (holding that "the absence of a relevant common law duty should be considered in deciding whether to apply negligence per se to the [criminal code's] reporting provision"); *Clinkscales v. Carver*, 136 P.2d 777, 778–79 (Cal. 1943) (holding that the defendant's failure to stop at a stop sign, despite an "irregularity" with the governing county ordinance related to the particular stop sign, was nonetheless conclusive of the defendant's negligence); *Osborne*, 41 N.W. at 544 (holding that the injury sustained must be within the class of injuries that the statute aims to prevent).

⁷¹ See, e.g., *supra* notes 58–60, 70 and accompanying text.

⁷² See *infra* notes 76–78 and accompanying text.

the value assigned evidence of manufacturer conformity with its relevance and the stringency of agency control, which resembles the effect that courts accord statutory violations in negligence *per se* cases.⁷³

Once courts allowed plaintiffs to show that a defendant's contravention of a legislative or agency mandate constituted negligence *per se*, defendants understandably argued that compliance with either should establish reasonable care as a matter of law.⁷⁴ Manufacturers often depended on this argument in the nascent field of products litigation, and judicial opinions verify this heritage.⁷⁵ A New York court afforded a trenchant illustration: "Just as failure to comply with a statute and regulations promulgated thereunder is evidence of negligence, full compliance therewith is some evidence of the exercise of due care" ⁷⁶ Analogously instructive was a Pennsylvania court's rejection of the argument: "Compliance with a law or administrative regulation relieves the actor of negligence *per se*, but it does not establish as a matter of law that due care was exercised."⁷⁷ A Texas court similarly observed that "mere compliance does not as a matter of law, in all cases, mean that the party is free from negligence."⁷⁸

Before the rise of modern products liability almost fifty years ago, no state legislature had prescribed the defense and courts issued few opinions regarding it.⁷⁹ Relevant decisions rarely governed products liability, applied to the FDA, or mentioned an express regulatory compliance defense.⁸⁰ Illustrative of notable exceptions were several opinions that implicated Chloromycetin.⁸¹ Most applicable was the California Supreme Court's ruling in *Stevens v. Parke, Davis & Co.*⁸² The court acknowledged the learned intermediary rule but rejected the regulatory compliance defense, asserting that "mere compliance with [FDA] regulations or directives as to warnings . . . may not be sufficient to immunize the manufacturer or supplier," as they could "be only minimal in nature, and [if] the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled."⁸³ Moreover, the court stated that an "adequate warning to the profession may be

⁷³ See *supra* notes 58–60, 69–70 and accompanying text.

⁷⁴ See *infra* notes 76–78 and accompanying text.

⁷⁵ See *infra* notes 76–78 and accompanying text.

⁷⁶ *Phillips v. Roux Labs., Inc.*, 145 N.Y.S.2d 449, 251 (N.Y. App. Div. 1955).

⁷⁷ *Berkebile v. Brantly Helicopter Corp.*, 281 A.2d 707, 710 (Pa. Super. Ct. 1971).

⁷⁸ *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387, 394 (Tex. Civ. App. 1968).

⁷⁹ See *Viscusi et al.*, *supra* note 26, at 1457–63 (describing how the *Restatement (Second) of Torts* sparked a revolution in products liability).

⁸⁰ See generally *id.* at 1457–75 (outlining how the "common law regulates pharmaceuticals").

⁸¹ See, e.g., *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973).

⁸² *Id.*

⁸³ *Id.* at 661.

eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given."⁸⁴

Typical were rulings outside the drug area, such as First Circuit and Pennsylvania Superior Court opinions that tersely rejected agency conformity as a defense⁸⁵ in part by relying on Section 288 in the *Restatement (Second) of Torts*,⁸⁶ which provided that an agency command is only a minimum floor.⁸⁷ The New York Appellate Division proffered a similar, cursory assertion: although a manufacturer's compliance with a regulation "is some evidence of the exercise of due care,' it does not preclude a conclusion that he was negligent."⁸⁸ There were exceptions. For instance, a minuscule number of judges applied a complete defense,⁸⁹ but a greater number accorded conformity less, although variable, weight as evidence.⁹⁰ Informative regarding the first notion is an Oregon Supreme Court holding that "a drug, properly tested, labeled with appropriate warnings, approved by the [FDA], and marketed properly under federal regulation, is, as a matter of law, a reasonably safe product."⁹¹ Equally instructive about the second position is a Kansas Supreme Court articulation: "Compliance is evidence of due care and that the conforming product is not defective, and may be conclusive in the absence of a showing of special circumstances."⁹²

The early history of products liability litigation indicates that substantial confusion attended the regulatory compliance defense's recognition and application.⁹³ Its origins are somewhat uncertain. Most jurisdictions failed to adopt the concept in explicit terms, and a number of states that apparently relied upon the precept granted con-

⁸⁴ *Id.*

⁸⁵ *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1028 (1st Cir. 1973); *Berkebile v. Brantley Helicopter Corp.*, 281 A.2d 707, 710 (Pa. Super. Ct. 1971).

⁸⁶ *Raymond*, 484 F.2d at 1028; *Berkebile*, 281 A.2d at 710.

⁸⁷ RESTATEMENT (SECOND) OF TORTS § 288C (1965).

⁸⁸ *Sherman v. M. Lowenstein & Sons, Inc.*, 282 N.Y.S.2d 142, 143-44 (N.Y. App. Div. 1967) (quoting *Phillips v. Roux Labs., Inc.*, 145 N.Y.S.2d 449, 251 (N.Y. App. Div. 1955)).

⁸⁹ *See, e.g., infra* note 91 and accompanying text.

⁹⁰ *See, e.g., infra* note 92 and accompanying text.

⁹¹ *Lewis v. Baker*, 413 P.2d 400, 404 (Or. 1966). *Lewis's* holding remained good law for fewer than ten years, however. It was overruled by *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 534-35 (Or. 1974). In this ruling, the Oregon Supreme Court relied heavily on the California Supreme Court's holding in *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973).

⁹² *Jones v. Hittle Serv., Inc.*, 549 P.2d 1383, 1390 (Kan. 1976). *See generally* OWEN, *supra* note 5, § 14.3, at 886-91 (providing background information about the regulatory compliance defense, including descriptions of legislative and judicial reform efforts).

⁹³ *See supra* notes 61-78 and accompanying text.

formity different weight.⁹⁴ More courts than legislatures articulated the idea, which may have added to this general confusion.⁹⁵

2. *Subsequent History*

a. *Doctrine*

As recounted above, state legislatures and judges conventionally assigned defendants' compliance with agency regulation no or minimal significance.⁹⁶ Before 1980, legislative bodies ceded to judges the articulation of substantive products liability law, including the value given conformity with agency and FDA mandates.⁹⁷ Quite a few jurisdictions have yet to confront the issue of agency or FDA compliance, but virtually all courts that have addressed it have assigned conformity no or de minimus relevance, and even legislatures that codified products doctrine frequently neglected to address this question. Many courts simply determined that compliance was not relevant or specifically rejected defendants' requests to recognize the defense, and a few eliminated or cabined the learned intermediary rule that judges often applied by effectively merging it with the compliance defense in warning suits.⁹⁸ However, several courts accorded conformity somewhat greater, albeit little, importance.⁹⁹ The jurisdictions that assigned compliance weight limited its value by, for example, attributing conformity relevance as a minimum or a floor. An Oklahoma Supreme Court decision afforded a thorough, nuanced rendition: "It is the widely held view that the FDA sets *minimum* standards for drug manufacturers as to design and warnings. . . . [C]ompliance with these minimum standards does not necessarily complete the manufacturer's duty."¹⁰⁰ The Eighth Circuit similarly held that "FDA regulations are generally minimal standards of conduct."¹⁰¹ The U.S. District Court for the Eastern District of Texas also stated that "numerous courts over the years have recognized that . . . [FDA] regulations set out minimum requirements that drug manufacturers must follow which may be supplemented by state tort laws which are stronger."¹⁰² The Eastern District of Pennsylvania analogously held that "compliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not

⁹⁴ See *supra* notes 79–92 and accompanying text.

⁹⁵ See *supra* notes 55–78 and accompanying text.

⁹⁶ See *supra* Part III.A.1.b.

⁹⁷ See *supra* Part II.A.1.b.

⁹⁸ See *infra* notes 100–26 and accompanying text.

⁹⁹ See *infra* notes 100–26 and accompanying text.

¹⁰⁰ *Edwards v. Basel Pharm.*, 933 P.2d 298, 302 (Okla. 1997) (citations omitted) (emphasis added).

¹⁰¹ *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989).

¹⁰² *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 882 (E.D. Tex. 2005).

necessarily absolve the manufacturer of all liability. Manufacturers must meet state safety requirements."¹⁰³

Indeed, the ALI's 1965 *Restatement (Second) of Torts* echoed this judicial authority, stating that a government safety standard is a "minimum and does not prevent a finding that a reasonable man would have taken additional precautions where the situation is such as to call for them."¹⁰⁴ The 1998 *Restatement (Third) of Torts: Products Liability* similarly advised that a court appropriately considers compliance when ascertaining defectiveness with regard to the dangers that the mandate seeks to avoid but "does not preclude as a matter of law a finding of product defect."¹⁰⁵ Moreover, comment e provides that safety regulations "generally are only minimum standards" and "establish a floor of safety below which sellers fall only at their peril."¹⁰⁶ Professor David Owen's authoritative contemporary hornbook *Products Liability* summarizes: "[I]t is fundamental law that governmental safety standards adopt only a minimum safety floor below which an actor may face criminal sanctions but above which due care may require the actor to be more cautious."¹⁰⁷ In accord with these basic tenets, "virtually all courts reject the general idea of a regulatory compliance defense to products liability" based on the major theories of negligence, warranty, and strict liability in tort.¹⁰⁸

Some judges have assigned conformity greater, although still relatively little, weight as evidence, and even for these judges, the impor-

¹⁰³ *Mazur v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990).

¹⁰⁴ RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965); accord KEETON ET AL., *supra* note 50, § 36, at 233 (A statutory "standard is no more than a minimum, and it does not necessarily preclude a finding that the actor was negligent in failing to take additional precautions."). Section 402A did not explicitly address regulatory compliance. See RESTATEMENT (SECOND) OF TORTS § 402A.

¹⁰⁵ RESTATEMENT (THIRD) OF PRODS. LIAB. § 4(b) (1998). This section reflects the more defendant-friendly hue of the 1998 Restatement. See Marshall S. Shapo, *In Search of the Law of Products Liability: The ALI Restatement Project*, 48 VAND. L. REV. 631, 660-64 (1995).

¹⁰⁶ RESTATEMENT (THIRD) OF PRODS. LIAB. § 4 cmt. e. Compliance with such a regulation may prove that a product is not defective as a matter of law if the regulation "was promulgated recently . . . the specific standard addresses the very issue . . . before the court . . . [and] the deliberative process by which the safety standard was established was full, fair, thorough and reflected substantial expertise." *Id.*; see also Rabin, *supra* note 8, at 2051 (stating that in section 4, comment e, the *Restatement (Third) of Torts: Products Liability* hints at "the strikingly more complex contemporary regulatory environment").

¹⁰⁷ OWEN, *supra* note 5, § 14.3, at 888; accord DOBBS, *supra* note 4, § 373, at 1034.

¹⁰⁸ OWEN, *supra* note 5, § 14.3, at 888. See, e.g., *Ake v. Gen. Motors Corp.*, 942 F. Supp. 869, 873 (W.D.N.Y. 1996) (holding that although a party's "'compliance with a statute may constitute some evidence of due care,'" a court is still free to find that a party's product is defective (quoting Lugo by Lopez v. LjN Toys, Inc., 539 N.Y.S.2d 922, 924 (N.Y. App. Div. 1989))); *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 519 (Ga. 1997) (holding that compliance with a federal statute is insufficient under Georgia state law to establish that a party has exercised due care); *Goodman v. Wenco Foods, Inc.*, 423 S.E.2d 444, 452 (N.C. 1992) (holding that a party's compliance with state and federal regulations is "no bar to recovery on a breach of warranty theory").

tance of compliance varies. The courts appear to invoke a case-specific analysis that encompasses the evidence's importance as well as the stringency and efficacy of regulation—which the fact-finder considers in ascertaining whether a manufacturer was careful or sold a product that lacks defects—yet any regulatory compliance is not dispositive.¹⁰⁹ For example, the Ohio Supreme Court held that FDA package-insert approval fails to “relieve the drug manufacturer from providing a warning of ‘all potential adverse reactions inherent in the use of the drug of which the manufacturer, being held to the standards of an expert in the field, knew or should have known to exist at the time of marketing.’”¹¹⁰ The Georgia Supreme Court analogously instructed that conformity is only “a piece of the evidentiary puzzle” rather than “an impenetrable shield from liability,” which “render[s] a manufacturer’s choice of design immune from liability,” but is a factor the jury reviews in addressing “whether the product design selected was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware.”¹¹¹ Numerous judges espouse similar formulations. Illustrative is the Eighth Circuit, which has mentioned that “FDA approval is not a shield to liability,”¹¹² while a plethora of federal district courts have admonished that compliance fails to relieve drug sellers of liability.¹¹³ Professor Owen asserts that these ideas have been the “rule since the early days of modern products liability law” and are “as firmly entrenched today as ever.”¹¹⁴

b. *Justifications*

There are myriad justifications for according conformity no or little relevance. Many judges have not been very forthcoming with these reasons, perhaps deeming the ideas so obvious that explication is unnecessary. Most judges essentially announced, with minimal elaboration, that regulatory compliance is irrelevant, tendered only de minimus support, or left their rationales implicit. For example, the

¹⁰⁹ OWEN, *supra* note 5, § 14.3, at 888.

¹¹⁰ Wagner v. Roche Labs., 671 N.E.2d 252, 258 (Ohio 1996) (quoting Seley v. G.D. Searle & Co., 423 N.E.2d 831, 834 (Ohio 1981)); *see also* Schaerrer v. Stewart’s Plaza Pharmacy, Inc., 79 P.3d 922, 928 (Utah 2003) (stating that FDA compliance and comment k do “not extinguish strict liability claims based on manufacturing flaws or inadequate warnings”).

¹¹¹ Doyle, 481 S.E.2d at 521 (citation omitted); *accord* Gable v. Vill. of Gates Mills, 784 N.E.2d 739, 748 (Ohio Ct. App. 2003), *rev’d on other grounds*, 816 N.E.2d 1049 (Ohio 2004).

¹¹² Hill v. Searle Labs., 884 F.2d 1064, 1068 (8th Cir. 1989); *see also supra* note 101 and accompanying text.

¹¹³ *See, e.g.*, Peters v. Astrazeneca, LP, 417 F. Supp. 2d 1051, 1056 (W.D. Wis. 2006); Mazur v. Merck & Co., 742 F. Supp. 239, 247 (E.D. Pa. 1990).

¹¹⁴ OWEN, *supra* note 5, § 14.3, at 889. Other scholars concur that the rule is enconced. *See, e.g.*, DOBBS, *supra* note 4, § 224, at 573, § 373, at 1034; Noah, *supra* note 8, at 967.

North Carolina Court of Appeals simply mentioned that "compliance with governmental standards is not determinative of whether the product is defective,"¹¹⁵ while the Ohio Court of Appeals merely remarked that "compliance in no manner insulates [a defendant] from liability . . . [but is] a factor to be weighed by the jury."¹¹⁶ However, others have been clearer or less terse, and their views receive analysis below.

Some judges have implicitly expressed concerns that involve agencies generally and the FDA in particular.¹¹⁷ These emphasize limitations on the regulatory process, such as agency capture, dependence on manufacturers, imprecision, narrowness, politicization, risk aversion, insufficient funding, stringency, and power.¹¹⁸ The Ohio Supreme Court grounded its explanation that "FDA approval of the package insert" fails to absolve sellers mainly on the view that "the FDA does no tests of its own, but bases its approval on data submitted by the manufacturer."¹¹⁹ The Sixth Circuit also remarked that a plaintiff introduced an

articulable basis for disregarding an FDA finding—in this case the finding that ritodrine was effective. . . . [T]he individual studies relied on by the FDA were insufficient to support a finding of efficacy as found by the FDA Advisory Committee, and the pooled data requested by the Advisory Committee was statistically invalid.¹²⁰

Judges have also invoked modern products liability goals, although some courts have cryptically treated the subject apparently because they found the justifications so clear that greater evaluation was unwarranted. Numerous judges have alluded to, or implicitly or effectively relied on, a compensation rationale—asserting that restoring individuals as much as possible to the condition they occupied before allegedly defective items harmed them is a leading products objective, so that the regulatory compliance defense frustrates its achievement by essentially leaving a "compensation gap."¹²¹ A second, rather im-

¹¹⁵ *Red Hill Hosiery Mill, Inc. v. MagneTek, Inc.*, 582 S.E.2d 632, 637 (N.C. Ct. App. 2003).

¹¹⁶ *Gable*, 784 N.E.2d at 748.

¹¹⁷ For commentator concerns, see *supra* notes 27–32 and accompanying text. Judges may be understandably reluctant to criticize the FDA, as it rarely makes blatant errors.

¹¹⁸ See *supra* notes 27–32 and accompanying text.

¹¹⁹ *Wagner v. Roche Labs.*, 671 N.E.2d 252, 258 (Ohio 1996). The court recognized that package insert contents "must reflect a balance between the need for conciseness and a drug company's temptation to include every potential effect . . . to avoid legal liability. . . ." [T]his FDA policy does not relieve the drug manufacturer from providing a warning
Id. Some may even argue that drugs are almost always less safe than they are thought to be, as testing rarely reveals *all* adverse effects.

¹²⁰ *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 538 (6th Cir. 1993). See generally OWEN, *supra* note 5, § 14.3, at 892–94 (discussing *Tobin* and the FDA approval's effect on products liability suits).

¹²¹ See Rabin, *supra* note 8, at 2073. But see Schuck, *supra* note 27.

portant objective that the defense can undercut is deterring manufacturers—both the one before the court and others that could behave similarly—from engaging in the tortious actions that led to the suit.

Several judges have referred to the compensation and deterrence rationales, particularly in asserting that sellers need to exercise reasonable care and manufacture safe articles, regardless of regulatory conformity. For example, the Georgia Supreme Court refused to assign regulatory compliance dispositive value, as that would undermine Congress's "paramount purpose" of reducing injuries and saving lives and allow "only minimum standards, as a matter of law, to represent [Georgia's] standard of care."¹²² "That outcome," said the court, "would 'have the perverse effect of granting complete immunity from design defect liability to an entire industry.'"¹²³ The Oklahoma Supreme Court analogously remarked that "[i]t has long been the concern of this state to protect the health and safety of its citizens."¹²⁴ Therefore, conformity with FDA "minimum standards does not necessarily complete the manufacturer's duty."¹²⁵ This court and the Eastern District of Pennsylvania also stated that requiring manufacturers to comply with a state law duty to warn *and* FDA regulations could increase pharmaceutical safety.¹²⁶ A closely related notion is manufacturer punishment for selling a defective article that harms a consumer. No court has expressly invoked a punishment rationale, but opinions that allude to compensation and deterrence appear to hint at the concept.¹²⁷

Another justification some courts have enunciated is that the defense—especially when applied with the learned intermediary rule in pharmaceutical duty-to-warn cases—eviscerates the modern products action as a "communicative or representational tort" based on the manufacturer's representations.¹²⁸ In essence, courts are concerned

¹²² Doyle v. Volkswagenwerk Aktiengesellschaft, 481 S.E.2d 518, 520–21 (Ga. 1997).

¹²³ *Id.* at 520–21 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 487 (1996)).

¹²⁴ Edwards v. Basel Pharm., 933 P.2d 298, 302 (Okla. 1997).

¹²⁵ *Id.* at 302; *see also* State *ex rel.* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 913 (W. Va. 2007) (finding a drug manufacturer responsible for protecting "ultimate consumers" in the context of rejecting the learned intermediary rule).

¹²⁶ Edwards, 933 P.2d at 303; *see* Mazur v. Merck & Co., 742 F. Supp. 239, 248 (E.D. Pa. 1990) (asserting that vaccine safety may be improved through civil judgments). Punishment is meant to deter harmful conduct and correspondingly to encourage socially responsible activity, like designing goods or including warnings as to risks that exceed agency standards, which involves the sale of consumer products. *See id.*

¹²⁷ *See, e.g.*, Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc., 133 F. Supp. 2d 162, 178 (E.D.N.Y. 2001) (observing that tort law may fill gaps in the criminal law by punishing conduct that deserves condemnation despite not being expressly criminal).

¹²⁸ *See* Marshall S. Shapo, *A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment*, 60 VA. L. REV. 1109, 1225 (1974) (describing the action as a communicative or representational tort and how courts analyze pharmaceutical companies' representations in tort actions); *see also supra* note 4.

about manufacturer compliance with a duty to provide accurate, clear information and warnings of possible harm, namely through labels and advertisements that manufacturers convey to physicians and patients.¹²⁹ A few judges have indicated that the defense alone, and particularly together with the learned intermediary rule, does not account for the contemporary realities of marketing, the American health care system, and FDA regulation.¹³⁰

In *Perez v. Wyeth Labs., Inc.*, the New Jersey Supreme Court thoroughly explicated these propositions.¹³¹ The Justices severely restricted the learned intermediary doctrine, which emphasizes warning the prescribing physician, as based upon antiquated views of the health care regime and pharmaceutical advertising.¹³² The court mandated manufacturers' warnings in the direct-to-consumer advertising context.¹³³ The court observed that managed care organizations now provide medical services, patients buy drugs in grocery pharmacies and related outlets, and sellers advertise products to consumers directly "on the radio, television, the Internet, billboards on public transportation, and in magazines."¹³⁴ The Justices found that numerous problems attend this consumer advertising, which facilitates the manipulation of information on safety and efficacy by presenting a diluted representation of drug risks.¹³⁵

The West Virginia Supreme Court endorsed these descriptive accounts and criticisms, which it reiterated practically verbatim in declining to adopt the learned intermediary "exception" to a general warning responsibility.¹³⁶ The Justices agreed with *Perez* that direct-to-consumer

advertising obviates each of the premises upon which the [learned intermediary] doctrine rests: ". . . (1) reluctance to undermine the doctor patient-relationship; (2) absence in the era of 'doctor knows best' of need for the patient's informed consent; (3) inability of

¹²⁹ See, e.g., Barbara J. Evans & David A. Flockhart, *The Unfinished Business of U.S. Drug Safety Regulation*, 61 FOOD & DRUG L.J. 45, 51-52 (2006).

¹³⁰ See *infra* notes 131-40 and accompanying text; see also *supra* notes 30-32 and accompanying text.

¹³¹ 734 A.2d 1245 (N.J. 1999); see also *infra* notes 144-45, 156-57 and accompanying text.

¹³² See *Perez*, 734 A.2d at 1246-47.

¹³³ See *id.* at 1257.

¹³⁴ *Id.* at 1246-47. See generally Rabin, *supra* note 8, at 2080-82 (describing the premises of tort liability based on overpromotion).

¹³⁵ *Perez*, 734 A.2d at 1252-53 (citations omitted). See generally OWEN, *supra* note 5, § 9.6, at 613-14 (describing *Perez's* holding and expressing concern that other courts will not adopt its reasoning).

¹³⁶ State *ex rel.* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 910-11, 914 (W. Va. 2007).

drug manufacturer to communicate with patients; and (4) complexity of the subject.”¹³⁷

The court also based its judgment on the policy notions that drug manufacturers “benefit financially from the sales of prescription drugs and possess the knowledge regarding potential harms, [but it is] consumers who bear the significant health risks of using those drugs” even though they possess inferior knowledge respecting drug side effects.¹³⁸ Certain 1970s opinions, most notably *Stevens v. Parke, Davis & Co.*,¹³⁹ analogously remarked that juries could ascertain that a drug company failed to warn adequately by so “watering down” warnings and overpromoting a drug that it caused prescribing physicians to ignore the warnings.¹⁴⁰

A few judges seemingly appreciated that, to the extent common law products liability actions operate as an informal regulatory system, the defense undercuts its efficacy. For instance, successful litigation can encourage manufacturers to test drugs with greater rigor before seeking approval, improve labeling, closely track subsequent usage, and promote pharmaceuticals with doctors and consumers no more aggressively than therapeutic benefits and risks warrant. These dynamics, thus, ostensibly fill a “regulatory gap” created when the agency discharges its responsibilities insufficiently.¹⁴¹ The defense of regulatory conformity undercuts this informal system.

¹³⁷ *Id.* at 910 (quoting *Perez*, 731 A.2d at 1255); see also *Edwards v. Basel Pharm.*, 116 F.3d 1341, 1343 (10th Cir. 1997) (acknowledging that for some courts, when all of the learned intermediary rule’s premises are absent, it “simply drops out of the calculus”).

¹³⁸ See *Karl*, 647 S.E.2d at 913; accord *Schaerrer v. Stewart’s Plaza Pharmacy*, 79 P.3d 922, 932 (Utah 2003); see also *supra* note 51 and accompanying text.

¹³⁹ 507 P.2d 653 (Cal. 1973).

¹⁴⁰ See *id.* at 660–61; *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971), *abrogated on other grounds by Kaczowski v. Bolubasz*, 421 A.2d 1027 (Pa. 1980); *Love v. Wolf*, 38 Cal. Rptr. 183, 197 (Cal. Ct. App. 1964).

¹⁴¹ The FDA may approve a new drug before it is certain about its safety and effectiveness because it relies heavily on industry experimentation and is under intense pressure to grant expeditious approval. However, Congress requires the FDA to consider broader societal norms and safety concerns; thus, expedited approvals can prompt trade-offs that may not fully account for a patient’s specific circumstances. For examples of this phenomenon, see *supra* notes 31, 119–20 and accompanying text. Some judicial opinions are laconic, even Delphic; yet others are not. Thus, the scholarly commentary’s textual analysis is unnecessary but may supplement judicial opinions when warranted. Scholars, including Professors Dan Dobbs, Teresa Schwartz, and Marshall Shapo, as well as Owen and Rabin, have recited a standard litany encompassing these ideas, as well as some additional ones. For example, more scholars than judges suggest that the defense may thwart other products liability goals, such as safeguarding individual autonomy and bodily integrity, retribution, and affording plaintiffs their day in court. For a thorough catalog of these principles, see David G. Owen, *The Moral Foundations of Products Liability Law: Toward First Principles*, 68 NOTRE DAME L. REV. 427 (1993).

c. *Application*

The courts that accorded conformity no or limited relevance applied these propositions similarly. For example, courts that considered compliance irrelevant had the fact-finder ascertain whether the consumer showed by a preponderance of the evidence that the manufacturer had acted negligently or was strictly liable because it purveyed defective goods, regardless of conformity.¹⁴²

A few courts even specifically abrogated or dramatically restricted the learned intermediary doctrine. That doctrine, when combined with the regulatory compliance defense, effectively absolves sellers of the responsibility to warn consumers.¹⁴³ For instance, the New Jersey Supreme Court's *Perez v. Wyeth Labs.* decision held that the learned intermediary doctrine should not protect pharmaceutical manufacturers that seek to influence patient choices through mass advertising from the obligation to warn consumers directly.¹⁴⁴ The justices stated that a "patient must be informed of material risks"—those dangers to which a reasonable patient would likely attach significance in choosing a needed pharmaceutical.¹⁴⁵ The West Virginia Supreme Court analogously declined to recognize a learned intermediary "exception" and imposed a duty to warn consumers on pharmaceutical manufacturers.¹⁴⁶ The *Restatement (Third) of Torts* also contemplates that a drug manufacturer will afford consumers adequate risk information directly when it "knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings."¹⁴⁷

Many judicial opinions according compliance with agency commands greater value have not been especially informative, particularly

¹⁴² See, e.g., *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027–28 (1st Cir. 1973) (rejecting the regulatory compliance defense in favor of an analysis of how the product performs under ordinary circumstances, "a standard fully consistent with the Restatement Rule which is geared to protect the consumer from conditions not contemplated or apparent that are unreasonably dangerous for *normal* handling and consumption").

¹⁴³ See *supra* notes 131–40 and accompanying text (discussing judicial treatment of the learned intermediary rule); *infra* notes 158–61 and accompanying text (documenting legislative implementation of the regulatory compliance defense).

¹⁴⁴ See *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1263 (N.J. 1999); see also *supra* notes 131–35, *infra* notes 156–57 and accompanying text.

¹⁴⁵ See *Perez*, 734 A.2d at 1257 (citation omitted); see also *Wagner v. Roche Labs.*, 671 N.E.2d 252, 258 (Ohio 1996). See generally OWEN, *supra* note 5, § 9.6, at 613–14 (discussing the *Perez* decision).

¹⁴⁶ *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 914 (W. Va. 2007).

¹⁴⁷ RESTATEMENT (THIRD) OF PRODS. LIAB. § 6(d)(2) (1998). However, the ALI does retain the learned intermediary rule. *Id.* at § 6(d)(1). Comment e supplies a caveat regarding an exception for drugs advertised directly to consumers. See OWEN, *supra* note 5, § 9.6, at 614 n.74; Rabin, *supra* note 8, at 2081; see also *Karl*, 647 S.E.2d at 911–13 (invoking the Restatement to support rejection of the learned intermediary rule and the imposition of a duty to warn).

about the evidentiary weight to give compliance. Typical were Illinois and New York courts, which merely announced that conformity to agency requirements was “some evidence” that the manufacturer was not negligent but observed that it was not controlling or determinative, which thus permitted the fact-finder to assign it some value.¹⁴⁸

Judges who regarded compliance as a minimum or floor attributed little significance to conformity and had the fact-finder decide whether the evidence of conformity adduced indicated that the manufacturer exercised reasonable care or sold a nondefective product. For instance, the Oklahoma Supreme Court and the Eastern District of Pennsylvania instructed that agency regulations are a minimum and their satisfaction does not absolve a manufacturer of liability.¹⁴⁹ Those judges who granted compliance enhanced importance ostensibly applied a case-specific analysis that enabled the fact-finder to accord the information differing weight vis-à-vis its relevance and strength as well as the efficacy and stringency of relevant FDA controls.

B. Increased Relevance of Regulatory Compliance

1. *Doctrine*

Although most legislatures and courts have ascribed conformity minimal or no value, a small yet increasing number have afforded compliance expanded relevance. Some jurisdictions have assigned it considerable or greater weight, and a few actually treat the precept as a complete defense. More legislatures than judges have adopted these changes in essence as tort reform substantially at the instigation of manufacturers, distributors, and insurers.¹⁵⁰

Certain courts accord compliance great value. A Texas appellate court ascertained that “[c]ompliance with government regulations is strong evidence, although not conclusive, that a machine was not defectively designed.”¹⁵¹ Many Fifth Circuit rulings applying Texas law have observed that compliance is “strong and substantial evidence that a product is not defective.”¹⁵²

¹⁴⁸ See *Jonescue v. Jewel Home Shopping Serv.*, 306 N.E. 2d 312, 316 (Ill. App. Ct. 1973); *Sherman v. M. Lowenstein, Inc.*, 282 N.Y.S.2d 142 (N.Y. App. Div. 1967); accord *Gable v. Vill. of Gates Mills*, 784 N.E. 2d 739, 748 (Ohio App. 2003), *rev'd on other grounds*, 816 N.E.2d 1049 (Ohio 2004).

¹⁴⁹ See *Mazur v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990); *Edwards v. Basel Pharm.*, 933 P.2d 298, 302 (Okla. 1997); see also *supra* notes 100–03 and accompanying text.

¹⁵⁰ See, e.g., *infra* notes 158–61.

¹⁵¹ *Sims v. Washex Mach. Corp.*, 932 S.W.2d 559, 565 (Tex. App. 1995).

¹⁵² See, e.g., *Lorenz v. Celotex Corp.*, 896 F.2d 148, 150–51 (5th Cir. 1990); accord *Dartez v. Fibreboard Corp.*, 765 F.2d 456, 471 (5th Cir. 1985); *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1144 (5th Cir. 1985).

A few courts have asserted that manufacturer conformity with agency strictures establishes reasonable care or nondefectiveness "as a matter of law."¹⁵³ For instance, the Utah Supreme Court, relying on comment k in the *Restatement (Second) of Torts* § 402A, held that prescription pharmaceuticals "cannot, as a matter of law, be defective if approved by" the FDA but admonished that approval "does not extinguish strict liability claims based on manufacturing flaws or inadequate warnings."¹⁵⁴ Related was the California Supreme Court's decision to adopt "for tort purposes the existing legislative and administrative standard of care," which "mandate[d] nonprescription drug package warnings in English only."¹⁵⁵

The New Jersey Supreme Court ascertained that manufacturer compliance with FDA regulations on pharmaceutical warnings in the direct-to-consumer advertising context generally supported a rebuttable presumption of adequacy.¹⁵⁶ The court explained: "For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims. By definition, the advertising will have been 'fairly balanced.'"¹⁵⁷

The Arkansas and Washington legislatures instruct that regulatory compliance makes an article nondefective,¹⁵⁸ while a Michigan statute treats FDA-approved pharmaceuticals as neither defective nor unreasonably dangerous.¹⁵⁹ Laws in Colorado, Indiana, Kansas, Michigan, North Dakota, Tennessee, and Utah establish that compliance yields a rebuttable presumption that the manufacturer's goods lack

¹⁵³ See *Beatty v. Trailmaster Prods., Inc.*, 625 A.2d 1005, 1014 (Md. 1993); see also *Jones v. Hittle Serv., Inc.*, 549 P.2d 1383, 1390 (Kan. 1976).

¹⁵⁴ *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003) (citing *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991); RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965)).

¹⁵⁵ *Ramirez v. Plough, Inc.*, 863 P.2d 167, 176, 177 (Cal. 1993); see also *Rabin*, *supra* note 8, at 2083-84.

¹⁵⁶ *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1259 (N.J. 1999).

¹⁵⁷ *Id.* The *Perez* court also limited the scope of the learned intermediary rule and criticized drug manufacturers' use of direct-to-consumer advertising. *Id.* at 1262-63; see also *supra* notes 131-35, 144-45 and accompanying text (restricting the learned intermediary rule and criticizing direct-to-consumer advertising). *But cf.* OWEN, *supra* note 5, § 9.6, at 613-14 (suggesting it is tautological that a plaintiff is unable to hold liable a manufacturer that satisfies a regulation for exercising the care mandated if there were no reason to be safer, as nonliability is predicated on the exercise of due care rather than regulatory conformity).

¹⁵⁸ See ARK. CODE ANN. § 16-116-105(a) (2006); WASH. REV. CODE ANN. § 7.72.050 (West 2007).

¹⁵⁹ See MICH. COMP. L. ANN. § 600.2946(5) (1996); see also *Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp. 2d 825, 828 (E.D. Mich. 2003); *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 130 (Mich. 2003).

defects,¹⁶⁰ while a New Jersey statute instructs that FDA-approved labels constitute adequate manufacturer warnings.¹⁶¹

2. Justifications

It is difficult to ascertain why legislatures in a number of states have assigned conformity greater weight, as these bodies rarely proffer explicit justifications for their actions. The courts of some jurisdictions have been equally uninformative and appear simply to declare the relevant doctrine. A few courts, however, were instructive.

Perhaps most essential, numerous courts touted the superior institutional competence that agencies, especially the FDA, possess vis-à-vis lay juries. The California Supreme Court's decision in *Ramirez v. Plough, Inc.*¹⁶² affords a very thorough explication of this rationale. The court contended that "legislative and administrative bodies are particularly well suited" for the task of deciding when second-language warnings are appropriate, recounted "the FDA's experience with foreign-language patient package inserts for prescription drugs," and chose not to adopt a case-by-case judicial articulation.¹⁶³ The court found resolution of the underlying substantive question "peculiarly susceptible to legislative and administrative investigation and determination, based upon empirical data and consideration of the viewpoints of all interested parties," as it required polycentric decision making grounded in much empirical information that the agency was best able to collect, analyze, and synthesize.¹⁶⁴ Thus, the court rea-

¹⁶⁰ COLO. REV. STAT. § 13-21-403(1)-(2) (2007); IND. CODE § 34-20-5-1(2); KAN. STAT. ANN. § 60-3304(a) (2005); MICH. COMP. L. ANN. § 600.2946(4); N.D. CENT. CODE § 28-01.3-09 (2006); TENN. CODE ANN. § 29-28-104 (2000); UTAH CODE ANN. § 78-15-6(3) (2002); see also *O'Gilvie v. Int'l Playtex, Inc.*, 821 F.2d 1438, 1443 (10th Cir. 1987); *Ehllis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198-99 (D.N.D. 2002) (examining the North Dakota statute); *Duffee v. Murray Ohio Mfg. Co.*, 879 F. Supp. 1078, 1084-85 (D. Kan. 1995); *Rogers ex rel. Rogers v. Cosco, Inc.*, 737 N.E.2d 1158 (Ind. Ct. App. 2000) (expanding on the Indiana statute), *overruled on other grounds by Schultz v. Ford Motor Co.*, 857 N.E.2d 977, 986 (Ind. 2006); *Hughes v. Lumbermans Mut. Cas. Co., Inc.*, 2 S.W.3d 218 (Tenn. Ct. App. 1999) (expanding on the Tennessee statute).

¹⁶¹ See N.J. STAT. ANN. § 2A:58C-4 (2000); see also *Perez v. Wyeth Labs Inc.*, 734 A.2d 1245, 1259 (N.J. 1999) (assessing the New Jersey statute). Most states accord little or no relevance to regulatory compliance when determining damages. A few states assign varying relevance, especially to punitive damages. One allows punitive damages only when the defendant knowingly withheld or misrepresented information that FDA regulations mandated be submitted and it was material and relevant to the injury sustained. See N.J. STAT. ANN. § 2A:58C-5. A few others proscribe these damages for FDA-approved drugs. See ARIZ. REV. STAT. ANN. § 12-701(A)(1) (2003); OHIO REV. CODE ANN. § 2307.80(C) (2005); OR. REV. STAT. § 30.927 (2007); UTAH CODE ANN. § 78-18-2.

¹⁶² 863 P.2d 167 (Cal. 1993).

¹⁶³ *Id.* at 174-75.

¹⁶⁴ *Id.* at 176.

soned that deferring to, and capitalizing on, the agency's "superior technical and procedural lawmaking resources" was justified.¹⁶⁵

Oregon Supreme Court Justice Hans Linde's 1978 concurring opinion in *Wilson v. Piper Aircraft Corp.*¹⁶⁶ provides a second valuable example. The justice astutely found that

once the common-law premise of liability is expressed as a balance of social utility so closely the same as the judgment made in administering safety legislation, it becomes very problematic to assume that one or a sequence of law courts and juries are to repeat that underlying social judgment de novo as each sees fit.¹⁶⁷

Instead, when a product's design receives agency-supervised testing and approval, no additional balance of whether it is unreasonably dangerous

needs to be struck by a court or a jury unless . . . the standards of safety and utility assigned to the regulatory scheme are less inclusive or demanding than the premises of the law of products liability, or . . . the regulatory agency did not address the allegedly defective element of the design or in some way fell short of its assigned task.¹⁶⁸

Related justifications for according compliance more value implicate agency controls. For example, deference to the FDA in *Ramirez* was based on arguments that it would "preserve . . . uniformity and clarity [and] avoid adverse impacts upon the warning requirements mandated by the federal regulatory scheme."¹⁶⁹ The Utah Supreme Court adverted to the "elaborate regulatory system overseen by the FDA" in fashioning a defense.¹⁷⁰ The California Supreme Court in *Brown* analogously observed

¹⁶⁵ *Id.* at 177. However, the court carefully admonished that a duty-to-warn suit could lie if "materially misleading" Spanish-language advertising led to the drug's purchase. *Id.* See generally Rabin, *supra* note 8, at 2083-84 (describing the *Ramirez* ruling as narrowly applicable only to dual language drug warning labels).

¹⁶⁶ 577 P.2d 1322, 1332 (Or. 1978) (citation omitted). Justice Linde was addressing the FAA, but his views are equally applicable to the FDA.

¹⁶⁷ *Id.* at 1334 (citations omitted).

¹⁶⁸ *Id.* at 1335. He found the factors especially compelling when the agency "certification of a design represents a more deliberate, technically intensive program to set and control a given level of safety in priority to competing considerations than is true of many run-of-the-mill safety regulations." *Id.* at 1333; see also *Dawson v. Chrysler Corp.*, 630 F.2d 950 (3d Cir. 1980) (expressing analogous sentiments when urging Congress to provide guidance on motor vehicle safety regulation and observing that generalist judges and lay juries are ill equipped to undertake the polycentric decision making required in resolving vehicle design liability issues); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991) (adverting to "elaborate regulatory system overseen by the FDA [and] the difficulties of relying on individual lawsuits as a forum in which to review a prescription drug's design").

¹⁶⁹ 863 P.2d at 177.

¹⁷⁰ *Grundberg*, 813 P.2d at 95.

that the consumers of prescription drugs are afforded greater protection against defects than consumers of other products, since “the drug industry is closely regulated by the [FDA], which actively controls the testing and manufacture of drugs and the method by which they are marketed, including the contents of warning labels.”¹⁷¹

The New York Court of Appeals similarly mentioned that “the tort system is not the only means of encouraging prescription drug safety; the [FDA] has primary responsibility for that task.”¹⁷²

Many judges have voiced concerns about the need to facilitate research and development on pharmaceuticals that save lives and ameliorate health problems as well as the risks of overdetering manufacturers. For instance, the New Jersey Supreme Court asserted that “a rebuttable presumption that the duty to consumers is met by compliance with FDA regulations helps to ensure that manufacturers are not made guarantors against remotely possible, but not scientifically-verifiable, side-effects of prescription drugs, a result that could have a ‘significant anti-utilitarian effect.’”¹⁷³ The court also cited academic literature that noted “that over deterrence in drug advertising context could impede and delay manufacturers from research and development of new and effective drugs, force beneficial drugs from market, lead to shortages in supplies and suppliers of pharmaceuticals, and create unnecessary administrative costs.”¹⁷⁴

The California Supreme Court espoused analogous ideas when it observed that “[p]ublic policy favors the [expeditious] development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering.”¹⁷⁵ The court stated that the fear of large judgments arising from heightened liability could make producers “reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed.”¹⁷⁶ The court concomitantly found that the greater expense of insuring for this liability and of “research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most.”¹⁷⁷ The New York Court of

¹⁷¹ *Brown v. Superior Court*, 751 P.2d 470, 483 n.12 (Cal. 1988) (citation omitted).

¹⁷² *Enright v. Eli Lilly & Co.*, 570 N.E.2d 198, 203 (N.Y. 1991).

¹⁷³ *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1259 (N.J. 1999) (citations omitted).

¹⁷⁴ *Id.* (summarizing Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 466–67 (1997)).

¹⁷⁵ *Brown*, 751 P.2d at 479. *Brown* addressed strict liability for prescription drugs, but the ideas enunciated seem applicable to the regulatory compliance defense.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

Appeals similarly observed that “public policy favors the availability of prescription drugs, even though most carry some risks,” demonstrating awareness of overdeterrence risks—“the possibility that research will be discouraged or beneficial drugs withheld from the market.”¹⁷⁸

3. *Application*

How those states that accord compliance more relevance apply the concept depends substantially on the applicable rules that legislatures or courts enunciate. For instance, jurisdictions that treat conformity as strong evidence that a manufacturer acted reasonably or sold a consumer product without defects in effect apply a rebuttable presumption that the harmed litigant can overcome by introducing more persuasive evidence. Illustrative is a federal district court that ascertained that evidence of a pharmaceutical’s “off-label” use rebutted a statutory presumption that FDA compliance meant that the drug lacked defects.¹⁷⁹ Another court found that a plaintiff might show that the regulation was outdated or that the manufacturer would be aware of product dangers not contemplated by the agency regulation.¹⁸⁰ A third court declared that a plaintiff may rebut the presumption even without expert testimony.¹⁸¹ The New Jersey Supreme Court observed that “in the area of direct-to-consumer advertising of pharmaceuticals [a] rebuttable presumption should apply when a manufacturer complies with FDA advertising, labeling and warning requirements.”¹⁸² However, the court contended that the “presumption is not absolute”¹⁸³ and indicated that it might be overcome in “unique circumstances” when the FDA imposed no warning strictures and “despite evidence of adequacy of product labeling.”¹⁸⁴

Jurisdictions that find regulatory compliance demonstrates reasonable care, the absence of defects, or proves as a matter of law that an item is not unreasonably dangerous, or that use the learned intermediary notion, especially together with the compliance defense, essentially recognize and apply a complete defense.¹⁸⁵ Thus, a

¹⁷⁸ *Enright v. Eli Lilly & Co.*, 570 N.E.2d 198, 204 (N.Y. 1991); *accord* *Grundberg v. Upjohn Co.*, 813 P.2d 89, 94 (Utah 1991). *Enright* addressed liability to a child whose grandmother ingested DES during pregnancy, but the ideas espoused are applicable to the regulatory compliance defense.

¹⁷⁹ *Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189 (D.N.D. 2002).

¹⁸⁰ *Duffee v. Murray Ohio Mfg. Co.*, 879 F. Supp. 1078 (D. Kan. 1995).

¹⁸¹ *Cansler v. Mills*, 765 N.E.2d 698, 706–07 (Ind. Ct. App. 2002). Because the plaintiff has the burden of proof anyway, Professor Owen found it difficult to understand what additional proof must be offered to rebut the presumption. *See* Owen, *supra* note 5, § 14.3 n.38, at 894.

¹⁸² *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1259 (N.J. 1999).

¹⁸³ *Id.* (citations omitted).

¹⁸⁴ *Id.* (describing *Feldman v. Lederle Labs., Inc.*, 592 A.2d 1176, 1197–98 (N.J. 1991)).

¹⁸⁵ *Cf. supra* notes 153–55, 158–59 and accompanying text.

manufacturer is absolved of liability unless it perpetrates fraud on the FDA.¹⁸⁶

In sum, a relatively small, but increasing, number of state legislatures and courts have assigned defendant conformity with agency regulation more value, and some jurisdictions have even specifically created an express defense. These considerations have restricted manufacturer exposure to liability for selling allegedly defective products. Thus, the next section reviews the downsides and the benefits of ascribing regulatory compliance greater weight.

IV COST-BENEFIT ANALYSIS OF AN FDA REGULATORY COMPLIANCE DEFENSE

A. Introduction

A comparatively small, yet mounting, number of legislative and judicial bodies have accorded regulatory conformity enhanced significance, and this phenomenon has yielded detriments and advantages. The previous section of this Article, which recounted or alluded to most of these disadvantages and benefits, intimated that the negative effects usually outweigh the positive impacts. However, the salience of this judgment warrants the more explicit analysis below, which reaffirms the somewhat tentative conclusion above. Because Part III of this Article comprehensively examined how states enunciate, justify, and apply a regulatory compliance defense, the impact of the notion on products liability actions merits abbreviated treatment here.

B. Disadvantages

The principal detriment of recognizing and applying a regulatory compliance defense is that it undermines consumer efforts to impose liability on manufacturers for the harm allegedly defective goods cause. This adverse feature in turn erodes the vindication of several products liability goals, which this Article investigated earlier¹⁸⁷ and revisits below.

Compensating victims hurt by defective items is the major objective that products liability jurisprudence now serves.¹⁸⁸ Consequently, a regulatory compliance defense subverts the realization of this goal—making individuals whole by returning them to the state enjoyed

¹⁸⁶ See, e.g., N.J. STAT. ANN. § 2A:58C-5 (2000); OHIO REV. CODE ANN. § 2307.80(C)(2) (2005); see also Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 Nw. U. L. REV. (forthcoming June 2008).

¹⁸⁷ See *supra* notes 121–41 and accompanying text.

¹⁸⁸ See *supra* notes 121–26 and accompanying text.

before defective articles caused injury—because it effectively allows a “compensation gap.”

The defense can undercut additional purposes. A relatively important one is specific deterrence, through court action, of the manufacturer from repeating its behavior and general deterrence of additional parties that may conduct themselves similarly.¹⁸⁹ Related is punishment for selling defective goods that hurt an individual. Another notion, which a few courts articulate, is that the regulatory compliance defense—which judges frequently apply with the learned intermediary rule in the duty-to-warn context—erodes the modern products action as a “communicative or representational tort.”¹⁹⁰

Insofar as products lawsuits essentially function as an informal regulatory system, the defense also undermines its effectiveness. For instance, plaintiffs’ successful pursuit of these cases may encourage sellers to institute numerous actions that will benefit consumers.¹⁹¹ Those incentives can fill a “regulatory gap” that arises when the FDA is overly lenient, sluggish, imprecise, narrow, dated, politicized, responsive to the drug industry, or risk-averse or makes an error.¹⁹² A concrete illustration is the possibility that the FDA will approve a new drug before the manufacturer has comprehensively tested the pharmaceutical and before the agency is justifiably convinced about safety and effectiveness, partly because it relies so heavily on industry experimentation and is under intense pressure to grant expeditious approval.¹⁹³ The FDA concomitantly analyzes and balances wider societal notions involving safety and efficacy, which implicate trade-offs that fail to account thoroughly for a specific patient, in marked contrast to liability actions, which effectively facilitate individualized consideration of someone whom an ostensibly bad pharmaceutical hurts.¹⁹⁴

Statutory adoption of the defense might also erode the long-standing tradition whereby courts articulate products liability rules, in the process sacrificing common law virtues—namely the inherent flexibility that the common law affords to craft these doctrines, which may reflect evolving societal norms. Federalizing the defense, as legisla-

¹⁸⁹ See *supra* notes 123–26 and accompanying text.

¹⁹⁰ See *supra* note 128 and accompanying text.

¹⁹¹ See *Mazur v. Merck & Co.*, 742 F. Supp. 239, 248 (E.D. Pa. 1990) (arguing that civil judgments provide incentives to improve drug safety).

¹⁹² See *supra* note 141 and accompanying text.

¹⁹³ See DEPT. OF HEALTH & HUMAN SERVS., *supra* note 31, at 22–24; *supra* notes 119–20 and accompanying text.

¹⁹⁴ See *supra* note 31 and accompanying text. These suits enable numerous particular consumers harmed by allegedly defective pharmaceuticals—who, unlike regulated interests, lack the subject matter expertise, organizational capabilities, and resources necessary to affect legislative and FDA determinations—partially to offset the advantages that regulated industries possess.

tors, manufacturers, insurers, and commentators have proposed, would similarly undercut another venerable convention—state assumption of lead responsibility to declare substantive products liability rules unless compelling justifications necessitate federalization.¹⁹⁵ Lawmakers across the political spectrum have apparently codified doctrine sparingly because they respect federalism and state autonomy, allowing state jurisdictions to operate as laboratories.¹⁹⁶

C. Benefits

Judicial or legislative recognition and application of a regulatory compliance defense should yield a number of benefits. Perhaps most importantly, this recognition would capitalize on substantial FDA expertise accumulated over the last century as the agency to which Congress assigns responsibility for protection of consumers through approving the safety, effectiveness, and labeling of new drugs, and monitoring them thereafter.¹⁹⁷ Numerous observers believe FDA technical mandates, methods for investigating and reviewing new drugs, continued monitoring of previously approved drugs, and scientific quality to be exceptional.¹⁹⁸

These attributes mean that the FDA possesses superior institutional competence, especially vis-à-vis an individual lay jury of a particular jurisdiction, when resolving a specific fact-bound inquiry. The agency enjoys great comparative advantage in collecting, analyzing, and synthesizing complicated empirical data that implicate science, technology, medicine, and public policy, as well as in evaluating and balancing risks, advantages, and cost when considering new drug applications and overseeing pharmaceuticals.¹⁹⁹ The FDA is also politically accountable because it has to rationalize its decision making and receives careful scrutiny from lawmakers, judges, the media, and experts in scientific, technological, medical, and policy areas.²⁰⁰ The FDA, therefore, sharply contrasts with juries throughout the nation,

¹⁹⁵ See generally Anthony J. Bellia, Jr., *Federal Regulation of State Court Procedures*, 110 YALE L.J. 947 (2001) (assessing the concerns that arise when federal lawmakers require state courts to adopt federal procedural rules).

¹⁹⁶ *Grundberg v. Upjohn Co.*, 813 P.2d 89, 103–04 (Utah 1991) (Stewart, J., dissenting); OWEN, *supra* note 5, § 1.1, at 4, § 1.2, at 24. As to the experimentation rationale for federalism, see *United States v. Lopez*, 514 U.S. 549, 581 (Kennedy, J., concurring) (1995); and *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (Brandeis, J., dissenting) (1932). However, the nationalized and globalized character of the market for drugs indicates that an argument favoring country-wide uniformity would be somewhat persuasive. See Schuck, *supra* note 27.

¹⁹⁷ See *supra* notes 13–26 and accompanying text.

¹⁹⁸ See, e.g., Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 163 (2005) (referring to the FDA's regulations as "exact-ing"); *supra* notes 25–26 and accompanying text.

¹⁹⁹ See, e.g., *supra* notes 162–78 and accompanying text.

²⁰⁰ See, e.g., Rabin, *supra* note 8, at 2076; Schuck, *supra* note 27.

which have a de minimus appreciation of, and no responsibility for, the larger context of the agency's ongoing, complex policy development.

Insofar as states prescribe a regulatory compliance defense, and especially if Congress legislated one, manufacturers would be able to satisfy a national, uniform command rather than diverse requirements articulated by juries in multiple states—which can overdeter and be expensive and unpredictable, frustrating technological, design, research, planning, and marketing activities.²⁰¹ The greater consistency and definiteness afforded by a national standard would encourage the huge manufacturer investments that are necessary to research, develop, label, gain approval for, and market reasonably priced new pharmaceuticals that save lives and temper health difficulties.²⁰²

D. Resolution

In sum, the above evaluation indicates that the quantitative and qualitative detriments of an FDA regulatory compliance defense eclipse the advantages that it furnishes. However, this conclusion is not definitive and may even appear controversial—the issue might actually present a somewhat close question. Accordingly, numerous recommendations deserve exploration.

V

SUGGESTIONS FOR THE FUTURE

A. An Introductory Word

Part IV ascertains that the downsides of a regulatory compliance defense outweigh the benefits. Thus, jurisdictions that have not instituted this defense should maintain the status quo and those recognizing the doctrine ought to abolish the defense or severely restrict its enforcement. Legislators and jurists that deem the concept's advantages greater than this Article suggests should at least rarely establish the defense as a complete one because this action precludes harmed

²⁰¹ See *supra* notes 162–78 and accompanying text.

²⁰² See *supra* notes 26, 162–78 and accompanying text. A regulatory compliance defense would also significantly reduce or temper a “products liability tax,” which manufacturers assert the common law products framework exacts inherently by unnecessarily exposing them to liability and substantial awards, the costs of defending against cases, and reputational and sales losses, even bankrupting some companies. Cf. Dorsey D. Ellis, Jr., *Fairness and Efficiency in the Law of Punitive Damages*, 56 S. CAL. L. REV. 1, 57 (1982) (“Uncertainty as to the amount of punitive damages that may be assessed also has incentive effects on the behavior of potential defendants. Some will overestimate not only the likelihood but also the amount of potential punitive damage assessments, and incur excessive avoidance costs; others will underestimate potential liability and underinvest in the avoidance of conduct that merits punitive damage liability.”); Viscusi, *supra* note 26, at 1455 (“[T]here can be great difficulty in determining the appropriate additional [punitive damage] award necessary to create appropriate deterrence, but not over-deterrence.”).

individuals' recovery and is too draconian. These jurisdictions might treat conformity as a minimum or floor. The remaining states ought to treat compliance as evidence in determining negligence or defect by applying a finely calibrated analysis that balances an FDA mandate's comparative stringency with the relative patient need for, and efficacy of, the pharmaceutical. To the extent that jurisdictions retain the defense, they should consider qualifying or limiting it. Illustrative conditions are: the FDA should approve the pharmaceutical risk in the new drug and label-approval regime and create an optimal safety level, while defendants must tender to the FDA and consumers all information on the drug's safety and efficacy required by the agency and Congress. Notwithstanding how states address regulatory conformity, federal lawmakers must expeditiously implement bipartisan legislation that would respond to valid concerns about the FDA by enhancing its power, resources, information, transparency, and insulation from manufacturers' pressures.²⁰³

B. Preferable Approaches

States that have yet to recognize and apply a regulatory compliance defense should retain this position mainly because the disadvantages imposed by the defense outstrip its benefits. Jurisdictions that now recognize and apply the defense should reconsider the idea's use and eliminate the doctrine, or sharply limit the relevance that they accord regulatory compliance.

States that find the concept's advantages greater should infrequently make the defense complete, as that is too extreme and generally prevents recovery by injured consumers. A valuable example of this phenomenon is the effect of the learned intermediary approach in combination with the defense, which essentially insulates from liability to consumers those manufacturers whose FDA-approved labels appropriately warn prescribing physicians. This rule should be abrogated or severely curtailed because it does not account for several modern realities.²⁰⁴ The FDA should also tailor label approval to modern marketing developments—mass advertising, especially on television and the internet—and differences in advertising's target audience—consumers, not physicians—with reforms, such as more efficacious patient package inserts and less technical directions for use.²⁰⁵

Jurisdictions that maintain this rule should assign it substantially decreased relevance or at least not treat it as a complete defense that

²⁰³ See, e.g., Editorial, *The F.D.A. in Crisis: It Needs More Money and Talent*, N.Y. TIMES, Feb. 3, 2008, at WK14; *supra* note 33 and accompanying text.

²⁰⁴ See *supra* notes 4, 30–31, 130–40 and accompanying text.

²⁰⁵ See *supra* notes 130–40 and accompanying text.

essentially alleviates manufacturers of responsibility. For instance, jurisdictions might consider compliance to be some evidence that the warning is adequate, depending on its relative comprehensiveness, accuracy, and clarity. They might also consider the stringency of agency controls, including how assiduously the company and the FDA track a label's use following approval and whether adverse consumer events prompt corrective label adjustments.

Those jurisdictions that conclude the regulatory compliance defense's benefits are greater than this Article asserts should investigate granting conformity some value by effectively treating it as a minimum or floor. Judges, accordingly, would not make compliance determinative of products liability. Rather, the fact-finder would ascertain whether the manufacturer committed negligence or sold a defective product by assigning weight to conformity in light of its strength vis-à-vis the regulation's relevance and persuasiveness, and balancing that against the FDA control's efficacy and strictness.

Jurisdictions that hold regulatory compliance must not be a minimum or floor for liability purposes should treat it as evidence bearing on negligence or defect. Judges would apply a meticulously calibrated assessment that invokes relative FDA stringency, a patient's comparative need for the drug, and the relative effectiveness of the pharmaceutical and its label. More specifically, when (a) the agency considered rigorous pre- and postapproval testing, carefully scrutinized the manufacturer's application, and weighed safety risks, benefits, and costs before tendering approval; (b) the plaintiff had a compelling need for the medication to preserve life; and (c) there were few or no effective, safer alternatives, the evidence of manufacturer negligence or defect would be rather weak. In contrast, when the agency was less demanding; the consumer wanted the medication for nonlife threatening conditions; and there were many, relatively effective, safe options, the evidence of negligence or defect would be stronger.

In short, I believe these approaches are preferable to a regulatory compliance defense, as they offer more advantages and better honor the important aims of contemporary products liability jurisprudence. Nonetheless, some legislatures and courts may find that this conclusion and its rationales are not persuasive, while the question is unclear. For example, in some circumstances it may be inappropriate either to apply a complete defense or to abrogate the rule. Thus, a qualified, or limited, regulatory compliance defense appears to warrant review.

C. Qualified Regulatory Compliance Defense

This defense is narrower than the idea canvassed throughout the Article because several preconditions would govern the concept's operation.²⁰⁶ One is that the FDA must have approved the exact risk or label terminology that the plaintiff contends makes the pharmaceutical defective or the warning inadequate. A second qualification is that the agency regulation must create an optimal safety level, not a floor above which a finding of defect remains proper. A third condition is that the manufacturer needs to divulge all safety and effectiveness information required by the FDA and Congress in a timely fashion. A defendant specifically must comprehensively apprise the FDA of facts and statistical analyses pertinent to the continuing rationale for drug approval and company advertising, while related communications must not mislead doctors or patients about safety or efficacy. One writer who champions the qualified defense acknowledges that "finding the regulatory sweet spot"—weighing the objectives of pharmaceutical safety and availability, reasonable expense, timely FDA decision making, as well as patient information and choice—is a daunting assignment, even as the proponent urges that the limited regulatory defense would help meet the challenge.²⁰⁷

D. FDA Reform

Notwithstanding how state legislatures and judiciaries resolve the controversial debate about the regulatory compliance defense, federal lawmakers must expeditiously implement promising FDA reforms that appear in a bipartisan measure that Congress enacted in 2007.²⁰⁸ Rigorous implementation, especially in conjunction with the preferable approaches that this Article presents, could well rectify or ameliorate the major disadvantages that the regulatory compliance defense imposes.

In a world of perfect agency regulation, the defense and common law suits would obviously be unnecessary, as the FDA would approve no pharmaceuticals that harm consumers. However, this rather utopian view fails to depict accurately the existing state of regulation or the world that consumers now inhabit.²⁰⁹ Moreover, particular agency flaws are effectively intrinsic or essentially so intractable that they defy constructive reform. Nonetheless, the statute that Congress recently enacted should improve the FDA by expanding its power,

²⁰⁶ I rely in this subsection on Noah, *supra* note 8, at 939–60 (describing different versions of the regulatory compliance defense); *see also* Schuck, *supra* note 27.

²⁰⁷ *See* Schuck, *supra* note 27.

²⁰⁸ *See supra* note 33 and accompanying text.

²⁰⁹ *See* OWEN, *supra* note 5, § 14.3, at 892–94; Rabin, *supra* note 8, at 2076. *But see* Schuck, *supra* note 27.

funding, information, and transparency, while the legislation might also limit the agency's politicization and dependence on those it regulates.²¹⁰ These notions, particularly in synergy with certain alternatives cataloged above, could enhance the prospect of discovering that regulatory ambit, which, together with products litigation, best decreases consumer injuries that result from defective pharmaceuticals.

CONCLUSION

A small, but growing, number of jurisdictions have recognized and applied an FDA regulatory compliance defense. However, this rule's detriments eclipse its advantages. If legislatures and courts follow the guidance proffered, they should be able to improve pharmaceutical consumers' safety through rigorous FDA oversight and a vibrant product liability cause of action.

²¹⁰ See *supra* note 33 and accompanying text.