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Preemption and Compensation under the Food, Drug and Cosmetic Act

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Introduction

Over the past several decades, the United States Supreme Court has provided greater guidance on the preemptive effect of the federal Food, Drug and Cosmetic Act (FDCA or Act).¹ The decisions in some of these cases have invited controversy and criticism because of the consequent effects on the plaintiff's ability to seek recourse for injuries due to dangerous products that are regulated under the Act. One of the threshold legal inquiries centers on whether common law state tort claims and their associated jury verdicts constitute "requirements" or "regulations" that can be expressly or impliedly preempted by federal regulations.²

In its first major preemption ruling under the FDCA, the Supreme Court held that state tort claims involving medical devices approved through the premarket notice procedure were not preempted.³ A four-Justice plurality practically scoffed at the idea that Congress intended to foreclose any remedies for consumers or that traditional state tort claims were "requirements" within the meaning of the preemption clause for medical devices.⁴ According to these Justices, "if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it."⁵ Furthermore, such a conclusion is "implausible" because it would mean that "Congress would have barred most, if not all, relief for persons injured by defective medical devices."⁶

¹ The fact that the last two years have seen a flurry of preemption cases is in no doubt due to the proactive stance of the FDA to seek the force of preemption for its pharmaceutical drug labeling regulations. *See* Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 504-505 (2008) (describing the FDA's intervention in relevant preemption cases and the express preemption statement in its drug labeling regulation).

² For an early discussion of this question by the Court, *see* *Cipollone v. Liggett Group*, 505 U.S. 504, 535-36 (1992) (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part). As will be discussed in Part III, *infra*, another legal inquiry focuses on what constitutes a "federal regulation" as well, particularly with respect to a medical device and its governing preemption clause.

³ *Medtronic v. Lohr*, 518 U.S. 470 (1996). Note that this holding would also apply to "grandfathered" Class III medical devices that were already on the market before being regulated by the FDA.

⁴ *See id.* at 487 (labeling such arguments as both "unpersuasive" and "implausible").

⁵ *Id.*

⁶ *Id.*

By 2008, the Court had retreated from its apparent position of safeguarding an avenue for compensatory relief for injured consumers.⁷ In *Riegel v. Medtronic*, eight Justices ruled that FDA regulations governing Class III medical devices preempt state tort claims because such claims do, indeed, constitute “requirements.”⁸ Remarkably, three of the Justices from the plurality in *Lohr* joined the majority in *Riegel*. These Justices had previously rejected the interpretation that state tort claims constitute “requirements” because such a reading would have the “perverse effect of granting complete immunity” to the medical device industry.⁹

The Court’s recent, and almost unanimous, view that a state tort law decision constitutes a requirement or regulation for the manufacturer has important consequences. Pharmaceutical drug regulations, which do not include an express preemption provision from Congress, may nevertheless impliedly preempt state tort claims if “compliance” with them would cause the manufacturer to violate a federal regulation. Thus, consumers may be left with no legal remedy if they are harmed by medical devices or pharmaceutical drugs.¹⁰ This result overturns the long history and direction of the common law and ignores one of its singular purposes: to compensate injured victims so that they do not bear the costs incurred by another’s conduct.

The purpose of this paper is to address the unjust reality in which many consumers who are injured by pharmaceutical drugs and medical devices are left uncompensated. Part I describes the history and compensatory function of tort law, which was ignored by the Supreme Court in its recent preemption decisions. Part II summarizes the introduction of notable federal statutes that govern pharmaceutical drugs and medical devices, as well as the peaceful co-existence with

⁷ Indeed, one commentator described the change in the Court’s position from *Lohr* to *Medtronic* as a “180-degree turnabout.” Sharkey, *supra* note 1, at 504-505.

⁸ *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008).

⁹ *Medtronic v. Lohr*, 518 U.S. 470, 487 (1996).

¹⁰ While the anti-preemption advocates achieved a victory in the Court’s recent decision in *Wyeth v. Levine*, governing pharmaceutical drugs, I discuss in Part III why its ruling may be substantially limited.

the state tort system. Part III analyzes the reasoning and outcomes of notable Supreme Court cases bearing on the preemptive effect of the FDCA. It then provides some criticism of the Court's inconsistent and misguided interpretation of the nature of state tort law. Finally, Part IV suggests several alternatives to the current system that may be more fair to injured individuals and would help alleviate concerns of both manufacturers and the FDA.

I. The History and Development of Tort Law

A. The Evolutions of Torts

1. Early History

The concept of compensating individuals for injuries caused by others has been in practice for time immemorial.¹¹ In relevance to modern American tort law, the legal requirements to pay for damages trace back to English common law beginning in the 13th century.¹² While there is some controversy among legal historians concerning the precise genesis of early precedents to modern tort claims,¹³ it is generally agreed that liability began with actions of trespass and trespass on the case, respectively.¹⁴ An action for trespass concerned a breach of the King's peace by the direct injury to a person or his property.¹⁵ The defendant in such cases was fined by the court and later was forced to directly compensate the injured individual as well.¹⁶

The action of trespass on the case, or "sur le cas" as it was originally known, emerged to provide justice to individuals who had suffered a loss, but could not bring a proper action for

¹¹ See George Woodbine, *Origins of the Action of Trespass*, 33 YALE L.J. 799, 812 - 813 (1923) (admitting that no conclusive evidence exists concerning the exact origins of the legal right to recover monetary damages in English common law, but nevertheless arguing that Roman law is the most likely source).

¹² W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 6, at 29 (5th ed. 1984).

¹³ See Elizabeth Jean Dix, *The Origins of the Action of Trespass on the Case*, 46 YALE L.J. 1142, 1142 - 1145 (1937).

¹⁴ KEETON ET AL., *supra* note 12, § 6, at 29.

¹⁵ *Id.*

¹⁶ *Id.*

trespass.¹⁷ Trespass only concerned direct injuries caused by the plaintiff. The King's Court, however, recognized that oftentimes injuries occur as the result of indirect actions or even inactions of the defendant.¹⁸ In other words, with an action of trespass on the case, plaintiffs could press for damages as a result of the defendant's negligence. In either form of action, the "element of damages seems to have been the chief invigorating force behind the origin and development of trespass."¹⁹ Gradually, by the 19th century, courts had delineated between intentional torts, most of which fell under an action for trespass, and negligent torts.²⁰

2. Rise of Strict Liability

One prerequisite development was required before a claim under a theory of strict liability could even be fathomed. This foundation started in the mid-19th century when courts began to carve out an exception to the "privity of contract" rule that had previously been necessary to establish a duty of care under a claim based on negligence. In *Thomas v. Winchester*, the defendant manufacturer of medicinal plant extracts mislabeled a bottle of the relatively toxic belladonna extract, so that it appeared to contain the generally harmless extract of dandelion.²¹ The plaintiff was severely injured when she mistakenly ingested what would have been an appropriate amount of dandelion extract from the mislabeled bottle.²² The New York Court of Appeals held that the defendant manufacturer could be liable to third parties not in

¹⁷ See Dix, *supra* note 13, at 1155.

¹⁸ In an age when proper procedure and forms were absolutely necessary in order to allow an action for damages to proceed, the courts appear to have created the "special writ" of trespass on the case to allow a cause of action for another's negligent acts. Several cases from the 14th century survive in which the court distinguishes the two forms of trespass. In *Waldon v. Marshall*, a doctor unsuccessfully attempted to cure the plaintiff's horse, which subsequently died because of his negligence. The court stated that an action for trespass was not permissible because the doctor did not directly kill the horse. The court then proceeded to acknowledge a "special writ according to the case, . . . for we can have no other writ." In another case, the court distinguished between an innkeeper who directly steals a guest's property, and one who negligently fails to adequately protect the property from theft. See *id.* at 1155 & note 62.

¹⁹ Woodbine, *supra* note 11, at 802.

²⁰ KEETON ET AL., *supra* note 12, § 6, at 30.

²¹ 6 N.Y. 397, 405 (1852).

²² *Id.*

privity of contract on the grounds that harm to the consumer is “the natural and almost inevitable consequence of” improperly prepared therapeutic drugs.²³ According to the court, it would be unjust not to create an exception in these types of cases because the one injured by the manufacturer’s negligence is the patient and not the pharmacist, who traditionally is the only party in privity of contract.²⁴ The court emphasized that its holding only pertained to products that may “put human life in imminent danger.”²⁵ Ultimately, the court attached an expanded duty of care to the manufacturer of drugs because these products have the potential to cause serious bodily harm and the vast majority of individuals who would be injured by defective or mislabeled drugs would not be in privity of contract with the manufacturer.

In 1916, the New York Court of Appeals further eroded and essentially “buried the general rule” of privity of contract that was ordinarily necessary to establish a duty of reasonable care between two parties.²⁶ In *MacPherson v. Buick Motor Co.*, the court extended the classification of products that could pose an imminent danger to human life to anything that “is reasonably certain to place life and limb in peril when negligently made.”²⁷ Thus, the expanded, but limited, duty created in *Thomas v. Winchester* was interpreted quite broadly by the court. One need not employ his or her skills of imagination long to discover that practically any product can pose an imminent danger if negligently made. The court, however, was generally undeterred by this potential expansion of liability. Justice Cardozo, speaking for the majority, stated: “We have put aside the notion that the duty to safeguard life and limb, when the consequences of

²³ *Id.* at 408-409.

²⁴ *See id.* at 409-410.

²⁵ *See id.* at 409.

²⁶ *See* William L. Prosser, *Assault upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1100 (1960) [hereinafter *Assault upon the Citadel*].

²⁷ 111 N.E. 1050, 1053 (N.Y. 1916) (applying the newly expanded duty of care between a manufacturer of automobiles and the purchaser and passengers).

negligence may be foreseen, grows out of contract and nothing else.”²⁸ And so, having begun the attack on the “citadel of privity” in tort law, courts started the foundation for actions in strict liability.²⁹

While the courts were busy subsuming the rule of privity of contract in negligence cases, they had also begun to recognize a limited form of strict liability that applied to food and drink.³⁰ Indeed, this concept traced back to the 15th century in England, though privity of contract was still a necessary component for recovery of damages at that time.³¹ Gradually, courts began to expand strict liability to products that were intended for “intimate bodily use,” such as personal hygiene products.³² Finally, in 1960, the New Jersey Supreme Court held the manufacturer of an automobile liable for a defect in its steering mechanism, despite the lack of privity of contract or any evidence showing negligence.³³ Soon after, in 1963, the California Supreme Court, via Judge Traynor, unequivocally endorsed and rationalized strict liability for defective products.³⁴ Many other states quickly followed suit,³⁵ necessitating several revisions to the ongoing draft of the second Restatement of Torts.³⁶

B. Principles of Tort Liability

Throughout the history and development of tort law, a trend can clearly be discerned in which courts have abandoned rigid principles of law and adopted more liberal principles that

²⁸ *Id.*

²⁹ *See Assault upon the Citadel*, *supra* note 26, at 1099 (quoting Justice Cardozo in *Ultramares Corp. v. Touche*, 255 N.Y. 170, 180 (1931)).

³⁰ *See id.* at 1110.

³¹ *See id.* at 1104. Note that criminal statutes for food and drink had been enacted as far back as the 13th century in England, when the actions for trespass and trespass on the case were being established. *See id.* at 1103.

³² *See id.* at 1111-12. Note that this expansion occurred at the expense of traditional causes of action based on a breach of warranty, which also required privity of contract. *See* Joseph A. Page, *Generic Product Risks: The Case against Comment k and for Strict Tort Liability*, 58 N.Y.U.L. REV. 853, 859 (1983).

³³ *See* William L. Prosser, *Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791, 793 (1966) [hereinafter *Fall of the Citadel*] (discussing *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960)).

³⁴ *See* John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 829 (1973) (describing *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963)).

³⁵ *Fall of the Citadel*, *supra* note 33, at 793-795.

³⁶ *Id.* at 793 n.9.

extend the availability of remedies to injured consumers. By no longer requiring privity of contract to establish a duty, the common law had evolved in order to protect and compensate those individuals who were most likely to be injured by defective products. The establishment of strict liability made it even easier for injured individuals to recover damages, since they no longer needed to establish negligence on the part of the manufacturer.

By the time tort actions for negligence had become common place, scholars recognized that “the purpose of the law of torts is to . . . afford compensation for injuries sustained by one person as the result of the conduct of another.”³⁷ Strict products liability, while furthering some additional objectives, did not alter the well-established compensatory function of tort law; indeed, it further enabled the recovery of damages for injuries that had previously been barred for lack of privity.³⁸ Judge Traynor reasoned that unsuspecting consumers should have “general and constant protection and the manufacturer is best situated to afford such protection.”³⁹

By the 1970’s, scholars had begun a new and lively debate over the objectives of tort law. Judge Posner and the economic school viewed tort law as a deterrent device that would minimize injuries in society.⁴⁰ Alternatively, a competing school of thought believed that tort law serves as a “corrective justice” system in which moral rights are vindicated.⁴¹ Both views, however, fail to address how they remain relevant in modern society, where insurance and even re-insurance companies abound.⁴² The deterrence theory, in which the threat of liability causes manufacturers to take precautionary safety measures, is undermined by the insurance policies that all

³⁷ Cecil A Wright, *Introduction to the Law of Torts*, 8 CAMBRIDGE L.J. 238 (1944).

³⁸ Professor Prosser and Judge Traynor particularly espoused strict liability for its “risk-spreading” effects; that is, a manufacturer should absorb the cost of injuries (to unsuspecting individuals) resulting from its products and then pass these losses on to the general public. See *Assault upon the Citadel*, *supra* note 26, at 1120; *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring).

³⁹ *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring).

⁴⁰ Jeffrey O’Connell & Christopher J. Robinette, *The Role of Compensation in Personal Injury Tort Law: A Response to the Opposite Concerns of Gary Schwartz and Patrick Atiyah*, 32 CONN. L. REV. 137, 138-139 (2000).

⁴¹ *Id.*

⁴² See *id.*

manufacturers now carry.⁴³ In other words, any additional safety measures that the threat of liability would have imposed on a manufacturer is practically negated by the knowledge that the award money would come from an insurance company. Furthermore, evidence suggests that insurance premiums do not appreciably rise for manufacturers who are found liable for injuries, since this often does not lead to a statistical probability for future accidents.⁴⁴ Similarly, the availability of insurance also undermines the theory of corrective justice. Although the victims are being compensated for their injuries, the money is coming from insurance companies and not the manufacturers who are responsible for the injuries.⁴⁵ Ultimately, the remaining principle of the law of torts is the compensation of injured individuals. This principle has survived centuries of legal development and is immune to the current rise of insurance schemes that serve to undermine modern theories of tort liability.

II. Federal Regulation of Pharmaceutical Drugs and Medical Devices

A. Introduction of the Food, Drug and Cosmetic Act

Amidst the expansion of tort liability in the 20th century arose greater federal regulation of industry as well. In 1938, Congress enacted the Food, Drug and Cosmetic Act, which significantly increased the oversight capabilities of the Food and Drug Administration.⁴⁶ Previously, the FDA could only *react* to debacles that were caused by unsafe drugs.⁴⁷ The 1938 Act, however, contained an important new provision providing for premarket review of new

⁴³ See PATRICK S. ATIYAH, *THE DAMAGES LOTTERY* 163-164 (1997).

⁴⁴ See *id.*

⁴⁵ See O'Connell & Robinette, *supra* note 40, at 147. While some scholars argue that the existence of insurance for individuals also undermines the compensatory function of tort law, they tend to overestimate the extent and adequacy of coverage. See, e.g., Douglas H. Cook, *Personal Responsibility and the Law of Torts*, 45 AM. U.L. REV. 1245, 1266-1267 (1996).

⁴⁶ Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761 (1996).

⁴⁷ *Id.*

drugs.⁴⁸ This shift in the burdens of the drug safety oversight process was actually made in response to a contemporaneous tragedy in which a medicine containing diethylene glycol killed nearly one-hundred individuals and sickened hundreds more.⁴⁹ Congress evidently signaled its intention to supplement existing state laws with a federal regulatory power aimed at preventing similar drug safety problems.⁵⁰

The 1962 Drug Amendments to the FDCA provided the FDA additional oversight capabilities resembling those enjoyed today, at least in the new drug arena.⁵¹ Of particular significance, the new drug amendments converted the premarket notice system into one for premarket approval.⁵² Under the former system, the FDA required companies to notify the agency about new drugs; but absent any challenges based on safety concerns, a manufacturer could sell a drug without explicit agency approval.⁵³ The drug amendments, however, made it unlawful to market a new drug without prior FDA approval.⁵⁴ Furthermore, in addition to safety assessments, premarket approval also required a finding that the new drug is effective for its intended use.⁵⁵ This new Congressional mandate led to a risk-benefit analysis in which the FDA compares the safety of a new drug with the benefits it would provide to society.⁵⁶ Despite this balancing act, the FDA has acknowledged its gatekeeper role and responsibility in preventing drug-related injuries.⁵⁷ Indeed, like the impetus for the 1938 Act, the new powers in the 1962

⁴⁸ *Id.* at 1761-62.

⁴⁹ Note, *Drug Efficacy and the 1962 Drug Amendments*, 60 GEO. L.J. 185, 186 & n.18 (1971).

⁵⁰ This attempt at supplementing state tort remedies with federal oversight was replicated in many other areas of consumer protection and perhaps reached its height in the 1960's-1970's. See Robert S. Adler & Richard A Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 895-96 (1994).

⁵¹ James To. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 950 (2008).

⁵² Merrill, *supra* note 46, at 1764-65.

⁵³ *Id.* at 1765.

⁵⁴ *Id.*

⁵⁵ O'Reilly, *supra* note 51, at 950.

⁵⁶ Merrill, *supra* note 46, at 1765, n.37.

⁵⁷ *Id.* at 1768.

drug amendments were granted, at least in part, in response to another tragedy involving a dangerous drug.⁵⁸

B. The Medical Device Amendments

In 1976, the FDA's expanded regulatory powers were extended to medical devices.⁵⁹ This broadening of the agency's oversight of health care products was significant because of the lack of attention that had previously been paid to medical devices. In fact, until 1938, medical devices were not regulated at all by the FDA.⁶⁰ And in 1962, when drugs were subjected to premarket approval requirements for safety and effectiveness, medical devices remained exempt.⁶¹ While the 1976 amendments did not entirely apply the premarket approval requirements for new drugs to medical devices,⁶² it did establish a regulatory regime that improved upon the agency's previously *ad hoc* regulatory efforts.⁶³

Specifically, the Medical Device Amendments of 1976 divided medical products into Class I, Class II, and Class III devices.⁶⁴ Class I devices are only subject to "general controls" because they do not "present a potential unreasonable risk of illness or injury."⁶⁵ Class II devices are subject to "special controls" because the "general controls" applied to Class I devices are "insufficient to provide reasonable assurance of the safety and effectiveness of the device."⁶⁶ Finally, Class III devices are regulated in an analogous way to new drugs. Such devices,

⁵⁸ *Id.* at 1764, n.35.

⁵⁹ *Id.* at 1800. Like so many other substantial modifications of the FDCA, the addition of the Medical Device Amendments was, in part, a response to a product safety debacle. In particular, the Dalkon Shield intrauterine device caused thousands of injuries to otherwise healthy young women. See David C. Vladeck, *The Problem of Medical Drugs and Devices: Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 103 (2005).

⁶⁰ Merrill, *supra* note 46, at 1801.

⁶¹ *Id.* at 1803-04.

⁶² *Id.* at 1809.

⁶³ See *id.* at 1807 (describing the FDA's attempt at regulating some medical devices as "new drugs" under the 1962 amendments, while realizing this application would not be possible or practical for many other potentially dangerous devices).

⁶⁴ *Id.* at 1809; *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 344 (2001).

⁶⁵ 21 U.S.C. § 360(c)(a)(1)(A).

⁶⁶ *Id.* § 360(c)(a)(1)(B).

therefore, are subject to premarket approval requirements for safety and effectiveness because they are intended to support, sustain, or prevent the impairment of human health, or they “present an unreasonable risk of illness or injury.”⁶⁷

The three-part classification of medical devices was a sensible acknowledgment of the reality that many of these products do not interact with the human body – and consequently do not pose any threat to human health – in a way that most drugs do.⁶⁸ The premarket approval requirements for Class III devices, however, have proven largely irrelevant since its creation, due to an exception known as the 510(k) process that was incorporated into the Medical Device Amendments.⁶⁹ Any devices that were already being marketed at the time of the amendments would not be subjected to premarket approval requirements.⁷⁰ Furthermore, any devices created after the amendments that are “substantially equivalent” to these pre-existing “predicate” devices would also be exempt.⁷¹ In addition, the FDA also made the 510(k) process available to devices that were “substantially equivalent” to these “substantially equivalent” devices.⁷² In other words, devices that were substantially equivalent to pre-amendment devices could, in turn, serve as predicate devices for subsequent products. This avenue around the pre-market approval requirements continues to be attractive to medical device manufacturers today. After all, the “510(k) notification requires little information, rarely elicits a negative response from the FDA,

⁶⁷ *Id.* § 360(c)(a)(1)(C). Some examples of Class III devices include “pacemakers, IUDs, artificial hearts, and artificial joints.” Robert Adler, *1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 513 (1988).

⁶⁸ See Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J. LAW & TECH. 1, 7 (1989) (stating that the dangers posed by medical devices “range from nonexistent to critical”). A representative example of a Class I medical device is a tongue depressor. *Id.* at 7 n.23 (citing 21 C.F.R. § 880.6230 (1988)). In addition, Class II examples include hearing aids and condoms. *Id.* (citing 21 C.F.R. § 874.3300(b)(2) and § 884.5300, respectively).

⁶⁹ See J. Derrick Price, *FDCA Medical Device Amendments and Federal Preemption: Putting the Screws to Spinal Fusion Patients*, 3 HOUS. J. HEALTH L. & POL’Y 83, 87 (2002).

⁷⁰ 21 U.S.C. § 360e(b)(1)(A). Note that this exemption was not meant to be permanent; rather, the FDA was responsible for classifying and eventually implementing regulations that would govern all pre-amendment devices as well as post-amendment substantially equivalent devices. See Adler, *supra* note 67, at 514.

⁷¹ 21 U.S.C. § 360e(b)(1)(B).

⁷² See Merrill, *supra* note 46, at 1819 (noting that this process was known as “piggybacking.”).

and gets processed very quickly.”⁷³ Indeed, the vast majority of medical devices are marketed under the 510(k) process.⁷⁴ Consequently, most medical devices, whether they are relatively innocuous or pose substantial risks to human health, are subjected to something more closely resembling a premarket notice system rather than the premarket approval system that is enforced with respect to new drugs.⁷⁵

C. Effect of Legislation on State Tort Law

Despite the expansion of federal regulatory requirements with respect to drugs and medical devices, individuals continued to be injured by these products and courts continued to entertain their lawsuits based on various state tort law theories.⁷⁶ For nearly seventy years, courts refused to hold that state tort actions for allegedly defective drugs are preempted by the FDCA,⁷⁷ though compliance with federal regulations could be presented as evidence that the product was not defective.⁷⁸ Indeed, the legislative history for the 1938 Act seems to clearly indicate that

⁷³ Adler, *supra* note 67, at 516.

⁷⁴ Leflar, *supra* note 68, at 28. In 1986, for example, 4,338 devices were approved via the 510(k) process while 72 devices were subjected to the more stringent premarket approval process. Adler, *supra* note 67, at 515-16.

⁷⁵ See Leflar, *supra* note 68, at 28-29. Note that the Safe Medical Devices Act of 1990 did impose the increased burden on manufacturers of having to wait for a finding of “substantial equivalence” by the agency before such devices could be marketed. Merrill, *supra* note 46, at 1830. In addition, the overall situation may finally be changing as a result of pressure to subject the pre-amendment devices to the premarket review process. See Lisa Richwine, *U.S. FDA Demands Data on Older Medical Devices*, (Apr. 8, 2009), at http://www.boston.com/news/science/articles/2009/04/08/us_fda_demands_data_on_older_medical_devices; *Older Medical Devices to Get FDA Review*, BOST. GLOBE, April 9, 2009, at 9 (stating that 25 types of previously exempt, Class III medical devices are now being reviewed for safety and effectiveness by the FDA). The FDA will review these devices to determine whether they should be subjected to the premarket approval process or re-classified as a Class I or II device. See Medical Devices; Order for Certain Class III Devices; Submission of Safety and Effectiveness Information, 74 Fed. Reg. 16,214 (April 9, 2009).

⁷⁶ *Wyeth v. Levine*, 129 S. Ct. 1187, 1195-96 (2009) (“As it enlarged the FDA’s powers to ‘protect the public health’ and ‘assure the safety, effectiveness, and reliability of drugs,’ Congress took care to preserve state law.”); see generally, David A. Kessler & David C. Vladeck, *Health Regulation and Governance: A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 GEO L.J. 461 (2008); James T. O’Reilly, *Drug Review “Behind the Curtain”: A Response to Professor Struve*, 93 CORNELL L. REV. 1075, 1075-1076 (2008).

⁷⁷ See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1017 & n.11, 1018-1019 & n.16 (2008) (Ginsburg, J., dissenting).

⁷⁸ This is the majority view, though some courts and states view such evidence as establishing a rebuttable presumption that the product is not defective. See Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL’Y 1013, 1023-24 (2007).

Congress did not intend to displace state tort suits with the proposed regulatory regime.⁷⁹ In addition, the FDA consistently disavowed any attempt at preempting state tort law with its regulations on drug safety.⁸⁰ In 2006, however, the FDA reversed its position and actively advocated a pro-preemption stance.⁸¹ This change in policy, in turn, precipitated a newfound vigor in manufacturers to argue that product defect claims were impliedly preempted by the FDCA.⁸²

One key difference between the statutory language governing drugs and medical devices has led to a somewhat different fate for the latter category of products. The 1976 Medical Device Amendments included a preemption provision that states, in part, that no state may “establish or continue in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any requirement applicable under this Act to the device. . . .”⁸³ Nevertheless, most courts treated medical devices similarly to drugs; that is, regulatory compliance could be asserted as a defense, but it could not shield manufacturers from state tort claims asserting product defects.⁸⁴ In fact, most courts did not entertain the preemption theory for medical devices for well over a decade after the enactment of the 1976 amendments.⁸⁵ In the first major case concerning medical device preemption in the Supreme Court, the FDA expressed its belief that “damage remedies in a tort action” are also not preempted by the Medical Device

⁷⁹ See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1017 n.10 (2008) (Ginsburg, J., dissenting) (citing testimony concerning the 1938 Act’s effect on existing state tort remedies).

⁸⁰ See, e.g., New Drugs Requirement for Labeling Directed to the Patient, 43 Fed. Reg. 4,214 (Jan. 31, 1978) (implicitly supporting state tort remedies based on product liability claims for failure to warn); Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,437 (June 26, 1979) (“It is not the intent of FDA to influence the civil tort liability of the manufacturer or of the physician.”).

⁸¹ See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,934 (Jan. 24, 2006); Sharkey, *supra* note 78, at 1037-38.

⁸² See Sharkey, *supra* note 78, at 1037-38.

⁸³ 21 U.S.C. § 360k(a) (2008).

⁸⁴ Adler & Mann, *supra* note 50, at 916.

⁸⁵ See *id.* (describing the impact of *Cipollone v. Liggett Group* on lower courts’ willingness to preempt medical device claims).

amendments that were incorporated into the FDCA, notwithstanding the preemption provision in the statute.⁸⁶ Indeed, it is certainly arguable that Congress did not intend to preempt such claims, given the prevalence of state tort lawsuits at the time of passage and the ambiguous language used in the statute.⁸⁷

After the Supreme Court’s decision in *Cipollone v. Liggett Group*,⁸⁸ however, the landscape for medical device preemption changed dramatically.⁸⁹ In *Cipollone*, the plaintiff filed claims against several cigarette manufacturers on the grounds that certain design defects caused the decedent to die from lung cancer.⁹⁰ The relevant federal statute governing cigarette labeling contained a preemption clause that barred states from imposing “requirements or prohibitions” with respect to “the advertising or promotion of any cigarettes.”⁹¹ The Court proceeded to hold that the state tort claims at issue were preempted because they constitute “requirements or prohibitions” within the meaning of the Act.⁹² Following this decision in 1992, the vast majority of lower courts preempted state tort claims against medical device manufacturers because the

⁸⁶ See Brief for the United States as Amicus Curiae at 13, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (Nos. 95-754, 95-886) (interpreting its regulation on the issue that was codified in 21 C.F.R. 808.1(d)(2) and (6)). In a subsequent brief, the FDA further clarified that even tort remedies for allegedly defective products that were approved under the stringent premarket approval process were also not preempted by the Medical Device Amendments. See Brief for the United States as Amicus Curiae at 14, *Smiths Industries Medical Systems, Inc. v. Kernats*, 522 U.S. 1044 (1988), *denying cert.* (No. 96-1405) (stating that premarket approval of a Class III device, like premarket notification for other devices, “established only that the manufacturer had complied with the applicable federal minimum standards for use and marketing” and did not serve to preempt state tort claims based on product defect theories).

⁸⁷ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996) (stating that it would have been “spectacularly odd” if Congress intended to broadly preempt state tort claims for medical devices since the legislative history seems to be silent on the matter); see also *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1015 (2008) (Ginsburg, J., dissenting) (arguing that Congress did not attempt to preempt any state tort claims for medical devices, in part, because of the “failure to create any federal compensatory remedy for . . . consumers injured by devices that receive FDA approval but nevertheless prove unsafe”); Brief for the United States as Amicus Curiae at 14-15, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (Nos. 95-754, 95-886) (describing the legislative history of the Medical Device Amendments).

⁸⁸ 505 U.S. 504 (1992).

⁸⁹ See *Adler & Mann*, *supra* note 50, at 916 (noting that nearly all lower courts preempted state lawsuits for medical devices because of the reasoning in *Cipollone*).

⁹⁰ 505 U.S. 504, 509-10.

⁹¹ See *id.* (citing Section 5(b) of the Public Health Cigarette Smoking Act of 1969).

⁹² *Id.* at 521.

relevant preemption clause also included the “requirements” language deemed pivotal in *Cipollone*.⁹³

III. From *Lohr* to *Levine* – The Supreme Court Rules on Preemption under the FDCA

In *Cipollone*, the Supreme Court opened the floodgates to preemption decisions in products liability cases. Consequently, the Court was faced with growing conflicts over the precise application of preemption principles to particular products. Unfortunately, the Court’s “resolution” of these cases has been characterized as incoherent⁹⁴ and even schizophrenic.⁹⁵ Certainly, the result of Supreme Court jurisprudence in this area has led to some inconsistencies and an unpredictable future for consumers who are injured by drugs and medical devices. The Court initially showed sympathy and a desire to ensure that injured consumers could maintain state tort claims in the face of federal regulatory schemes. In *Silkwood v. Kerr-McGee*, for example, the Court upheld a state damages award for radiation exposure despite broad and practically exclusive federal regulation of nuclear power plants.⁹⁶ In so doing, the Court paid special attention to the fact that preemption would have left the injured plaintiff without any remedy at all: “It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.”⁹⁷ During the same term, the Court denied *certiorari* in another case where preemption of state tort claims based on an inadequate label for pesticides regulated by the Environmental Protection Agency was rejected.⁹⁸ The D.C. Circuit Court of Appeals had stated that the “provision of tort remedies to compensate for personal injuries ‘is a subject matter of the kind [the] Court has traditionally regarded as properly

⁹³ Adler & Mann, *supra* note 50, at 916-17 & n.108.

⁹⁴ Sharkey, *supra* note 1, at 459.

⁹⁵ Betsey J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U.L. REV. 559, 559-60 (1997).

⁹⁶ 464 U.S. 238 (1984).

⁹⁷ *Id.* at 251.

⁹⁸ *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984).

within the scope of state superintendence.”⁹⁹ Not long after the Supreme Court decided *Cipollone*, however, it began applying its preemption jurisprudence to the realm of products regulated by the FDCA. As a result, a consumer’s ability to recover damages based on state tort claims became less certain.¹⁰⁰

A. Medical Devices

1. *Medtronic v. Lohr*

In *Medtronic v. Lohr*, the plaintiff claimed that Medtronic’s pacemaker, which had been marketed under the 510(k) process, was defective and injurious to her health.¹⁰¹ Three years after being implanted with the Activitrac, Lora Lohr had to undergo emergency surgery when the pacemaker suddenly failed.¹⁰² According to the treating physician, the failure occurred as a result of a defective lead, which is “the wire carrying electrical impulses from the pacemaker to the patient’s heart tissues.”¹⁰³ Lohr filed several claims against Medtronic based on strict liability and the negligent design, manufacture, and warnings related to the Activitrac pacemaker.¹⁰⁴

As an initial matter, the Court stated several guiding propositions, which have since become familiar phrases in preemption cases. First, “because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”¹⁰⁵ Second, “the purpose of Congress is the ultimate touchstone’ in every pre-emption case.”¹⁰⁶ Next, the Court examined the preemption clause for medical devices, which prohibits states from “establish[ing] or [continuing] in effect with respect

⁹⁹ See *id.* at 1542 (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963)).

¹⁰⁰ Indeed, at least one commentator believes the Court has taken a “180-degree turnabout in cases that stand for the proposition that the call for the uniformity of national regulation should not be taken so far as to justify the displacement of state common-law remedies for accident victims.” Sharkey, *supra* note 1, at 466.

¹⁰¹ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

¹⁰² *Id.* at 480-81.

¹⁰³ *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1340 (11th Cir. 1995).

¹⁰⁴ *Id.* at 1338.

¹⁰⁵ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

¹⁰⁶ *Id.*

to a device intended for human use any requirement which is different from, or in addition to, any requirement applicable under this Act to the device. . . .”¹⁰⁷ It then held that a finding of “substantial equivalence” under the 510(k) process, even for Class III devices such as the Activitrac, does not constitute a “requirement applicable under this Act.”¹⁰⁸ According to the Court, this premarket notice process focuses more on “substantial equivalence” than safety or effectiveness.¹⁰⁹ Thus, the FDA did not impose any requirements with respect to the design of the pacemaker. Furthermore, the 510(k) process merely preserved the status quo for pre-amendment devices until regulations governing them could be promulgated.¹¹⁰ Since the status quo for medical devices at the time of the amendments included liability for state tort claims, Congress did not intend to displace them with this process.¹¹¹ In sum, “[g]iven this background behind the ‘substantial equivalence’ exemption, the fact that ‘the purpose of Congress is the ultimate touchstone’ in every pre-emption case, and the presumption against pre-emption . . . the ‘substantial equivalence’ provision did not pre-empt the Lohrs’ design claims.”¹¹²

The Court also held that the manufacturing and labeling claims were not preempted by the FDCA. For purposes of the preemption provision, the Court found that FDA requirements for manufacturing and labeling the pacemaker were merely general requirements that were not “specific to the device.”¹¹³ The Court, however, left the door open to future findings of preemption if a state requirement, even if general in nature, has the effect of “establishing a substantive requirement for a specific device” that is subject to specific federal regulations.¹¹⁴ While the Court did not provide any examples to illustrate such a situation, it did reiterate that

¹⁰⁷ 21 U.S.C. § 360k(a) (2008).

¹⁰⁸ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493-94 (1996).

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 494.

¹¹¹ *See id.*

¹¹² *Id.*

¹¹³ *Id.* at 498-500.

¹¹⁴ *Id.* at 500.

the state-based claims at issue in the case were not preempted because they only imposed general duties on manufacturers to use due care to avoid foreseeable dangers and to inform users of the risks associated with their products.¹¹⁵ In addition, the Court held that state negligence *per se* claims were not preempted because they are not “different from, or in addition to,” federal regulations.¹¹⁶ The Court reasoned that such claims “merely [provide] another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.”¹¹⁷

Ultimately, in spite of an explicit preemption clause governing medical device regulation, the Court broadly upheld the Lohrs’ state tort claims against Medtronic for its defective pacemaker. A plurality even noted that “given the critical importance of device specificity” in the preemption clause, “it is apparent that few, if any, common-law duties have been pre-empted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has ‘the effect of establishing a substantive requirement for a specific device.’”¹¹⁸ This four-Justice plurality also strongly disagreed with Medtronic’s contention that any common law duty is a “requirement” that must be preempted under the FDCA.¹¹⁹ According to the plurality, such a view is “implausible” because it would mean that “Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device.”¹²⁰

2. Riegel v. Medtronic

In *Riegel v. Medtronic*, the Supreme Court was presented with another opportunity to clarify the preemption doctrine with respect to medical devices. In this case, a physician used

¹¹⁵ *Id.* at 501.

¹¹⁶ *Id.* at 495.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 502-03.

¹¹⁹ *See id.* at 486.

¹²⁰ *Id.* at 487.

Medtronic's Evergreen Balloon Catheter to dilate Riegel's coronary artery after he suffered a heart attack.¹²¹ The actual use of the catheter in Riegel's case was contraindicated by the product's label, both because Riegel's heart had calcified stenosis and because the physician inflated the catheter beyond the maximum pressure indicated as being safe.¹²² In fact, the catheter ruptured and blocked the heart, necessitating the use of life support and an emergency bypass surgery.¹²³ Riegel subsequently filed state law claims asserting that the catheter was inadequately designed, manufactured, and labeled under theories of negligence and strict liability.¹²⁴

The Court first established that unlike the pacemaker at issue in *Lohr*, the catheter here was marketed under the premarket approval process in which the FDA examines the device for safety and effectiveness.¹²⁵ Thus, the catheter was subject to specific federal requirements concerning its design, manufacture, and labeling.¹²⁶ The Court also departed from *Lohr* in finding that state tort claims can be considered, and in fact are, requirements within the context of the preemption provision for medical devices.¹²⁷ The Court characterized tort judgments as indicating violations of state-law obligations.¹²⁸ According to the Court, "while the common-law remedy is limited to damages, a liability award 'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'"¹²⁹ Consequently, Riegel's state tort claims were preempted by the FDCA because they imposed requirements different than the ones imposed by

¹²¹ Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1005 (2008).

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.* at 1006.

¹²⁶ *See id.* at 1007.

¹²⁷ *See id.* at 1007-08.

¹²⁸ *See id.* at 1008.

¹²⁹ *See id.* (quoting *Cipollone v. Liggett Group*, 505 U.S. 504, 521 (1992)).

the FDA through the premarket approval process.¹³⁰ Conversely, however, the Court reiterated the specific holding in *Lohr* that negligence *per se* claims based on a breach of federal requirements, though not at issue in *Riegel*, are not preempted by the Act.¹³¹

In *Riegel*, Justice Ginsburg was alone in carrying the mantle of compensation for injured victims of defective products, a concern previously espoused by other Justices. While Justice Ginsburg agreed with the majority that negligence *per se* claims should not be preempted, she was additionally concerned about “consumers injured by devices that receive FDA approval but nevertheless prove unsafe.”¹³² In her dissent, Justice Ginsburg argued that Congress only intended to preempt state agency regulations that were beginning to emerge throughout the country at the time of the Medical Device Amendments.¹³³ As for state tort claims, “[w]here the text of a preemption clause is open to more than one plausible reading, courts ordinarily ‘accept the reading that disfavors pre-emption.’”¹³⁴ Justice Ginsburg, accordingly, presumed that Congress did not intend to additionally preempt such claims, especially since it did not simultaneously create a federal compensatory remedy.¹³⁵ In other words, “[i]t is ‘difficult to believe that Congress would, without comment, remove all means of judicial recourse’ for large numbers of consumers injured by defective medical devices.”¹³⁶

The *Riegel* Court fulfilled its warning in *Lohr* that some state tort claims may constitute requirements for purposes of the preemption clause. Indeed, in *Riegel*, the Court preempted a large swath of state tort claims that are based on the inadequate design and labeling of medical devices that have received premarket approval from the FDA. The practical effect of this ruling

¹³⁰ See *id.* at 1007-08.

¹³¹ See *id.* at 1011.

¹³² *Id.* at 1015 (Ginsburg, J., dissenting).

¹³³ *Id.* at 1013 (Ginsburg, J., dissenting).

¹³⁴ See *id.* at 1014 (Ginsburg, J., dissenting) (quoting *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 718 (1985)).

¹³⁵ See *id.* at 1015 (Ginsburg, J., dissenting).

¹³⁶ See *id.* at 1013 (Ginsburg, J., dissenting) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

will become even more severe as the FDA embarks on its recent initiative to subject all Class III medical devices to the premarket approval process for safety and effectiveness.¹³⁷ Once complete, lawsuits such as the one upheld in *Lohr* and numerous other cases will be preempted, leaving injured victims without a remedy. Although displeased with the Court's holding in *Riegel*, Justice Ginsburg noted that the case did not address the scenario in which a consumer is injured because of a product defect that was not evident at the time of premarket approval.¹³⁸ This remark proved to be somewhat prescient, since the Court would address this issue in its next term with respect to pharmaceutical drugs.

B. Pharmaceutical Drugs

1. *Wyeth v. Levine*

In *Wyeth v. Levine*, the Supreme Court applied its preemption analysis in the realm of pharmaceutical drugs, which are not subject to the express preemption clause that governs medical devices. In this case, Donna Levine went to a local clinic to receive treatment for a migraine.¹³⁹ She received shots of Demerol for her headache and Phenergan for her nausea.¹⁴⁰ When this treatment did not provide relief of her symptoms, Levine received additional Phenergan through the alternate method of an IV-push.¹⁴¹ Phenergan's warning label noted the potential for gangrene if the drug comes into contact with arterial blood, which is a risk when using the IV-push method.¹⁴² The label further stated that the IV-drip method is preferred, whereby the drug is diluted in a saline solution before entering the patient's vein.¹⁴³ The label did not, however, specifically note that the IV-drip method would generally avoid the risk of

¹³⁷ See note 66, *supra*, discussing the outside pressure on the FDA to finally classify and review all grandfathered and "substantially equivalent" devices.

¹³⁸ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1015 n.1 (2008) (Ginsburg, J., dissenting).

¹³⁹ *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009).

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.* at 1191 & n.1.

¹⁴³ *Id.*

gangrene, a finding that was made by the trial court.¹⁴⁴ In fact, the IV-push administration of Phenergan caused gangrene in Levine's arm because some of the drug came into contact with arterial blood.¹⁴⁵ Consequently, Levine's hand, and then arm, were amputated to prevent further injury.¹⁴⁶ Levine subsequently filed claims against Wyeth, the manufacturer of Phenergan, under state tort theories of negligence and strict liability for failing to warn against the use of the IV-push method.¹⁴⁷ In rejecting Wyeth's argument for preemption, the Vermont trial court found that the FDA permitted a company to strengthen its warnings, at least pending agency review, that the FDA did not seriously consider any proposed warning against IV-push for Phenergan, and that "state law serves a compensatory function distinct from federal regulation."¹⁴⁸ The Vermont Supreme Court affirmed, noting the ability of Wyeth to unilaterally strengthen its warning against the IV-push method without FDA approval and its belief that, in any event, "federal labeling requirements create a floor, not a ceiling, for state regulation."¹⁴⁹

Since there is no relevant preemption clause, Wyeth argued that Levine's claims should be impliedly preempted either because it would have been impossible to comply with both the state and federal labeling requirements¹⁵⁰ or because the state law judgment served to frustrate the FDA's decision about the safety and effectiveness of Phenergan.¹⁵¹ The Supreme Court dismissed the first contention on the same basis as the Vermont Supreme Court; that is, under FDA regulations, Wyeth was permitted to change its label to correspond to newly evident or

¹⁴⁴ *Id.* at 1192.

¹⁴⁵ *Id.* at 1191.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* at 1193 (citing the unpublished opinion of the trial court).

¹⁴⁹ *Id.* (quoting *Wyeth v. Levine*, 944 A.2d 179, 184 (Vt. 2006)).

¹⁵⁰ Wyeth characterized the unfavorable jury verdict as a state labeling requirement because it would have been forced to change its label in order to avoid future liability. *See id.* at 1193-94.

¹⁵¹ *See id.*

perceived dangers.¹⁵² Since Levine presented evidence that Wyeth was aware of a significant number of gangrene cases involving the IV-push method for Phenergan, the jury could reasonably hold Wyeth liable for failing to warn of this possibility.¹⁵³

The Court also rejected Wyeth's second preemption defense. Wyeth argued that state jury verdicts – finding FDA-approved labels to be inadequate – frustrate the intent of Congress to entrust the FDA to strike the appropriate risk-benefit balance for new drugs.¹⁵⁴ Thus, according to Wyeth, FDA's approval constitutes “a floor and a ceiling for drug regulation,” and therefore, state tort claims to the contrary are preempted.¹⁵⁵ The Court, however, inferred from the lack of a federal remedy that Congress intended to preserve “state rights of action [to provide] appropriate relief for injured consumers.”¹⁵⁶ The Court also cited the FDA's previously long-standing support of state tort law as a supplement to its regulations, necessitated in part by a chronic lack of resources.¹⁵⁷ According to the Court, such a stance was sensible for the additional reasons that state lawsuits can uncover unknown drug hazards and “also serve a distinct compensatory function. . . .”¹⁵⁸

The Court never stated that all state tort claims against drug manufacturers would overcome a preemption defense, even in cases like Levine's involving failure to warn claims. Indeed, the Court noted near the end of its opinion that part of Wyeth's preemption argument was undermined by the fact that “the FDA did not consider and reject a stronger warning against IV-push injection of Phenergan.”¹⁵⁹ The Court seems to imply that had the FDA done so, the state jury verdict finding the label inadequate for not including a more stringent warning could

¹⁵² *See id.* at 1196-98.

¹⁵³ *See id.* at 1197.

¹⁵⁴ *Id.* at 1199.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 1202 & n.11.

¹⁵⁸ *Id.* at 1202.

¹⁵⁹ *Id.* at 1203 n.14.

be preempted. Indeed, the Court ended its opinion by stating: “Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case.”¹⁶⁰ Just as the Court had left the door open in *Lohr* for a future holding in favor of preemption, the *Levine* opinion’s closing statements seem ominous.

2. *Colacicco v. Apotex, Inc.*

The extent of the recent holding in *Levine* will only truly be known as more cases with similar, though significantly different, facts are decided. The *Levine* Court stated that “absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”¹⁶¹ Thus, an obvious candidate for further clarification in this area would be a case in which the FDA *did* reject a specific warning that a state jury subsequently deemed necessary.

In *Colacicco v. Apotex*, the 3rd Circuit Court of Appeals reviewed two consolidated cases concerning failure to warn claims for SSRI anti-depressants.¹⁶² The plaintiffs in these cases filed claims on behalf of decedents who committed suicide after taking these types of drugs, claiming that the deaths resulted from a reaction to the drugs and not the underlying depression.¹⁶³ The claims and defenses asserted were similar to the *Levine* case; however, in *Colacicco*, there was evidence that the FDA had specifically considered the risk of suicide from taking this class of drugs. Indeed, according to the court, the “FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.”¹⁶⁴ In other words, manufacturers would violate federal law if they modified their labels to include

¹⁶⁰ *Id.* at 1204.

¹⁶¹ *Id.* at 1198.

¹⁶² *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 256 (3rd Cir. 2008).

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 269.

warnings about the risk of suicide related to using these drugs. The Court of Appeals, therefore, held that the plaintiffs' claims were preempted because it would have been impossible for manufacturers to abide by federal law if they had changed their labels in accordance with the state jury verdicts. According to the court:

Because the standard for adding a warning to drug labeling is the existence of 'reasonable evidence of an association of a serious hazard with a drug,' and the FDCA authorizes the FDA to prohibit false or misleading labeling, a state-law obligation to include a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA's oft-repeated conclusion that the evidence did not support such an association.¹⁶⁵

Colacicco was decided before the Supreme Court's decision in *Wyeth v. Levine*. In fact, both cases were granted *certiorari* by the Supreme Court for the same term. The Supreme Court, however, vacated its previous grant and remanded *Colacicco* to the 3rd Circuit "for further consideration in light of *Wyeth v. Levine*."¹⁶⁶ Ironically, the 3rd Circuit's opinion in *Colacicco* had specifically distinguished the Vermont Supreme Court's decision in *Wyeth v. Levine*, which was affirmed by the U.S. Supreme Court. Specifically, the 3rd Circuit distinguished *Levine* on the basis that Wyeth could have complied with federal and state law because the warning that the state jury deemed necessary was not assessed and rejected by the FDA, unlike the suicide warning at issue in its case.¹⁶⁷ Thus, the Supreme Court's decision to remand could mean that in light of the rationale used in its decision of *Levine*, it did not view the distinction made by the 3rd Circuit in *Colacicco* as compelling. Indeed, the Supreme Court employed broad language at times in viewing Congressional intent to preserve the coexistence of state tort claims with FDA regulations.¹⁶⁸ However, it largely referred to this history in the context of undermining Wyeth's reliance on the FDA's recent policy reversal in favor of preemption.¹⁶⁹ Furthermore, the Court

¹⁶⁵ *Id.* at 271.

¹⁶⁶ *Colacicco v. Apotex, Inc.*, 77 U.S.L.W. 3504 (2009).

¹⁶⁷ *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 271 n.17 (3rd Cir. 2008).

¹⁶⁸ *See Wyeth v. Levine*, 129 S. Ct. 1187, 1201-02 (2009).

¹⁶⁹ *See id.* at 1199-1203.

never explicitly embraced the second aspect of the Vermont Supreme Court’s holding, which was based on the belief that “federal requirements create a floor, not a ceiling, for state regulation.”¹⁷⁰

The Court’s focus in *Levine* on whether it was possible for Wyeth to comply with the state jury verdict and federal labeling requirements also seems to suggest that it does not view the FDA’s explicit determination as a floor that can be supplemented by state tort claims for inadequacy. In other words, throughout its argument, the Court implicitly accepted that state jury verdicts for failure to warn impose requirements on the drug’s manufacturer; therefore, the Court concedes that such requirements can conflict with federal labeling requirements.¹⁷¹ In fact, the Supreme Court seemed to leave the door open to cases like *Colacicco* when it expressly refused to comment on the type of fact pattern that is really at issue there.¹⁷² As noted above, the Court stated in *Levine* that the case did not involve a situation where the FDA had specifically considered and rejected the warning deemed necessary by the state jury verdict.¹⁷³ Consequently, it remains unclear whether failure to warn claims based on risks that the FDA explicitly considered and rejected are preempted.

C. Critical Considerations

1. A Threshold Inquiry

The Court’s preemption decisions were only made possible by its concurrent determination that state tort law and jury verdicts constitute requirements that can conflict with federal regulations. Without this presupposition, there would be nothing for federal law to

¹⁷⁰ *Id.* at 1193.

¹⁷¹ *See id.* at 1198 (“[W]e recognize that some state-law claims might well frustrate the achievement of congressional objectives. . . .”)

¹⁷² *See id.* at 1203 & n.14, 1204 (stating that one of Wyeth’s arguments for preemption “is belied by the record” because “the FDA did not consider and reject a stronger warning against IV-push injection of Phenergan”).

¹⁷³ *Id.* at 1198-99, 1203 n.14.

preempt, aside from state statutes and regulations. The Court has been inconsistent in this regard, and its settled interpretation seems far from compelling. In *Bates v. Dow Agrosiences*, for example, the Court stated that “a requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”¹⁷⁴ And yet three years later, in *Riegel v. Medtronic*, the Court informed Congress that it would generally interpret the term “requirements” as encompassing state tort claims and jury verdicts.¹⁷⁵

It is unclear whether this latest pronouncement by the Court will constrain any future cases that rely on the interpretation of the term “requirements;” in any event, the reasoning is certainly not convincing. A tort-based jury verdict “would not *require* the manufacturer to do anything other than pay money damages.”¹⁷⁶ This view is consistent with the compensatory function of tort law. The effects of a jury verdict on a manufacturer’s behavior, if any, are indirect.¹⁷⁷ They certainly should not be viewed as having the force or characteristics of a true regulation. At best, a jury verdict may influence the behavior of manufacturers, who might attempt to avoid future tort awards by taking added precautions or implementing various measures to educate consumers about the potential dangers associated with their products.¹⁷⁸ But the manufacturer can also do absolutely nothing, and choose to pay the award as a cost of doing business.¹⁷⁹ Ultimately, “the level of choice that a defendant retains in shaping its own behavior

¹⁷⁴ 544 U.S. 431, 445 (2005).

¹⁷⁵ 128 S. Ct. 999, 1009 (2008).

¹⁷⁶ Kessler & Vladeck, *supra* note 76, at 478.

¹⁷⁷ See *Cipollone v. Liggett Group*, 505 U.S. 504, 536 (1992) (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part).

¹⁷⁸ See *id.* (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) (detailing several different ways in which a manufacturer may respond to a failure-to-warn verdict).

¹⁷⁹ See Kessler & Vladeck, *supra* note 76, at 478.

distinguishes the indirect regulatory effect of the common law from positive enactments such as statutes and administrative regulations.”¹⁸⁰

2. The Outlook for Consumers

In the end, the Supreme Court has provided additional guidance for courts deciding cases involving tort claims against drug and medical device manufacturers who assert preemption defenses. Unfortunately for consumers, the availability of compensation for injuries has been eliminated in many of these cases and become uncertain in others. With respect to medical devices, the Court made the pivotal decision in *Riegel* to interpret the term “requirements” in the preemption clause as encompassing state tort law and jury verdicts. Consequently, any state-based claims implicating a Class III medical device, which is subject to specific federal requirements, is preempted by the FDCA. In other words, the devices most likely to cause an injury because of their nature are now immune from liability. While Justice Ginsburg claimed in her dissent that the case did not address a scenario in which product defects come to light after FDA approval, the majority opinion never conceded this point. Thus, it is far from clear whether or not her contention will prove to be prophetic at some point in the future.

The preemption jurisprudence on pharmaceutical drugs is not much clearer than with respect to medical devices. While the former category of products is not subject to a preemption clause, the Court could achieve the same result in *Riegel* in a drug case using an implied preemption analysis. Thus, using the facts from *Colacicco*, the Court could determine that the state-law requirement – in the form of a tort law verdict – frustrates the FDA’s risk-benefit decision in rejecting an added warning for suicidality to the drug’s label. In this scenario, both Class III medical devices and drugs could be immune from liability, unless the alleged design

¹⁸⁰ *Cipollone v. Liggett Group*, 505 U.S. 504, 536 (1992) (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part).

defect surfaces after agency approval, though this has yet to be decided by the Court with respect to medical devices. Ultimately, a significant number of consumer-patients currently have no recourse if they are injured by a medical device. In addition, a substantial number of pharmaceutical drug consumers may be left uncompensated if the Court finds that an explicit rejection of a strengthened warning label by the FDA impliedly preempts state verdicts to the contrary.¹⁸¹

IV. The Problem of Compensation

A. Congressional Intervention

Having noted some objections to the Supreme Court’s decisions described above, this section addresses where we should go from here, having to live with the current preemption landscape for FDA-regulated drugs and medical devices. The *Riegel* Court clearly offered one option. In conceding the ambiguity of the term “requirements,” as used in the medical device preemption clause, the Court put Congress on notice as to how it would interpret this usage. According to the majority opinion, “Congress is entitled to know what meaning this Court will assign to terms regularly used in enactments. Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”¹⁸² Thus, the Court invited Congress to take action if it disagreed with how its term was being interpreted. Indeed, Congress has introduced

¹⁸¹ This preemption argument is being vigorously pursued by the defendants’ attorneys in the remanded *Colacicco* case. See Brief of Appellant Pfizer Inc., *Colacicco v. Apotex, Inc.* (3rd Cir. 2009) (No. 06-5148), available at [http://druganddevicelaw.net/Colacicco%20materials/Colacicco%20\(McNellis\)%20post-Levine%20preemption.pdf](http://druganddevicelaw.net/Colacicco%20materials/Colacicco%20(McNellis)%20post-Levine%20preemption.pdf) (last visited Apr. 30, 2009); Memorandum of Appellees GlaxoSmithKline and Apotex on the Effect of *Wyeth v. Levine* and in Support of Affirmance on Remand, *Colacicco v. Apotex, Inc.* (3rd Cir. 2009) (No. 06-3107), available at <http://druganddevicelaw.net/Colacicco%20materials/Colacicco%20post-Levine%20preemption%20brief.pdf> (last visited Apr. 30, 2009).

¹⁸² *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008).

legislation that would effectively overturn *Riegel* and reinstate tort liability for all medical device manufacturers.¹⁸³

Aside from restoring a compensatory remedy for injured consumers, there are additional powerful policy arguments that would support Congressional action here. Two of the more notable, and practical, considerations focus on the lack of agency resources and the nature of assessing the true safety profile of a drug or medical device. The actual risks associated with a new drug or medical device can only be known after it has been introduced to the general population, which is much larger and more diverse than the participants of a clinical trial.¹⁸⁴ Thus, FDA approval of a drug or medical device does not guarantee safety, nor does it even rely on a truly accurate risk-benefit analysis since all of the potential hazards remain unknown. Furthermore, because of budget constraints and other factors, the FDA only employs 100 individuals to monitor and detect adverse events associated with more than 11,000 different drugs and medical devices that have been approved by the agency.¹⁸⁵ The FDA is therefore ill-equipped to require modifications to a warning label or to withdraw approval of a product in a timely fashion. Because of these inherent limitations in the FDA's ability to ensure the safety of all pharmaceutical drugs and medical devices, Congress has a strong argument for preserving the co-existence of state tort law and federal regulatory oversight. Alternatively, Congress could provide some sort of federal remedy that would similarly accomplish the compensatory goals of state tort law.

B. No-Fault Compensation

¹⁸³ See *Industry Fights for Preemption by Educating Congress*, PUB. DEVICES & DIAGNOSTICS LETTER, Apr. 20, 2009.

¹⁸⁴ See Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 19-20 (1973) (noting that “consumers of prescription drugs serve as guinea pigs for the pharmaceutical industry, for every new drug remains basically ‘experimental’ even after it has been approved for general use”).

¹⁸⁵ See Kessler & Vladeck, *supra* note 76, at 485.

Rather than restore the status quo, some commentators advocate an alternative to traditional state tort liability that would arguably be more fair to both consumers and manufacturers. In a perfect world, all pharmaceutical drugs and medical devices would only have benefits and no inherent risks. In reality, no drug or device is absolutely safe; thus, when “the FDA approves the marketing of a drug it tacitly acknowledges that some users will be injured.”¹⁸⁶ From the vantage point of society as a whole, a utilitarian risk-benefit analysis reveals that “some injuries are not worth avoiding.”¹⁸⁷ Clearly, then, “the regulatory perspective is not a compensation perspective.”¹⁸⁸ Proponents of no-fault compensation schemes are concerned about the welfare of the unlucky individuals who do not benefit from pharmaceutical drugs and medical devices, but rather, suffer significant injuries that may or may not have been foreseeable by manufacturers or the FDA.¹⁸⁹ These proponents do not believe that such injuries should go uncompensated and considered acceptable losses merely because the majority of consumers benefit from a given drug or device.¹⁹⁰

Administrative no-fault schemes have been implemented with varying success in several different fields, including the workplace, automobile accidents, and childhood vaccinations. This type of compensation system has several advantages over the traditional tort system. First, it ensures that all victims, regardless of fault, are compensated for their injuries.¹⁹¹ Second, a well-designed system will achieve greater efficiencies for both injured individuals and

¹⁸⁶ Merrill, *supra* note 184, at 15.

¹⁸⁷ Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2074 (2000).

¹⁸⁸ *Id.*

¹⁸⁹ Some scholars also deride the “negligence lottery,” whereby the vagaries of traditional tort law can leave one plaintiff fully compensated while another similarly situated and injured plaintiff may be left with nothing. *See, e.g.*, Marc A. Franklin, *Replacing the Negligence Lottery: Compensation and Selective Reimbursement*, 53 Va. L. Rev. 774, 785 (1967).

¹⁹⁰ *See, e.g.*, Merrill, *supra* note 184, at 29 (noting that “society has failed altogether to provide any means of compensating those who, as forecast, are injured when the drug regulation system operates precisely as intended”).

¹⁹¹ Stephen D. Sugarman, *Doing Away with Tort Law*, 73 CAL. L. REV. 555, 625 (1985).

manufacturers.¹⁹² For instance, no-fault administrative schemes inherently avoid protracted litigation, thereby reducing the cost of legal fees and resulting in quicker payments to injured individuals.¹⁹³ Finally, such schemes are also designed to produce a more equitable distribution of compensation by ensuring that all injured individuals receive payments and by preventing windfalls that are often comprised of exorbitant punitive damages.¹⁹⁴

The National Childhood Vaccine Injury Compensation Act of 1986 could be used as a model for a no-fault compensatory scheme for pharmaceutical drugs and medical devices. The Act generally provides tort immunity to vaccine manufacturers by making it difficult for an individual to maintain an action in state court.¹⁹⁵ It also sets a minimum threshold for the severity of a vaccine-related injury that can be compensated. Thus, individuals are only entitled to compensation if they suffer side-effects for more than six months or require hospitalization and surgery.¹⁹⁶ In addition, surviving claimants are entitled to compensation in the case of an individual's death resulting from a vaccination.¹⁹⁷ The Act provides for the streamlined adjudication of claims conducted by special masters, who must render a decision within a timeframe not much longer than a year.¹⁹⁸ This is made possible, in part, because claimants need not prove the critical issue of causation if the injury is associated with the particular vaccine listed on the Vaccine Injury Table.¹⁹⁹ Claimants seeking damages for an unlisted injury,

¹⁹² *See id.*

¹⁹³ *Id.*

¹⁹⁴ *See id.*

¹⁹⁵ *See* 42 U.S.C. §§ 300aa-11 & 300aa-16 (2008) (describing the limitations on bringing forth a claim based on a vaccine-related injury).

¹⁹⁶ *Id.* § 300aa-11(c)(1)(D).

¹⁹⁷ *Id.*

¹⁹⁸ *See id.* § 300aa-12 (establishing the special masters and creating a framework providing for the adjudication of claims within 420 days).

¹⁹⁹ *See* 42 C.F.R. § 100.3 (listing the latest version of the Vaccine Injury Table).

however, face the more burdensome task of proving causation.²⁰⁰ Successful claimants in either case are compensated from a fund that relies on a seventy-five cent tax on each dose of vaccine.²⁰¹ The Act limits such awards to \$250,000 for injuries or death and forbids punitive damages.²⁰²

Applying the vaccine no-fault scheme to pharmaceutical drugs and medical devices would resolve some concerns from both manufacturers and victims alike. As previously stated, manufacturers would have more uniform and predictable liabilities and injured consumers would be guaranteed compensation in most cases. One of the rationales for creating the no-fault scheme for vaccines also readily applies to pharmaceutical drugs and medical devices; that is, all of these products serve a useful function in society, but they also cause a significant number of injuries as well.²⁰³ A no-fault scheme seems to be a workable compromise at insulating the manufacturers of needed drugs and devices while also ensuring reasonable compensation for related injuries. This type of an alternative to traditional tort liability seems even more compelling in the case of a drug or device that has a particularly high value to society, but nevertheless continues to pose risks as well.²⁰⁴ An agency such as the FDA could perhaps designate drugs and devices as being subject to the no-fault scheme based on a risk-benefit analysis. If the drug or device exceeds a threshold utility to society, then it could be protected from traditional liability by being placed in

²⁰⁰ See Gordon Shemin, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know before Rushing out of Vaccine Court*, 58 AM. U.L. REV. 459, 475-76 (2008).

²⁰¹ See 42 U.S.C. § 9510 (2008) (establishing the trust fund); 26 U.S.C. § 4131 (2008) (designating the per-dose tax rates).

²⁰² 42 U.S.C. § 300aa-15.

²⁰³ See Joan E. Bertin & Mary S. Henifin, *Science, Law, and the Search for Truth in the Courtroom: Lessons from Daubert v. Merrell Dow*, 22 J.L. MED. & ETHICS 6, 14-15 (1994).

²⁰⁴ See *id.* at 16.

the no-fault class of products.²⁰⁵ All other drugs and devices would be subject to normal tort liability.

The precise details of a worthwhile no-fault administrative scheme for pharmaceutical drugs and medical devices is beyond the scope of this paper. Indeed, there are certainly reasons why it would be inadvisable to apply the no-fault scheme for vaccines to drugs and medical devices, due to some significant differences between these types of products and the intended recipients.²⁰⁶ The broader point, however, is that useful drugs and medical devices can be protected and encouraged without foreclosing all modes of compensation for injured individuals. Regardless of whether Congress intended to preempt claims against medical devices, and in light of the possibility that courts will continue to dismiss other claims against drug manufacturers on the basis of implied conflict preemption, some form of a compensation scheme can and should be established to provide for innocent victims who are injured by these products.

Conclusion

For nearly 800 years, the common law has recognized an injured person's right to be compensated. During the 19th and 20th centuries, the common law adapted to the increasing complexity of societal interactions by abandoning the requirements of privity, and in some cases, culpability. In the field of products liability, courts recognized that individuals should not bear the costs imposed by manufacturers, who are in a better position to monitor the safety of their products and to spread losses. In response to several notable tragedies, the federal government

²⁰⁵ This classification procedure could be used to achieve other objectives as well, such as a *de facto* implementation of comparative effectiveness. In other words, if a drug merits FDA-approval for safety and effectiveness, but is not more effective or safer than currently marketed drugs for the same targeted ailment, then the agency responsible for no-fault classifications could refuse to include it in this category.

²⁰⁶ Vaccinations are usually administered to healthy young children and have generally predictable side-effects. Drugs and medical devices, however, are constantly being re-designed (with unknown side-effects) and are often administered to individuals who suffer from multiple ailments and are taking other drugs as well. See Michael D. Green & William B. Schultz, *Regulatory Compliance as a Defense to Products Liability: Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2121 (2000).

began regulating the safety of pharmaceutical drugs and medical devices before they reached the public. Meanwhile, state tort law continued to provide compensatory relief for injuries that were not prevented by the FDA. Thus, state tort law and federal regulations combined to provide increasing protection to consumers while preserving a compensatory remedy for injuries. The early part of the 21st century, however, has seen this balance upset by the Supreme Court's preemption jurisprudence. By perceiving state compensatory judgments as a form of regulation on manufacturers, the Court has preempted state tort judgments against many medical device manufacturers and may do so with respect to manufacturers of pharmaceutical drugs as well. Since Congress did not provide a federal remedy under the FDCA, however, many consumers are no longer entitled to compensation for their injuries. This development is at odds with the longstanding history of tort law and the relatively recent trends of both state and federal law to provide more protection to consumers. In order to avoid this unjust result, Congress must restore a compensatory scheme for injured consumers. Whether through traditional state tort liability or a no-fault system, consumers should not be foreclosed from recovering for injuries due to inherently dangerous pharmaceutical drugs and medical devices.