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Preemption of Drug and Medical Device Claims: A Legal Overview

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Summary

The interaction between state tort laws and the federal regulation of medical devices and drugs has been a source of constant litigation in recent years. In the last two decades, the Supreme Court has issued several decisions concerning whether the Federal Food, Drug, and Cosmetic Act (FDCA) preempts state tort law. The results have been mixed: in some cases a person injured by an allegedly defective drug or device is barred from suing a manufacturer, whereas in other cases, the Supreme Court has allowed a lawsuit to proceed. Following these decisions, ambiguities exist concerning the scope of federal preemption in these medical device and drug cases.

With respect to medical devices, state-law tort claims brought against device makers are restricted by a provision of the FDCA that expressly preempts state “requirements” that are “different from, or in addition to” federal requirements applicable to a device and that “relate[] to the safety or effectiveness of the device.” The Supreme Court has generally found that under this provision, the ability of an individual to bring a state-law tort suit alleging certain defects with a medical device can hinge on, among other things, how that device received marketing approval from the Food and Drug Administration (FDA). In *Medtronic v. Lohr*, the Court found that state-law claims involving “substantially equivalent” medical devices cleared through the § 510(k) process were not barred by the FDCA’s express preemption provision. However, in *Riegel v. Medtronic*, the Court concluded that if the FDA grants approval to a medical device under its more rigorous premarket approval process, the device manufacturer is immune from certain suits under state tort law. The Court has also found in *Buckman v. Plaintiff’s Legal Committee* that state-law tort claims stemming from violations of the FDCA may be impliedly preempted by federal law. Despite these three decisions, questions remain about what state-law tort claims survive federal preemption.

In contrast to its provisions on medical devices, the FDCA does not contain an express preemption clause with respect to its prescription drug mandates. Nonetheless, the elaborate premarket approval scheme for drugs created by the FDCA has the potential to clash with state tort law, raising questions as to whether these laws may be preempted. The Court has recently handed down three landmark rulings that clarify when the FDCA’s drug requirements preempt state tort law. In 2009, the Supreme Court, in *Wyeth v. Levine*, held that a person hurt by a brand name drug could sue the manufacturer under state tort law for a failure to properly warn about the dangers of the drug. However, in a second case, *PLIVA v. Mensing*, the Supreme Court ruled that a person hurt by a generic drug could not bring the same failure-to-warn claim because changing the labeling of a generic drug would conflict with federal law that requires a generic drug to be the “same” as its branded equivalent in all material respects, including its labeling. Finally, in *Mutual Pharmaceutical v. Bartlett*, the question for the Court was whether a person harmed by a generic drug could obtain relief on a theory other than a failure-to-warn claim. The Court held that such claims, much like the failure-to-warn claims in *Mensing*, by imposing heightened duties that would conflict with the “sameness” requirements of federal law regarding generic drugs, were preempted by the FDCA.

This report provides background on the doctrine of preemption and the types of state-law tort claims that have been brought against medical device and prescription drug manufacturers. The report also addresses the federal regulation of medical devices and drugs under the FDCA. With that background in mind, the report discusses the major FDCA preemption cases that have been recently issued by the Supreme Court. Finally, the report covers possible judicial and legislative developments that may affect this dynamic area of law.

Contents

Introduction..... 1

Constitutional Preemption 1

 Types of Preemption..... 2

 Express Preemption..... 2

 Implied Preemption..... 3

 Interaction Between Implied and Express Preemption..... 4

 Who Can Preempt?..... 5

Tort Liability With Respect to Drugs and Medical Devices 6

 Older Theories of Recovery 7

 Negligence..... 7

 Breach of Warranty 9

 Fraud 10

 Strict Liability..... 11

Medical Devices and the FDCA 14

 Premarket Approval..... 15

 Premarket Notification (§ 510(k) Submissions)..... 15

Preemption and Medical Devices 17

 Express Preemption: *Lohr* and *Riegel* 17

Medtronic v. Lohr 18

Riegel v. Medtronic..... 19

 Implied Preemption: *Buckman v. Plaintiff’s Legal Committee*..... 21

 Future of Preemption and Medical Devices 22

Pharmaceutical Drugs and the FDCA..... 23

 Premarket Approval of Drugs..... 24

 Approval of Generic Drugs 25

Preemption and Prescription Drugs 26

Wyeth v. Levine 27

 The Concurring Opinions in *Levine* 30

PLIVA v. Mensing 30

Mutual Pharmaceutical v. Bartlett 32

 Future of Preemption Issues and the Food, Drug, and Cosmetic Act..... 34

 The Broad Principles of *Levine*, *Mensing*, and *Bartlett* 34

 Potential Changes to the Generic Sameness Requirement..... 35

 Other Developing Areas Regarding Preemption and Prescription Drugs 36

Contacts

Author Contact Information..... 38

Introduction

Federal preemption of state tort law actions brought against drug and medical device manufacturers, which has the legal effect of immunizing manufacturers from tort liability, has been a source of great controversy in recent years. These cases arise when individuals are allegedly harmed by a defective product and sue the manufacturer. The Federal Food, Drug, and Cosmetic Act (FDCA)¹ does not expressly allow these injured individuals to bring such a claim, and, accordingly, someone injured by a medical device or drug may be limited to bringing a suit under state tort law in order to obtain compensation for the resulting injuries. For example, an injured plaintiff may allege that a manufacturer was negligent with respect to the design of the drug or device and seek monetary relief for the injuries suffered. However, because of the doctrine of constitutional preemption, a court may dismiss such a claim because the claim is superseded by federal law. The Supreme Court has evaluated medical device and drug preemption cases on a number of occasions over the past two decades, and the results have been mixed: in some instances a person injured by an allegedly dangerous drug or device is barred from suing a manufacturer, whereas in other cases, the Court has allowed a suit to go forward.

In order to explain the major Supreme Court cases in this area of law, this report begins by providing background on three general subject matters. First, the report examines the doctrine of constitutional preemption, the legal basis for determining when a state law must yield to a federal law. From there, the report discusses both the state law and federal laws at issue in the recent Supreme Court FDCA preemption cases. Specifically, the report addresses the types of state-law tort claims that are commonly brought against drug and medical device manufacturers. After discussing preemption and tort liability, the report examines federal law regulating prescription drugs and medical devices. With the background on the general subjects of preemption, tort law, and federal regulation of drugs and devices in mind, the report concludes by examining the major Supreme Court FDCA preemption cases and analyzing possible judicial and legislative developments that may affect this complicated and ever-changing area of law.

Constitutional Preemption

Because of the Supremacy Clause found in Article VI of the Constitution, the “Laws of the United States” made in pursuance of the Constitution are by definition “the supreme Law of the Land” “notwithstanding” “the Constitution or the Laws of any State to the Contrary.”² Under the doctrine of federal preemption, state laws are invalid if they “interfere with, or are contrary to federal law.”³ Accordingly, preemption is a necessary product of a specific federal law’s reach,⁴ and, in that vein, the Court has repeatedly recognized that the intent of Congress is the “‘ultimate touch-stone’ in every pre-emption case.”⁵

¹ 21 U.S.C. §§ 301 et seq.

² U.S. Const. Art. VI, § 1, Cl. 2.

³ See *Hillsborough Cnty. v. Automated Med. Labs*, 471 U.S. 707, 712 (1985).

⁴ See Richard A. Epstein and Michael S. Greve, *Federal Preemption* 19 (2007) (“The congressional intent baseline raises the specter that preemption law can only be as coherent as the statutory universe on which it operates.”).

⁵ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

Another principle that sometimes guides the Supreme Court's jurisprudence in preemption cases is the so-called "presumption against preemption." Specifically, the Court in the past has held that in "all pre-emption cases" an assumption exists that "the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress."⁶ Notwithstanding the Court's previous pronouncements regarding the presumption against preemption, in recent terms, the Court arguably appears to be moving away from embracing the presumption. Following *Wyeth v. Levine*,⁷ the presumption has largely been ignored or distinguished away by a majority of the Court over the past four terms.⁸ In *PLIVA v. Mensing*, three Justices joined a portion of Justice Thomas's opinion that argued that the original meaning of the Supremacy Clause "suggests that federal law should be understood to impliedly repeal conflicting state law," a theory that would conflict with the presumption against preemption.⁹ Two years later, in *Mutual Pharmaceutical v. Bartlett*, a majority of the Court, while acknowledging that the preemptive scope of the federal law in question had posed "difficult ... questions" and "repeatedly vexed the Court," still found a state law unconstitutional without discussing the presumption against preemption.¹⁰ As a consequence, the presumption against preemption, formerly called one of the "cornerstones of ... pre-emption jurisprudence,"¹¹ appears to be no longer consistently applied, if not rejected, by the Court.¹²

With these principles in mind, there are two general categories of preemption: express preemption and implied preemption.¹³

Types of Preemption

Express Preemption

The first way in which federal law can foreclose the operation of a state law is by express language in a congressional enactment, often called an express preemption clause.¹⁴ In those instances, determining the scope of the preemption clause is a matter of statutory construction.¹⁵

⁶ See *Medtronic, Inc.*, 518 U.S. at 485 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

⁷ See *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (applying the presumption).

⁸ See, e.g., *Arizona v. Inter Tribal Council of Ariz., Inc.*, 133 S. Ct. 2247, 2256 (2013) (holding that the presumption against preemption does not apply in Election Clause cases); *Tarrant Reg'l Water Dist. v. Herrmann*, 133 S. Ct. 2120, 2132 (2013) ("There is, however, one interpretive tool that is inapplicable [with respect to interstate compacts]: the presumption against pre-emption."); *Cuomo v. Clearing House Ass'n, L.L.C.*, 557 U.S. 519, 534 (2009) ("We have not invoked the presumption against pre-emption, and think it unnecessary to do so in giving force to the plain terms of the National Bank Act."); but see *Hillman v. Maretta*, 133 S. Ct. 1943, 1950 (2013) (applying the presumption with respect to the preemption of state laws governing domestic relations).

⁹ 131 S. Ct. 2567, 2580 (2011).

¹⁰ See 133 S. Ct. 2466, 2480 (2013).

¹¹ See *Levine*, 555 U.S. at 565.

¹² See, e.g., Ernest A. Young, "The Ordinary Diet of the Law:" *The Presumption Against Preemption in the Roberts Court*, 2011 Sup. Ct. Rev. 253, 307 ("Notwithstanding this and similar endorsements, many scholars have noted the Court's failure to consistently employ the *Rice* canon. The 2010 Term was no exception to this tendency: The Justices ignored *Rice* in *Williamson* and *Concepcion* and invoked it only in dissent in *PLIVA* and *Bruesewitz*.").

¹³ See *Treasurer of N.J. v. U.S. Dep't of Treasury*, 684 F.3d 382, 406 (3d Cir. 2012).

¹⁴ See *Lorillard Tobacco v. Reilly*, 533 U.S. 525, 541 (2001).

¹⁵ See *Chamber of Commerce of the United States v. Whiting*, 131 S. Ct. 1968, 1977 (2011) ("When a federal law contains an express preemption clause, we 'focus on the plain wording of the clause, which necessarily contains the (continued...)

While the existence of an express preemption clause may imply a relatively straightforward resolution of whether a particular state law is preempted by federal law, express preemption cases can be as complex as implied preemption cases. For example, in a case called *Cipollone v. Liggett Group*, a very divided Supreme Court interpreted a provision in the Public Health Cigarette Smoking Act of 1969 that barred a state from imposing a “requirement or prohibition based on smoking or health ... with respect to advertising or promotion of any cigarettes.”¹⁶ The Court issued three different opinions, none of which garnered a majority of the Justices, and ultimately concluded that the express provision in the 1969 law preempted state negligence and strict liability claims, but did not preempt claims for a breach of an express warranty.¹⁷ Nine years later, in *Lorillard Tobacco Co. v. Reilly*, a 5-4 ruling, the Court concluded that the same language from the Public Health Cigarette Smoking Act of 1969 preempted a state law banning outdoor cigarette advertising near schools.¹⁸ Together *Cipollone* and *Lorillard* illustrate that interpreting express preemption clauses in federal statutes can raise complicated and difficult questions for courts to resolve.

Implied Preemption

A federal law can also preempt state law even in the absence of an express preemption clause.¹⁹ Courts have recognized two ways in which a federal law can implicitly displace a state law: field preemption and conflict preemption. The latter form of preemption may be further subdivided into impossibility preemption and obstacle preemption.

Field Preemption

The Court has struck down state laws when Congress has evidenced a desire to occupy the entire field of regulation, such that there is “no room for the states to supplement it.”²⁰ The classic example of a field preemption case is *Rice v. Sante Fe Elevator Corp.*, which held that states cannot regulate grain elevators licensed by the federal government because the implicit intent of the underlying federal scheme was to replace a system of dual regulation with a system of exclusive federal licensing.²¹ Other examples of where the doctrine of field preemption is implicated include state regulation of the construction of nuclear power plants,²² the registration of aliens,²³ and foreign affairs.²⁴

(...continued)

best evidence of Congress’ pre-emptive intent.”) (internal citations omitted).

¹⁶ 505 U.S. 504 (1992).

¹⁷ *Id.* at 526 (Stevens, J., plurality opinion).

¹⁸ 533 U.S. 525, 595 (2001).

¹⁹ Implied preemption stems from the notion that a state cannot impose an obstacle that would nullify the effect of or contradict a federal edict. See *McCulloch v. Maryland*, 17 U.S. 316, 4 Wheat 316, 427 (1819) (“[Article VI] is of the very essence of supremacy, to remove all obstacles to its action within its own sphere, and so to modify every power vested in subordinate governments.”).

²⁰ *City of Charleston, S.C. v. A Fisherman’s Best, Inc.*, 310 F.3d 155, 169 (4th Cir. 2002).

²¹ 331 U.S. at 234-36.

²² *Pacific Gas & Electric Co. v. State Energy Resources Conservation and Development Comm’n*, 461 U.S. 190, 205 (1983)

²³ *Arizona v. United States*, 132 S. Ct. 2492, 2503 (2012).

²⁴ *Zschoernig v. Miller*, 389 U.S. 429, 440-41 (1968).

Conflict Preemption

Finally, preemption can occur when a particular state law conflicts with federal law. A conflict exists most obviously when “compliance with both federal and state regulations is a physical impossibility.”²⁵ The quintessential example of impossibility preemption was provided by the Supreme Court in a case called *Florida Lime & Avocado Growers v. Paul*.²⁶ Specifically, the Court, in providing a hypothetical example of what impossibility preemption would look like, stated that a federal law forbidding the picking and marketing of any avocado testing more than 7% oil would preempt for reasons of impossibility a state law excluding from the state any avocado measuring less than 8% oil content.²⁷ Impossibility preemption has rarely been invoked by the Supreme Court,²⁸ as impossibility has been described as a “demanding defense” when attempting to defeat the effect of a state law.²⁹

Conflict preemption can also occur when a state law serves as an “obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”³⁰ Obstacle preemption ultimately becomes a question regarding how much conflict is tolerable between the state and federal law.³¹ The answer to that question rests in the balancing of interests between the degree of impedance to the national purpose and the value of state autonomy in a given context.³² A clear example of obstacle preemption occurred in *Nash v. Florida Industrial Commission*, where the Court held that federal unfair labor practice laws preempted a state law denying unemployment benefits to employees that filed an unfair labor practice charge with the National Labor Relations Board.³³ In *Nash*, the Court reasoned that the financial burden imposed by the state law impedes resorting to federal law as a means to stop an unfair labor practice.³⁴ Obstacle preemption is perhaps the most difficult of the preemption doctrines to apply because of the “inherent uncertainty in determining Congress’s intent to preempt based on an *ex post* judicial assessment of congressional objectives.”³⁵

Interaction Between Implied and Express Preemption

While one might assume the existence of an express preemption clause in a statute eliminates the need for a court to examine whether a statute implicitly preempts a state law,³⁶ the Supreme Court

²⁵ See *Hillsborough Cnty.*, 471 U.S. at 713.

²⁶ 373 U.S. 132 (1963).

²⁷ *Id.* at 143.

²⁸ See *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 430 (D. Vt. 2008).

²⁹ *Levine*, 555 U.S. at 573.

³⁰ See *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

³¹ See *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (noting that “[w]hat is a sufficient obstacle is a matter of judgment to be informed by examining the federal statute as a whole and identifying its purpose and intended effects.”).

³² See Young, *supra* footnote 12 at 275.

³³ See 389 U.S. 235, 240 (1967).

³⁴ *Id.* at 239.

³⁵ See Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. Rev. 967, 970 (2002).

³⁶ The Court suggested such a position in *Cipollone*. See 505 U.S. at 517 (“In our opinion, the pre-emptive scope of the 1965 Act and the 1969 Act is governed entirely by the express language in ... each Act. When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a ‘reliable indicium of congressional intent with respect to state authority,’ ... ‘there is no (continued...)”).

in *Geier v. American Honda Motor Co.* rejected such an assumption.³⁷ In that case, Alexis Geier, after suffering severe injuries in a car crash, sued Honda, arguing that the car company had negligently and defectively designed the car without a driver’s side airbag that might have protected her.³⁸ Honda argued that Geier’s claim was preempted by a federal motor vehicle safety regulation that allowed car companies the choice of installing an airbag, an automatic seatbelt, or some other passive restraint system.³⁹

Justice Breyer, writing for a five-person majority, held that an express preemption clause in the Safety Act containing language that compliance with a federal motor vehicle safety standard did “not exempt any person from liability under the common law” excluded common law tort claims from the statute’s preemptive reach.⁴⁰ Nonetheless, the Court proceeded to explain that while the savings language removed “tort actions from the scope of the express pre-emption clause,” it did not limit the operation of ordinary preemption principles, such as conflict preemption, because to do otherwise would allow states to “impose legal duties that would conflict directly with federal regulatory mandates.”⁴¹ In other words, the Court would not apply an overly broad reading of the savings clause to defeat the ordinary operation of a federal regulatory scheme.⁴² In examining whether the federal motor vehicle safety standard impliedly preempted state tort law, the Court held Geier’s state tort suits preempted on the ground that liability for failing to provide airbags would stand as an obstacle to the purpose of the federal regulation, which was to have a “variety and mix of” passive restraint devices on the market, allowing a gradual phase-in of airbags to the market.⁴³

In the wake of *Geier*, the Court has consistently held that implied preemption principles must be applied even in cases where a federal statute contains a savings clause.⁴⁴

Who Can Preempt?

Beyond the question of “what counts as preemption,” an important ancillary question is what federal institutions have the authority to preempt state law.⁴⁵ The text of the Supremacy Clause implies that Congress, through laws made in pursuance of the Constitution and through treaties

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need to infer congressional intent to pre-empt state laws from the substantive provisions’ of the legislation.”) (plurality) (internal citations omitted).

³⁷ See 529 U.S. 861.

³⁸ *Id.* at 865.

³⁹ *Id.*

⁴⁰ *Id.* at 868.

⁴¹ *Id.* at 869.

⁴² *Id.* at 871-72.

⁴³ *Id.* at 881-82.

⁴⁴ See, e.g., *Hillman*, 133 S. Ct. at 1954 (“[W]e have made clear that the existence of a separate pre-emption provision “does not bar the ordinary working of conflict pre-emption principles.”) (quoting *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002)); see also *Arizona*, 132 S. Ct. at 2504-05 (“But the existence of an ‘express pre-emption proviso[n]’ does not bar the ordinary working of conflict pre-emption principles’ or impose a ‘special burden’ that would make it more difficult to establish the preemption of laws falling outside the clause.”) (internal citations omitted) (emphasis in original).

⁴⁵ See Young, *supra* footnote 12 at 269.

made under the authority of the United States, can act to create law that is supreme to state law.⁴⁶ Beyond Congress, the Supreme Court has recognized that federal administrative agencies, exercising authority delegated by Congress, may also preempt state law in certain circumstances.⁴⁷ Specifically, executive preemption is dependent upon whether administrative action lies within the agency's statutory authority or whether the agency has acted arbitrarily,⁴⁸ which may ultimately be a product of how much deference a court is willing to accord an agency's judgment.⁴⁹ Moreover, in the narrow areas of law in which federal courts can fashion federal common law rules, such as admiralty law, the Court has allowed such rules to preempt state law.⁵⁰

Tort Liability With Respect to Drugs and Medical Devices

Having discussed the doctrine of constitutional preemption and the different ways a federal law can negate the effect of a state law, in order to properly understand the Supreme Court's FDCA preemption case law and how state tort law can be negated by federal law, it is important to also examine both the state and federal laws at issue in the High Court's cases.

An individual harmed by a product, including a drug or a medical device, can potentially utilize tort law as a means to recover any losses caused by such product. Tort law in the United States is "built on the bedrock of state common law,"⁵¹ or judge-created legal norms.⁵² While the objectives of tort law are manifold, there are four central principles that underlie the American tort system. First, tort law aims to compensate people for injuries brought about by the wrongdoing of others.⁵³ Second, beyond compensation, tort law attempts to incentivize safety such that people are deterred from engaging in behaviors that are either intended to harm others or unreasonable enough that they are likely to harm others.⁵⁴ Third, tort law rests on the

⁴⁶ See U.S. Const. Art. VI, § 1, Cl. 2.

⁴⁷ See *Fidelity Savings & Loan v. De la Cuesta*, 458 U.S. 141, 153-54 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes.").

⁴⁸ *Id.*

⁴⁹ See, e.g., *Levine*, 555 U.S. 576 (quoting *Geier*, 529 U.S. at 883) (giving "some weight" to agency's reasoning about preemption); see generally CRS Report R43203, *Chevron Deference: Court Treatment of Agency Interpretations of Ambiguous Statutes*, by (name redacted) and (name redacted).

⁵⁰ See *Southern Pacific Co. v. Jensen*, 244 U.S. 205, 222 (1917).

⁵¹ See Robert L. Rabin, *Federalism and the Tort System*, 50 Rutgers L. Rev. 1, 1 (1997).

⁵² Such an approach to tort law is in keeping with the English tradition of the common law. See, e.g., Roger C. Henderson, *The Tort-Liability Insurance System and Federalism: Everything in its Own Time*, 38 Ariz. L. Rev. 953, 953 (1996) ("Probably our greatest legacy from the English system is the common law, a system that prevails in every jurisdiction of the United States, save Louisiana. And, of course, it was the common law process that gave birth to and brought to maturity the body of law that passes under the head of American tort law today.").

⁵³ See Fowler V. Harper, Fleming James, Jr. & Oscar S. Gray, *The Law of Torts* 25.1, at 490 (2d ed. 1986) ("The cardinal principle of damages in Anglo-American law is that of compensation for the injury caused to plaintiff by defendant's breach of duty.").

⁵⁴ See Steven Shavell, *Economic Analysis of Accident Law* 298 (1987) ("The principal justification for use of accident liability today should not be compensation of victims because this can be accomplished with our well-developed and comparatively cheaply operating insurance system. Hence, if liability is to be employed in some area of accident, the major justification should be that liability creates incentives toward safety."); see also William M. Landes & Richard A. Posner, *The Economic Structure of Tort Law* 9-12, 58 (1987).

assumption that the payment of monetary damages is the most effective and most efficient way of accomplishing the dual goals of compensation and deterrence.⁵⁵ Finally, in cases where an individual's behavior is especially egregious, tort law, through punitive or exemplary damages, allows a person to be punished beyond what is required to compensate a victim.⁵⁶

With these basic principles in mind,⁵⁷ when suing a drug manufacturer for an injury caused by its product, plaintiffs typically raise products liability claims sounding in negligence, warranty, fraud, and strict liability.⁵⁸ Each theory and its application to medical device and prescription drug litigation will be briefly discussed.

Older Theories of Recovery

Negligence

To establish a traditional *prima facie* negligence case, plaintiffs must prove four basic elements: (1) a duty of care owed to the plaintiff by the defendant; (2) a breach of that duty by the defendant; (3) the defendant's breach was a "proximate cause" of the plaintiff's damages; and (4) a cognizable injury or harm to the plaintiff.⁵⁹ Generally, product manufacturers owe a duty of due care to all foreseeable users or others who may be affected by the products, and this duty extends to "all aspects of the product," including the "design, manufacture, inspection, labeling, marketing, and promotion."⁶⁰ The level of care must comport with that of a "prudent manufacturer ... under the circumstances of the particular case."⁶¹

With respect to prescription drug or medical device manufacturers, the duty of due care could be breached in a number of ways. For example, entities that manufacture prescription drugs must ensure that the product contains the appropriate concentration, activity, strength, and purity to prevent injury from the use of such a drug.⁶² Likewise, manufacturers of medical devices must exercise reasonable care in the production of their wares to ensure that they are not defective.⁶³ However, for many adverse incidents resulting from prescription drugs and medical devices, no negligence occurred in crafting the product, as the manufacturer adhered to the standards of care

⁵⁵ See *Ciraolo v. City of New York*, 216 F.3d 236, 243 (2d Cir. 2000) (Calabresi, J., concurring) ("[U]nless approximately all the costs of the activity are borne by the actor ... the actor will not be adequately deterred from undesirable activities.").

⁵⁶ See Linda L. Schlueter and Kenneth R. Redden, *Punitive Damages*, at 264 (3d ed. 1995) ("In order to receive punitive damages, a plaintiff must show that the defendant acted with malice, either actual or legal.")

⁵⁷ As tort claims are state-law based, the law may vary state to state.

⁵⁸ See Susan F. Scharf, *Orphan Drugs: The Question of Products Liability*, 10 Am. J. L. and Med. 491, 497 (1985).

⁵⁹ See James T. O'Reilly & Nancy C. Cody, *The Products Liability Resource Manual* 135 (General Practice Section, American Bar Association 1993).

⁶⁰ *Id.* at 136.

⁶¹ *Id.*

⁶² See, e.g., *Peters v. Johnson*, 50 W. Va. 644, 648 (1902) ("Apothecaries, druggists and all persons engaged in manufacturing, compounding or vending drugs, poisons or medicines, are required to be extraordinarily skillful and to use the highest degree of care known to practical men to prevent injury from the use of such articles and compounds ... Such persons are liable for the slightest negligence and for ignorance and incapacity. They handle things dangerous to human life and health, and must be most alert to avoid mistakes, and they are bound to have adequate skill.") (citing to several cases).

⁶³ See, e.g., *Palmer v. A.H. Robins Co.*, 684 P.2d 187, 209-210 (Colo. 1984).

for the industry. Nonetheless, the very nature of the product, even when properly manufactured and distributed, will often entail serious risks, as the product can be misapplied or misused.⁶⁴ As a result, with medical devices and prescription drugs, the duty to exercise due care extends to a duty to warn of all possible risks of which the manufacturer knows or should know.⁶⁵ Under a well-established rule called the “learned intermediary doctrine,” a manufacturer satisfies its duty to warn of dangers associated with the use of a prescription drug or medical device by providing adequate warnings to the medical professional administering the drug or device, and not the ultimate user.⁶⁶

Once a plaintiff harmed by a drug or device establishes that the manufacturer of the article breached a duty to exercise due care, the plaintiff must then establish causation. Proof of causation requires a plaintiff to prove both causation in fact (i.e., that “but for” the defendant’s breach the plaintiff’s injuries would not have occurred) and causation in law (or proximate causation).⁶⁷ Proximate causation is the “legal allocation of responsibility for the injury-causing event,”⁶⁸ such that a defendant is only responsible for those injuries that are direct and reasonably anticipated, and not those injuries that are unforeseeable or remote.⁶⁹ In the context of failure-to-warn lawsuits over drugs and medical devices, in the “vast majority” of jurisdictions where a warning is inadequate, the plaintiff is entitled to a rebuttable presumption that “an adequate warning would have been heeded if one had been given.”⁷⁰ Nonetheless, proximate cause has been referred to as the “plaintiff’s Achilles Heel,”⁷¹ as the defendant can rebut the presumption through testimony that a different warning would not have made a difference in the actions of the physician,⁷² forcing the plaintiff to then present evidence that the physician would have altered his or her behavior and injury would have been avoided with a different warning.⁷³ This burden can be quite difficult, and, indeed, proximate cause has been the demise of several lawsuits alleging injuries resulting from a failure to warn about the risks of a drug or medical device.⁷⁴

⁶⁴ See Restatement 2d of Torts § 402A, comment k.

⁶⁵ See, e.g., *Glucksman v. Halsey Drug Co., Inc.*, 160 A.D.2d 305, 307, 553 N.Y.S.2d 724 (1st Dep’t 1990) (explaining the duty to warn with respect to medical device manufacturers); see also *Hoffmann-La Roche, Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. 1st DCA 2009) (discussing the duty to warn with respect to prescription drug manufacturers).

⁶⁶ See, e.g., *Kirk v. Michael Reese Hosp. and Med. Ctr.*, 117 Ill. 2d 507, 513 N.E.2d 387, 392 (Ill. 1987) (holding that if a drug manufacturer satisfies the duty to warn prescribing physicians about the risks of prescription drugs, the manufacturer can rely on doctors to pass along the warnings to consumers).

⁶⁷ See O’Reilly and Cody, *supra* footnote 59 at 140.

⁶⁸ *Id.*

⁶⁹ See *Palsgraf v. Long Island R. Co.*, 248 N.Y. 339, 346 (1928) (Cardozo, J.).

⁷⁰ See *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 855 (10th Cir. 2003).

⁷¹ James M. Campbell and Richard L. Edwards, *Products Liability: The Duty to Warn* 22 (1989).

⁷² For example, when evidence demonstrates that a physician “fails to read or rely on a drug manufacturer’s warnings,” such failure is commonly looked upon as an “intervening, independent and sole proximate cause” of the plaintiff’s injuries, even if the warnings were inadequate. See *Formella v. CIBA-GEIGY Corp.*, 100 Mich. App. 649, 300 N.W.2d 356, 358-59 (Mich. App. 1980) (“The fact [that] Dr. Murguz failed to read the package inserts and PDR negates any possible negligence on the part of Ciba-Geigy in not emphasizing the hazards in those publications.”); see also *Harris v. McNeil Pharm.*, No. CIV 3:98CV105, 2000 WL 33339657, at *3 n.3 (D.N.D. Sept. 5, 2000) (“The presumption that had an adequate warning been given it would have been read and heeded is rebutted by [the physician’s] testimony that he did not read the warning.”).

⁷³ See *Thom*, 353 F.3d at 855; see generally Douglas R. Richmond, *Products Liability: Corporate Successors and the Duty to Warn*, 45 Baylor L. Rev. 535, 551 (Summer 1993).

⁷⁴ See, e.g., *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1021 (10th Cir. 2001) (holding that the defendants provided sufficient evidence that the prescribing physician would not have changed her course of treatment with a different warning); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003-04 (4th Cir. 1992) (summary judgment appropriate where (continued...))

Breach of Warranty

A breach of a warranty, a legal theory that is equally associated with contract law and tort law,⁷⁵ can also be the basis for a products liability claim against a drug or device manufacturer. Liability for a breach of a warranty is premised on the principle that manufacturers implicitly warrant that their products are “fit for the ordinary purposes for which they are used” and “merchantable,” in that they are of a sufficient quality.⁷⁶ Both of these implied warranties are found in Article Two of the Uniform Commercial Code (UCC), which has been codified in nearly all jurisdictions.⁷⁷ To establish a *prima facie* case for breach of the implied warranty of merchantability, a plaintiff must prove (1) the existence of the warranty, (2) a breach of that warranty, and (3) damages proximately resulting from that breach.⁷⁸

Two central difficulties arise for plaintiffs asserting a breach of an implied warranty in a products liability suit regarding prescription drugs or medical devices. First, warranty law, because of its partial basis in contract law, retains several legal doctrines from contract law that tend to prevent a consumer of a prescription drug or the user of a medical device from recovering damages from the manufacturer. For example, state contract law, and with it warranty law, commonly requires that a contract term, including an implied warranty, run only to a buyer who is in “privity” (or has a direct relationship) with the seller.⁷⁹ The privity requirement can undermine drug or medical device breach of warranty lawsuits, as the manufacturer of a drug or device typically does not have a seller-buyer relationship with the end user, barring recovery.⁸⁰ Moreover, under the UCC, an implied warranty may be excluded or modified through the use of a disclaimer that “mention[s] merchantability” and is “conspicuous.”⁸¹ Finally, another important defense available

(...continued)

physician testified a different warning, one advising physicians not to prescribe an intrauterine device to women who might later want children, would not have changed his decision to prescribe the device); *Willett v. Baxter Intern., Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991) (alleged failure to warn of less than one percent increase in the risks associated with heart valve replacement was not the proximate cause of plaintiff’s fear of future heart valve failure where the only reasonable conclusion is that an adequate warning would not have affected the physician’s decision to proceed with the surgery); *Kirsch v. Picker Intern., Inc.*, 753 F.2d 670, 671-73 (8th Cir. 1985) (manufacturer’s failure to warn of potential risks associated with radiation therapy for the treatment of acne was not the proximate cause of plaintiff’s injuries where treating physician was aware of the risks); *Oppenheimer v. Sterling Drug, Inc.*, 7 Ohio App. 2d 103, 219 N.E.2d 54, 58 (Ct. App. 1964) (“Even assuming negligence on the part of the defendant ... there is nothing to indicate that the doctor relied upon any information furnished by the defendant in prescribing Aralen for his patient, the plaintiff ...”); *Douglas v. Bussabarger*, 73 Wn.2d 476, 478, 438 P.2d 829 (Wash. 1968) (“If defendant-drug company was negligent in not labeling its container so as to warn of dangers, this negligence was not a proximate cause of plaintiff’s disability” because plaintiff’s doctor “did not read the labeling which was on the container.”).

⁷⁵ See, e.g., William L. Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 Minn. L. Rev. 791, 800 (1966) (characterizing a warranty as a “freak hybrid born of the illicit intercourse of tort and contract.”).

⁷⁶ See Uniform Commercial Code (U.C.C.) § 2-314.

⁷⁷ Every state, save Louisiana, has adopted Article Two of the Uniform Commercial Code. See Cornell University Law School, Uniform Commercial Code Locator (Mar. 15, 2004), <http://www.law.cornell.edu/uniform/ucc.html>.

⁷⁸ See, e.g., *Bodie v. Purdue Pharma Co.*, 236 Fed. Appx. 511, 522 (11th Cir. 2007) (applying Alabama law).

⁷⁹ See, e.g., *Cobb County Sch. Dist. v. Mat Factory*, 215 Ga. App. 697, 702 (Ct. App. 1994); *Burr v. Sherwin Williams Co.*, 42 Cal. 2d 682, 268 P.2d 1041, 1048-49 (1954).

⁸⁰ While some states have eliminated the privity requirement for an implied breach of warranty claim, see, e.g., *Dawson v. Canteen Corp.*, 158 W. Va. 516, 212 S.E.2d 82 (W. Va. 1975), these claims are more akin to strict liability claims and will be evaluated as such in this report. See *Garcia v. Edgewater Hosp.*, 244 Ill. App. 3d 894, 613 N.E.2d 1243, 1249, 184 Ill. Dec. 651 (App. Ct. 1993) (“[S]trict liability theory is essentially the liability of implied warranty divested of the contract doctrines of privity, disclaimer and notice.”).

⁸¹ See U.C.C. § 2-316(2)

to manufacturers against claims of a breach of the implied warranty of merchantability is lack of notice or opportunity to cure the defect. The UCC requires that a plaintiff give the seller notice of the breach of the warranty within a reasonable time after he or she has discovered or should have discovered the breach.⁸² If the plaintiff fails to provide notice to the seller, the plaintiff is barred from any remedy.⁸³

Second, assuming that the doctrines of privity, disclaimer, and notice do not derail a consumer's lawsuit against a drug or device manufacturer, a claim based on the manufacturer implicitly warranting that the product is fit for ordinary uses may not be applicable in a drug or device case. For example, physicians frequently prescribe drugs or employ medical devices for conditions for which they are not actually approved ("off label use")—conduct that is perfectly legal under federal law.⁸⁴ If an injury results because of an off label use, by definition there cannot be a breach of the implied warranty of merchantability, as the drug or device was not used for its intended purpose. More broadly, some have argued that the nature of prescription drugs and sophisticated medical devices removes them entirely from the realm of warranty law, which is typically applied with respect to the sales of ordinary goods and services. Specifically, some courts have held that because drugs and certain devices are not available to the general public, but may only be obtained through a licensed physician, the very nature of the product precludes the imposition of a warranty for fitness for ordinary purposes.⁸⁵ After all, each individual who uses a drug or device presents a unique circumstance that makes warranty law a poor vehicle to assign liability to a manufacturer.⁸⁶

Fraud

Another common basis for a drug or medical device products liability suit is the allegation that the manufacturer engaged in fraud by marketing an unsafe product. For example, a plaintiff could allege fraud exists because a drug manufacturer, through their advertising or package insert, painted an undeservedly favorable picture of their drug and minimized the drug's side effects. To succeed on a fraud claim, the plaintiff must establish six elements: (1) a representation or, where there is a duty to disclose, concealment; (2) which is material; (3) made falsely, with knowledge of its falsity or with reckless disregard for the truth; (4) with the intent to mislead; (5) justifiable reliance upon the representation or concealment; and (6) resulting injury that is proximately caused by the justifiable reliance.⁸⁷

These requirements are often difficult for plaintiffs to meet for several reasons. With respect to affirmative misrepresentations, the plaintiff must establish that the manufacturer made a false

⁸² *Id.* § 2-607(5).

⁸³ *Id.*

⁸⁴ See *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. N.Y. 2012) ("[O]ff-label drug usage is not unlawful, and the FDA's drug approval process generally contemplates that approved drugs will be used in off-label ways ... physicians can prescribe, and patients can use, drugs for off-label purposes."); see also *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 439 (E.D. Pa. 2004)("[I]t is well established that the FDA does not prohibit 'off-label' use of medical devices.").

⁸⁵ See *Makripodis v. Merrell-Dow Pharms.*, 523 A.2d 374, 377 (Pa. Super. Ct. 1987); see also *Bichler v. Willing*, 397 N.Y.S.2d 57, 58-59 (App. 1977); *McLeod v. W. S. Merrell Co.*, 174 So. 2d 736, 738-739 (Fla. 1965).

⁸⁶ See *Makripodis*, 523 A.2d at 377.

⁸⁷ See *Lazar v. Super. Ct.*, 12 Cal. 4th 631, 637, 49 Cal. Rptr. 2d 377, 909 P.2d 981 (1996) (California law); see generally Restatement (Second) of Torts § 767.

representation of *material* fact, as opposed to merely using broad, vague, or commendatory language.⁸⁸ For example, a federal court rejected the argument that a drug manufacturer, in its promotion of Actimmune, engaged material misrepresentations by broadly lauding selected medical journals supportive of a drug when the underlying literature was quite mixed on the value of the drug.⁸⁹ In regard to fraudulent concealment claims, the case law generally requires that there be a duty of disclosure.⁹⁰ Much like the doctrine of privity in the context of warranty claims, a fraudulent concealment claim must rest upon an independent fiduciary duty owed to the plaintiff by the manufacturer or a confidential relationship between the parties,⁹¹ neither of which will typically exist in a case where a consumer is harmed by a drug or medical device. Most importantly, regardless of whether the claim is based on a fraudulent misrepresentation or a fraudulent concealment, claims of fraud require that the manufacturer had an intent to mislead, which is either not the case in the typical products liability suit or will be very difficult for a plaintiff to prove.⁹²

Strict Liability

Given the difficulties in pursuing a theory of negligence, breach of warranty, or fraud in a products liability suit regarding drugs or devices, plaintiffs have frequently relied on a newer theory of liability, strict products liability, as the central basis to recover damages for injuries caused by a drug or device. To establish a *prima facie* strict liability claim in a products liability lawsuit, like a negligence claim, the plaintiff must show that a product harmed the plaintiff and the defendant's conduct caused the plaintiff's harm.⁹³ However, in contrast to a negligence claim, a plaintiff need not establish that the defendant acted unreasonably in breach of the duty of due care. Instead, strict liability focuses on the condition of the underlying product itself and on the adequacy of the warning.⁹⁴ Specifically, in addition to proving injury and causation, the plaintiff asserting a strict liability claim must establish that a manufacturer or distributor sold a product that contained some sort of "defect" that made it "unreasonably dangerous" causing an injury.⁹⁵

⁸⁸ See *American Italian Pasta Co. v. New World Pasta Co.*, 371 F.3d 387, 391 (8th Cir. 2004) ("if the statement is not specific and measurable, and cannot be reasonably interpreted as providing a benchmark by which the veracity of the statement can be ascertained, the statement constitutes puffery").

⁸⁹ See *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1055 (N.D. Cal. 2009).

⁹⁰ See, e.g., *Roney v. Gencorp*, 431 F. Supp. 2d 622, 637 (S.D. W. Va. 2006).

⁹¹ See *California Architectural Bldg. Prod., Inc. v. Franciscan Ceramics, Inc.*, 818 F.2d 1466, 1472 (9th Cir. 1987).

⁹² See, e.g., Sharon L. Davies & Timothy Stoltzfus Jost, *Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse?*, 31 Ga. L. Rev. 373, 397-99 (1997).

⁹³ See Restatement (Second) of Torts § 402A.

⁹⁴ In this sense, strict liability claims recognize that injuries can result from a product even when the manufacturer or distributor has not been negligent but instead has operated reasonably in exercising due care over the product. See *Escola v. Coca Cola Bottling Co.*, 24 Cal. 2d 453, 462 (1944) (Traynor, J., concurring).

⁹⁵ *Id.* Strict liability was recognized by the Supreme Court of California in 1963 in a case called *Greenman v. Yuba Power Products, Inc.*, where the California high court reasoned that imposing liability regardless of the reasonableness of the behavior of the manufacturer was optimal for social welfare. See 59 Cal. 2d 57, 63 (1963). Soon after the California court created the new claim, other states followed suit, with nearly every jurisdiction recognizing some form of strict products liability today. See O'Reilly and Cody, *supra* footnote 59 at 54 ("The great majority of states have recognized strict liability, many through legislative definitions."). Strict liability is driven by the goal of loss-spreading, whereby the decision to impose strict liability turns on whether the actor engaging in an injurious activity is the appropriate party to incur and then redistribute the loss. See Joseph King, *A Goals Oriented Approach to Strict Tort Liability for Abnormally Dangerous Activities*, 48 Baylor L Rev 341, 349-59 (1996). With respect to strict liability in the context of defective products, the California Supreme Court reasoned that the manufacturer, as opposed to the end (continued...)

The central issue in strict products liability, therefore, is whether a given product is “defective.” Generally, a “defect” is a “problem, weakness, omission, or error” that exists in a product and is generally manifested in one of three forms.⁹⁶ The first type of defect, a manufacturing defect, arises from a mishap in the manufacturing process, such that the finished product does not conform to the manufacturer’s own design specifications.⁹⁷ The second type of defect is called a design defect and exists when an entire product line shares a common dangerous characteristic.⁹⁸ A design defect can be demonstrated by showing that the risks posed by the product could have been reduced or avoided by a reasonable alternative design.⁹⁹ In some cases, the social utility of a product can be so minimal that it is outweighed by the risks it poses, making proof of a reasonable alternative design unnecessary to demonstrate that the product is defective.¹⁰⁰ Finally, the third type of defect, a warning defect, occurs when a manufacturer fails to provide adequate instructions or warnings.¹⁰¹

With respect to drugs and medical devices, strict products liability litigation over such products primarily focuses on warning defects. Manufacturing defects, such as when a prescription drug contains an impurity or contaminant, are “legally simple” and tend to affect a small number of people, as errors found in the manufacturing process tend to be corrected.¹⁰² Successful design defect claims for drugs and medical devices are also rare for two primary reasons. First, especially with respect to prescription drugs, design defect challenges are “uncommon” because it is difficult for a plaintiff to show that a drug, which often consists of a simple molecule, can be alternatively designed in a manner that removes an undesirable feature.¹⁰³ Second, even if a plaintiff can demonstrate that a drug or device can have a reasonably alternative design, the majority of jurisdictions¹⁰⁴ have adopted “comment k” to section 402A of the Second Restatement of Torts, which limits liability for so-called “unavoidably unsafe products.”¹⁰⁵

(...continued)

user, is in the best position to not only anticipate and prevent any problems that may arise in the manufacturing process, but to also bear the costs associated with the product because the manufacturer can spread the costs of a unfavorable judgment to the marketplace. *See Greenman*, 59 Cal. 2d at 63-64. Nonetheless, strict liability is not the equivalent of an absolute liability system, and under strict liability “the manufacturer does not thereby become ... the insurer of safety of the product’s user,” as liability depends upon a device being defective. *See generally* Guido Calabresi and Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 Yale L.J. 1055, 1056 (1972) (“Strict liability has never meant that the party held strictly liable is to be a general insurer for the victim no matter how or where the victim comes to grief.”).

⁹⁶ *See* O’Reilly and Cody, *supra* footnote 59 at 3.

⁹⁷ *See* Restatement (Third) of Products Liability § 2(a).

⁹⁸ *See* Restatement (Third) of Products Liability § 2(b).

⁹⁹ *See* Restatement (Third) of Products Liability § 2 cmt d.

¹⁰⁰ *See* Restatement (Third) of Products Liability § 2 cmt. e.

¹⁰¹ *See* Restatement (Third) of Products Liability § 2(c).

¹⁰² *See* William M. Brown, *Deja Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 Brandeis L.J. 1, 19 (Fall 2001).

¹⁰³ *Id.*

¹⁰⁴ *See, e.g.*, Nitin Shah, *When Injury is Unavoidable: The Vaccine Act’s Limited Preemption of Design Defect Claims*, 96 Va. L. Rev. 199, 235 n.159 (March 2010) (listing the jurisdictions that have adopted comment k in the prescription drug context).

¹⁰⁵ *See* Restatement (Second) of Torts § 402A, cmt. k.

Comment *k* recognizes that some products “are quite incapable” of ever being made safe for their intended and ordinary use.¹⁰⁶ However, because certain “unavoidably unsafe products,” which are “especially common in the field of drugs,” prevent and alleviate serious health concerns, their value outweighs any risks posed by the product.¹⁰⁷ Accordingly, comment *k* “exempts” from typical rules of strict liability “unavoidably unsafe products,”¹⁰⁸ such that manufacturers are not held liable as long as the product is “properly prepared” and manufacturers properly warn of the inherent dangers associated with the product.¹⁰⁹ Comment *k* does not explain how courts should go about determining what products are “unavoidably unsafe,”¹¹⁰ and state courts are split on whether drugs and medical devices are *per se* “unavoidably unsafe” products or whether the determination should be made on a case-by-case basis.¹¹¹ Regardless, a majority of courts agree that comment *k* applies to drugs and medical devices at least in some contexts, which functionally eliminates a design defect theory in favor of manufacturing and warning defect claims.¹¹²

As a result, drug and device litigation based on a strict products liability theory tends to be premised on an allegation of a defective warning. A warning defect exists when the warnings accompanying a product are insufficient to prevent reasonably foreseeable harm.¹¹³ While a failure-to-warn negligence claim and a strict products liability claim premised on a warning defect stem from distinct legal theories, in practice the two claims are largely assessed under the same standard. In fact, the majority of courts that have interpreted strict products liability defective warning claims have required a consideration of the user’s awareness of a danger and the ability of the warning to enlighten the user, factors that underlie whether a manufacturer has a duty to warn a consumer under a traditional negligence claim.¹¹⁴ Ultimately, the question of whether a manufacturer can be held strictly liable for a warning defect “depends on the standards for determining a duty to warn under a negligence action,”¹¹⁵ which includes the learned

¹⁰⁶ See Restatement (Second) of Torts § 402A, cmt. *k*.

¹⁰⁷ *Id.*

¹⁰⁸ See *Brusewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1077 (2011).

¹⁰⁹ See Restatement (Second) of Torts § 402A, cmt. *k*.

¹¹⁰ See *Brusewitz*, 131 S. Ct. at 1077 (“An unavoidably unsafe product is defined [in the Restatement] by a hodge-podge of criteria and a few examples, such as the Pasteur rabies vaccine and experimental pharmaceuticals.”); see also Shah, *supra* footnote 104 at 235.

¹¹¹ See *Brusewitz*, 131 S. Ct. at 1077 n.41; see also Todd Paul Myers, *Halcion Made Me Do It: New Liability and A New Defense*, 62 U. Cin. L. Rev. 603, 613-614 (Fall 1993). For those courts that adopt a case-by-case approach to the application of Comment *k*, a product is “unavoidably unsafe” when, given proper manufacture and labeling, “no feasible alternative design would reduce the safety risks without compromising the product’s utility and cost.” See *Brusewitz*, 131 S. Ct. at 1089 & n.5 (Sotomayor, J., dissenting) (noting the standard adopted by three states in applying comment *k*).

¹¹² See Myers, *supra* footnote 111 at 614. Indeed, the Third Restatement of Torts (Products Liability), the American Law Institute’s update to Comment *k*, would limit products liability claims for prescription drugs or medical devices to claims where the “foreseeable risks of harm posed by [a] drug or medical device” are “sufficiently great,” such that “reasonable health-care providers” “would not prescribe the drug or medical device for any class of patients.” See Restatement (Third) of Torts: Products Liability § 6(c) (emphasis added). As one commentator has noted, this provision would effectively limit design defect liability of drug or device manufacturers to situations where the product has virtually no therapeutic value. See Jerry J. Phillips, *Products Liability: Beyond Warnings*, 26 N. Ky. L. Rev. 595, 604 (1999).

¹¹³ See Restatement (Second) of Torts § 402A, cmt. *h* (“Where ... the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and danger.”).

¹¹⁴ See *Ex parte Chevron Chem. Co.*, 720 So. 2d 922, 928 (Ala. 1998) (collecting cases).

¹¹⁵ See *Anguiano v. E.I. DuPont De Nemours & Co.*, 44 F.3d 806, 811-12 (9th Cir. 1995).

intermediary doctrine.¹¹⁶ As a consequence, regardless of the specific theory asserted, questions of liability stemming from a drug or medical device tend to center on the question of adequacy of the warning attached to the product in question.

Medical Devices and the FDCA

Having discussed how state tort law attempts to ensure that medical devices and prescription drugs are safe, to understand how these laws can be displaced by federal law it is essential to delve into the underlying federal laws governing the safety of devices and drugs.

The FDCA contains a comprehensive statutory scheme designed to ensure that medical devices are safe and effective.¹¹⁷ As part of this scheme, medical devices must meet certain minimum requirements in order to be marketed in the United States. For example, like other medical products, a device cannot be adulterated or misbranded, and there are registration, good manufacturing practices, and labeling requirements.¹¹⁸ There are also more specific requirements that a device manufacturer must follow based on the level of risk that a device poses to patients from its use or misuse.

Although the FDCA has always expressly required drugs to be reviewed by the FDA in some manner before going on the market, this was not the case with medical devices. Historically, the regulation of devices was primarily left up to the states. But concerns about the safety of these products spurred Congress to enact the Medical Device Amendments of 1976 (MDA),¹¹⁹ which amended the FDCA to create a detailed regime for the oversight of medical devices. The MDA established three classes of devices based the degree of control needed to provide assurance of the device's safety and effectiveness. Class I devices are subject to the least amount of oversight. These devices "present no unreasonable risk of illness or injury" and are subject to minimal regulation by "general controls."¹²⁰ Class II devices pose a moderate risk to patients, and are subject to general controls as well as certain "special controls" to reduce or mitigate risk.¹²¹ Finally, Class III devices are generally considered the devices with the highest risk and are typically at issue in medical device preemption litigation. These devices are used to support or sustain human life, for a use which is of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.¹²² Class III

¹¹⁶ See, e.g., *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 208 (5th Cir. 2008) ("The learned-intermediary doctrine applies to both strict-liability and negligence claims.").

¹¹⁷ For more information on the federal regulation of medical devices, see CRS Report R42130, *FDA Regulation of Medical Devices*, by (name redacted).

¹¹⁸ 21 U.S.C. §§ 351-52, 360; 21 C.F.R. Parts 801, 809, and 820.

¹¹⁹ P.L. 94-295, 90 Stat. 539 (1976).

¹²⁰ 21 U.S.C. § 360c(a)(1)(A). Examples of Class I devices include elastic bandages and examination gloves. General controls include mandatory device listing, labeling, and registration requirements.

¹²¹ 21 U.S.C. § 360c(a)(1)(B). Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes. Special controls may include special labeling requirements, mandatory performance standards, and post-market surveillance.

¹²² 21 U.S.C. § 360c(a)(1)(C)(ii). Examples of Class III devices include replacement heart valves, silicone gel-filled breast implants, and pacemaker pulse generators.

devices receive the greatest amount of federal oversight and are generally subject to premarket approval by the FDA.¹²³

Premarket Approval

As noted above, the premarket approval process, often described as rigorous and time-consuming, is generally used for Class III devices, subject to exception.¹²⁴ As part of this process, the FDA determines if these devices have a “reasonable assurance of ... safety and effectiveness.”¹²⁵ A premarket approval application is lengthy and must include, among other things, information regarding proposed labeling; reports of information “concerning investigations which have been made to show whether or not such device is safe and effective”; a description of the manufacturing and processing methods; samples of the device and its components; and information regarding the components, ingredients, and operating principles of the device.¹²⁶ An application will be denied approval if “there is a lack of a showing of reasonable assurance that such device is safe [and effective] under the conditions of use” in the proposed labeling; if the methods of manufacturing, processing, packing, or installing the device do not conform to good manufacturing practices; if the proposed labeling is false or misleading; or if the device does not meet performance standards.¹²⁷ After a device has received premarket approval, “the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.”¹²⁸ All new devices are automatically designated as Class III, and therefore must receive premarket approval unless the device meets one of the exceptions specified under federal law.¹²⁹

Premarket Notification (§ 510(k) Submissions)

One common exception to the requirement for premarket approval is for devices that the FDA has determined under the § 510(k) premarket notification process to be “substantially equivalent” to those already on the market.¹³⁰ Class III devices generally require a premarket notification as well as premarket approval. However, some Class III devices may be marketed only with a § 510(k) submission—if the device was introduced after the passage of the MDA in 1976 and is substantially equivalent to a pre-1976 device.¹³¹ The majority of new Class III medical devices

¹²³ *Id.*

¹²⁴ 21 U.S.C. § 360e(a). The three exceptions to the PMA requirement are: (1) devices on the market prior to the enactment of the Medical Device Amendments of 1976, 21 U.S.C. §§360e, 360c(f); (2) devices for which there is an investigational device exemption, 21 U.S.C §360j(g); and (3) devices that the FDA has determined are substantially equivalent to those already on the market under the §510(k) premarket notification process, discussed *infra*, 21 U.S.C. §360c(f)(1)A(ii).

¹²⁵ 21 U.S.C. § 360c(a)(C).

¹²⁶ 21 U.S.C. § 360e(c)(1).

¹²⁷ 21 U.S.C. § 360e(d)(2); 21 C.F.R. Part 814.

¹²⁸ *Riegel v. Medtronic*, 552 U.S. 312, 319 (2008) (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

¹²⁹ 21 U.S.C. § 360c(f)(1).

¹³⁰ 21 U.S.C. § 360c(f)(1)A(ii). Premarket notification is known as a § 510(k) submission, after the section of the FDCA that requires it.

¹³¹ *See* 21 U.S.C. §§ 360c(f)(1), 360e(b), (i).

reach the marketplace after only a § 510(k) submission, as opposed to the receipt of a premarket approval application.¹³²

Under the § 510(k) process, a new device is considered “substantially equivalent” if the FDA makes such a determination based on a comparison of the new device with a “predicate” device.¹³³ A device is “substantially equivalent” if it has (1) the same intended use and the same technological characteristics as the predicate device, or (2) the same intended use, different technological characteristics, and information and data that demonstrate safety and effectiveness, and does not “raise different questions of safety and effectiveness than the predicate device.”¹³⁴ In order for a device to be cleared under the § 510(k) process, a manufacturer must submit a premarket notification submission to the FDA.¹³⁵ Information generally required to be provided to the FDA as part of this submission includes, among other things, the name and description of the device; proposed labeling and advertisements for the device and directions for its use; and information comparing the device to predicate devices.¹³⁶

It may be noted that medical devices cleared through the § 510(k) pathway tend to receive considerably less scrutiny from the FDA than devices receiving premarket approval.¹³⁷ For example, unlike the § 510(k) submission, the FDA generally requires clinical data for most premarket approval applications.¹³⁸ Other characteristics of the § 510(k) process that make it less rigorous than the premarket approval process include (1) premarket inspections of how devices were manufactured are generally not required by the FDA, and (2) post-market studies are not required by the FDA as a condition of clearance.¹³⁹

¹³² *Riegel*, 552 U.S. at 317. According to a 2009 GAO report, of the more than 50,000 devices that were listed by manufacturers with FDA from FY2003 through FY2007, about 67% were exempt from premarket review; the remainder entered the market via the 510(k) process (31%), the PMA process (1%) or via other means (such as the “Humanitarian Device Exemption (HDE)”). U.S. Government Accountability Office, *Medical Devices: FDA should take steps to ensure that high-risk device types are approved through the most stringent premarket review process*, GAO-09-190, January 2009, p. 9.

¹³³ 21 U.S.C. § 360c(i)(1)(A).

¹³⁴ 21 U.S.C. § 360c(i)(1)(A).

¹³⁵ It should be noted that there are three types of § 510(k) submissions for premarket clearance: traditional, special, or abbreviated. A discussion of the differences between these submissions is beyond the scope of this report. For more information, see FDA, Medical Devices, 510(k) Submission Methods, at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>.

¹³⁶ 21 C.F.R. § 807.87.

¹³⁷ See Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device “Parallel Claims,”* 9 J. Health & Biomedical 159, 162-63 (2013).

¹³⁸ 21 U.S.C. § 360e(c)(1).

¹³⁹ However, it should be noted that manufacturers of § 510(k) devices may be required by the FDA to conduct post-market surveillance studies. 21 U.S.C. § 360l.

Preemption and Medical Devices

Express Preemption: *Lohr* and *Riegel*

The Supreme Court has evaluated three medical device preemption cases, and these cases have arisen in both the express and implied preemption context. With respect to express preemption, the Medical Device Amendments of 1976 (MDA) added a provision to FDCA which states,

... no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.¹⁴⁰

The MDA also included an exception to this provision stating that the FDA may, upon application by a state or a political subdivision thereof, exempt state requirements that are “more stringent” than federal ones or state requirements “required by compelling local conditions” if “compliance with the requirement would not cause the device to be in violation of any applicable requirement” under the FDCA.¹⁴¹ The FDA has also issued regulations that address the scope of the preemption provision.¹⁴² These regulations state, among other things, that the MDA preemption provision “does not extend to “[s]tate or local requirements of general applicability [whose] purpose ... relates either to other products in addition to devices.”¹⁴³

The Supreme Court has evaluated the scope of the MDA preemption provision on two occasions in *Medtronic v Lohr*¹⁴⁴ and *Riegel v. Medtronic*.¹⁴⁵ The Supreme Court has generally found that under the provision, the ability of an individual to bring a state tort lawsuit alleging certain defects with a medical device can hinge on, among other things, how that device received marketing approval from the FDA. Particularly in light of the most recent case, *Riegel v. Medtronic*, this provision has been generally viewed as severely limiting the ability of individuals to sue after they have been injured by a defective medical device receiving premarket approval. However, as discussed below, the Supreme Court has recognized that this provision is not a complete bar to state-law tort claims.

¹⁴⁰ 21 U.S.C. § 360k(a). This provision will hereinafter be referred to in this report as “the MDA preemption provision.”

¹⁴¹ 21 U.S.C. § 360k(b). It appears that the FDA has issued various exceptions. See 29 C.F.R. § 808.53 et seq.

¹⁴² See 43 Fed. Reg. 18665 (May 2, 1978); 45 Fed. Reg. 67336 (Oct. 10, 1980); 61 Fed. Reg. 52606, 52654 (Oct. 7, 1996).

¹⁴³ 21 C.F.R. § 808.1. The regulation provides examples of these state requirements, including general electrical codes, the Uniform Commercial Code, and unfair trade practices in which the requirements are not limited to devices.

¹⁴⁴ 518 U.S. at 470.

¹⁴⁵ 552 U.S. at 312.

Medtronic v. Lohr

In 1996, the Supreme Court first evaluated the scope of the MDA preemption provision in *Medtronic v. Lohr*. Plaintiffs brought suit against a pacemaker manufacturer, alleging negligence and strict liability claims after a component of the device failed and the patient suffered a heart block that required emergency surgery.¹⁴⁶ The device maker claimed that the plaintiff's suit was preempted under the express preemption provision of the MDA.¹⁴⁷ The pacemaker in question was a Class III medical device that was deemed substantially similar to a predicate device under § 510(k) and, accordingly, had not gone through the premarket approval process. In a fractured opinion, the Court found that the plaintiff's state-law claims were not preempted by the MDA. While a majority of Justices agreed on the outcome of the case, there was disagreement as to the scope of the MDA preemption provision and, in particular, the extent to which the provision preempts state-law tort actions.

The device manufacturer had argued that because the device was cleared under the § 510(k) process, this clearance equates to federally enforceable design requirements that should be immune from the specific state-law claim at issue in these cases.¹⁴⁸ However, the majority of the Court disagreed, opining that the § 510(k) process does not impose requirements regarding the “safety” and “effectiveness” of the device; it merely establishes that the device is equivalent to a device that is already on the market.¹⁴⁹ The Court explained that the FDA did not “require” Medtronics’ pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed [before the MDA] to be marketed without running the gauntlet of the [premarket approval] process.”¹⁵⁰ The Court reasoned that the § 510(k) exemption to premarket approval is generally intended to maintain the status quo with respect to marketing medical devices, which included the potential for the manufacturer to be subject to state law negligent design claims.¹⁵¹

The patient had argued that even if state-law claims were “requirements” under the MDA preemption provision, the claim was not preempted unless it was “different from or in addition to” these federal requirements. The Court’s majority agreed, and indicated that nothing in the MDA denies a state the ability to provide a remedy for violations of common law duties “when those duties parallel federal requirements.”¹⁵² The Court noted that FDA regulations confirm this view, and given that Congress had authorized the FDA to exempt state law from federal preemption, the Court found this to be a “sound basis” for relying on the agency’s interpretation of the statute.¹⁵³

¹⁴⁶ *Lohr*, 518 U.S. at 480-81.

¹⁴⁷ *Id.* at 481.

¹⁴⁸ *Id.* at 492.

¹⁴⁹ *Id.* at 493.

¹⁵⁰ *Id.* at 493-94.

¹⁵¹ *Id.* at 494.

¹⁵² *Lohr*, 518 U.S. at 495.

¹⁵³ *Id.* at 496. It should be noted that Justice Stevens, joined by three other Justices, provided additional reasoning as to why the MDA preemption provision did not preempt the plaintiff's claim. Justice Stevens examined the language of the provision and rejected the manufacturer's argument that any common law claim is a “requirement” that is “different from or in addition to” the federal standards and therefore barred under the MDA preemption provision. Such a construction, the Court noted, was problematic as it “would have the perverse effect of effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent (continued...)”

Despite the conclusion that the plaintiff's state-law tort claims were not preempted by federal law, the majority of Justices in *Lohr*, in concurring and dissenting opinions, expressly indicated that some types of these state-law claims could nevertheless be preempted by the MDA.¹⁵⁴ This conclusion caused confusion in the lower courts.¹⁵⁵ For example, it was uncertain whether claims brought by plaintiffs injured by devices receiving premarket approval review were preempted under the MDA.

Riegel v. Medtronic

In 2008, the Supreme Court examined the scope of the MDA preemption provision for the second time in *Riegel v. Medtronic*, holding that state tort law claims for injuries related to a medical device that received premarket approval were preempted by federal law. The device at issue in *Riegel* was a catheter that had received premarket approval from the FDA to be marketed by Medtronic as a Class III device.¹⁵⁶ Despite the fact that the device's label stated that the device was contraindicated for individuals like the patient, his physician nevertheless used the catheter.¹⁵⁷ After the patient's doctor inflated the catheter beyond the recommended amount, the catheter ruptured and the patient was seriously injured.¹⁵⁸ The patient and his wife filed suit, claiming violations of New York common law. The district court found that these common law claims were preempted by federal law, and the court of appeals affirmed the dismissals. The Supreme Court agreed, and, in an 8-1 decision, held that the MDA expressly preempted the plaintiff's state tort law claims.

To reach its holding, the Court examined two questions in light of the MDA preemption provision: (1) whether the federal government established "requirements" applicable to the device; and second, if so, (2) whether the plaintiffs' common law claims are based on state requirements that are "different from, or in addition to" the federal requirements, "and that relate to safety and effectiveness."¹⁵⁹

In evaluating the first question, the Court concluded that the federal government had indeed "established requirements applicable to" the catheter. The fact that the catheter had received premarket approval was central to this finding.¹⁶⁰ The Court distinguished its earlier decision in *Lohr*, where the device at issue had received substantial equivalence review under § 510(k). Under the § 510(k) process, the Court in *Lohr* explained, the federal requirements at issue were general in nature, and the process is essentially an exemption from safety review.¹⁶¹ However, the

(...continued)

regulation...." *Lohr*, 518 U.S. at 487 (plurality). Justice Stevens then analyzed the language and the legislative history of the MDA preemption provision and concluded that Congress was mainly concerned about preempting "specific, conflicting state statutes" and did not intend to make device manufacturers immune from all general state law duties and remedies. *Id.* at 491-92.

¹⁵⁴ See *Lohr*, 518 U.S. at 504 (Breyer, J. concurring), 510-12 (O'Connor, J. dissenting).

¹⁵⁵ See generally, Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. Ill. U. L. J. 453 (2011).

¹⁵⁶ 552 U.S. 312, 310 (2008).

¹⁵⁷ *Id.* at 320.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 321-22.

¹⁶⁰ *Id.* at 322-23.

¹⁶¹ *Lohr*, 518 U.S. at 491-92.

Court in *Riegel* explained there is a notable difference: the premarket approval process is safety review, and it imposes “requirements” under the MDA that are *specific* to particular devices.¹⁶² The Court also observed that unlike the § 510(k) process, premarket approval includes formal FDA review, and devices that receive premarket approval may not deviate from the FDA-approved specifications in the approval application.¹⁶³

Second, the Court found that “New York’s tort duties constitute ‘requirements’ under the MDA”¹⁶⁴ and that these requirements were “different from, or in addition to” federal requirements for medical devices. The Court began by noting that five Justices in *Lohr* concluded that state common law duties could constitute “requirements” that may be preempted by the MDA.¹⁶⁵ It then elaborated on the meaning of the term “requirement” and stated that “[a]bsent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”¹⁶⁶ The Court further explained that state liability is “premised on the existence of a legal duty,” and that “a tort judgment therefore establishes that the defendant has violated a state-law obligation.”¹⁶⁷ While the patient had argued that the state-law claims (e.g., negligence, strict-liability, and implied-warranty claims) are not preempted because these general common-law duties are not maintained “with respect to devices,” the Court declined to accept this reasoning. It stated that nothing in the text of the MDA suggests that a preempted state requirement must apply solely to the relevant medical device or to medical devices generally.¹⁶⁸

Notably, however, the Court also expressly recognized that not all state-law claims are preempted by the MDA preemption provision. The Court reaffirmed its holding in *Lohr* and reasoned that the MDA express preemption provision “does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”¹⁶⁹ The Court provided no further analysis as to what types of state duties it had in mind. It also declined to address whether the patient in *Riegel* raised parallel claims, as the patient did not make that argument in their briefs to the Second Circuit or in their petition for Supreme Court review.¹⁷⁰

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Riegel*, 552 U.S. at 323.

¹⁶⁵ *Id.* at 323-24 The *Riegel* Court also referred to two other cases—*Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—in which the Court held that statutory language regarding preemption of state “requirements” was the equivalent of preemption of state common law. *Riegel*, 552 U.S. 312, 324. In *Bates*, the Court stated: “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.” 544 U.S. at 445. In *Cipollone*, as discussed *infra* “Express Preemption,” the Court held that a preemption provision was intended to preempt some common law claims.

¹⁶⁶ *Id.* at 324.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 328.

¹⁶⁹ *Id.* at 330.

¹⁷⁰ *Id.*

Implied Preemption: *Buckman v. Plaintiff's Legal Committee*

As noted above, the Supreme Court has concluded that implied preemption principles may still apply even in cases where a federal statute contains an express preemption provision.¹⁷¹ The concept of implied preemption has arisen in medical device preemption cases in light of the fact that the FDCA contains no explicit private right of action authorizing a person to sue based on injuries suffered because of an unlawfully defective medical product. Further, the FDCA provides that subject to an exception for certain actions that may be brought by a state, “all such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States.”¹⁷² Thus, when an individual has brought a state tort claim premised on alleged violations of the FDCA, courts have evaluated whether such claims may go forward, or whether they are, in effect, usurping the FDA’s role in enforcing federal requirements and are impliedly preempted by federal law.

In 2001, the Supreme Court in *Buckman v. Plaintiff's Legal Committee*¹⁷³ examined whether federal law preempted state-law tort claims that alleged fraud on the FDA. In this case, plaintiffs with injuries resulting from the use of orthopedic bone screws sued a consulting company that had assisted the manufacturer of the screws in obtaining FDA approval (under the § 510(k) process) to market the devices.¹⁷⁴ The patients alleged that the manufacturer of these screws committed fraud on the FDA by giving the agency misleading information in order to obtain this approval. Plaintiffs argued that had the proper information been provided to the agency, the devices would not have been approved and the plaintiffs would not have been injured.¹⁷⁵

The Court held that the plaintiffs were barred from bringing an action against the company for noncompliance with federal device requirements. Instead of relying upon the express preemption provision of the MDA to reach this conclusion, the Court found that the state law fraud-on-the-FDA claims were impliedly preempted because they conflicted with the federal scheme for enforcement of the FDCA. The Court opined that federal law authorizes the FDA to address fraud against the agency and allowing this state-law claim to proceed would interfere with federal statutory objectives.¹⁷⁶ The Court observed that the FDCA contains several mechanisms for addressing fraud (e.g., seeking injunctive relief and civil penalties).¹⁷⁷ The High Court further indicated state law fraud-on-the-FDA claims interfere with the FDA’s role in policing fraud, and that to force compliance with the agency’s regulatory scheme in light of 50 separate state tort law systems would place a burden on applicants that was not envisioned by Congress.¹⁷⁸ The Court also explained that allowing such claims would lead to concern from device applicants that their disclosures to the FDA, while acceptable to the agency, would later be held to be insufficient under state law. Such a finding would incentivize applicants “to submit a deluge of information that the agency neither wants nor needs” and lead to burdens on the agency and delay in the

¹⁷¹ See *supra* “Interaction Between Implied and Express Preemption.”

¹⁷² 21 U.S.C. § 337(a).

¹⁷³ 531 U.S. 341 (2001).

¹⁷⁴ *Id.* at 343.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.* at 348-49.

¹⁷⁷ *Id.* at 349.

¹⁷⁸ *Id.* at 350.

§ 510(k) process.¹⁷⁹ The Court also stated that it was expressing no view as to whether the claims were subject to the MDA preemption provision, but did indicate that the existence of the express preemption provision did not interfere with a finding of implied conflict preemption.¹⁸⁰

Finally, the Court distinguished the *Buckman* case from its decision in *Lohr*. The Court explained that besides the fact that *Lohr* did not directly address the question of implied preemption, the patient's claims in *Lohr* stemmed from the manufacturer's alleged failure to use reasonable care in the production of the medical device, and not solely from the violation of FDCA disclosure requirements.¹⁸¹ The Court stated that "although [*Lohr*] can be read to allow certain state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim."¹⁸²

Future of Preemption and Medical Devices

Following the *Lohr*, *Buckman*, and *Riegel* decisions, the question of whether an individual can bring a state-law tort claim after suffering an injury caused by a medical device can be a complex inquiry with varied results. While the Supreme Court has generally found that under the MDA preemption provision, the ability of an individual to bring a state-law tort suit alleging certain defects with a medical device can turn on how that device received marketing approval from the FDA, (i.e., through either the § 510(k) process or premarket approval), the inquiry is not this straightforward,¹⁸³ and questions remain about which state-law tort claims brought against medical device manufacturers are preempted by federal law.

For example, following the *Riegel* case, lower courts have often concluded that consumers of Class III medical devices are prevented from suing device manufacturers on most state common law claims if the device receives premarket approval.¹⁸⁴ However, as recognized in both the *Lohr* and *Riegel* decisions, state-law claims that are "parallel" to federal requirements are not expressly preempted by the MDA preemption provision. As noted above, while the Court in *Riegel* briefly indicated that parallel claims are those that provide for a "damages remedy for claims premised on a violation of FDA regulations," it did not further address which state-law tort claims survive federal preemption.¹⁸⁵ Several lower courts have grappled with this issue.¹⁸⁶ Additionally, when a plaintiff brings a state-law claim that involves a violation of federal medical device requirements, which may survive under the MDA's express preemption provision, courts nevertheless have

¹⁷⁹ *Buckman*, 531 U.S. at 351.

¹⁸⁰ *Id.* at 352.

¹⁸¹ *Id.* at 352-53.

¹⁸² *Id.* at 353.

¹⁸³ See, e.g., *Gross v. Stryker Corp.*, 858 F. Supp.2d 466 (W.D. Pa. 2012) (motion to dismiss granted against claims involving artificial hip prosthesis that had received premarket approval with components that received FDA approval through § 510(k) process; court finds preemption extended to all components of the device, even those originally receiving § 510(k) clearance).

¹⁸⁴ See generally John B. Reiss, et al., *Your Business in Court and at Federal Agencies*, 68 Food Drug L.J. (2013).

¹⁸⁵ *Riegel*, 552 U.S. at 330.

¹⁸⁶ See, e.g., *Walker v. Medtronic, Inc.*, 670 F.3d 569, 576 (4th Cir. 2012) (plaintiff's state-law claims against manufacturer do not parallel federal requirements); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (claim against medical device manufacturer preempted; plaintiff failed to allege parallel claim in complaint); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 782 (5th Cir. 2011) (plaintiff's failure-to-warn claim not expressly or impliedly preempted by federal law); *Bass v. Stryker Corp.*, 669 F.3d 501, 512-13 (5th Cir. 2012).

struggled with determining whether these claims are impliedly preempted under the Court's reasoning in *Buckman*.

One case that illustrates some of these issues is *Medtronic v. Stengel*.¹⁸⁷ This case addresses whether a person can sue a medical device manufacturer under state law for failing to report information about an adverse event to the FDA. In *Stengel*, a patient was rendered paraplegic by a pain pump that was a Class III device that had received premarket approval.¹⁸⁸ After the FDA approved the pump, but before the plaintiff's injury, the device manufacturer purportedly learned of the issues with the device, but did not notify the FDA. The patient and his wife filed suit under state law, alleging certain negligence and strict liability claims, including a failure-to-warn claim as part of an amended complaint. The Ninth Circuit unanimously held that where, as here, violations of the MDA occur *outside* of the premarket approval process, the MDA preemption provision does not preempt the state-law claims, as they "parallel" federal duties.¹⁸⁹ The Ninth Circuit further indicated that the patient's claim was different from the plaintiff's claim in *Buckman*, as the state-law claim was "independent" of the federal device requirements.¹⁹⁰ Other courts of appeal have addressed this issue and reached varying conclusions.¹⁹¹ Medtronic has appealed this case to the Supreme Court, but the Court has not yet determined whether it will grant review.¹⁹²

Finally, it should be noted that Congress has considered amending the FDCA to clarify the relationship between the federal preemption provision of the MDA and state tort claims. In response to the Supreme Court's decision in *Riegel*, Representative Pallone and Senator Kennedy introduced H.R. 1346/S. 540, the Medical Device Safety Act of 2009. The bill would have effectively overturned *Riegel* by amending the MDA's express preemption provision to state that "[n]othing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State." The addition of this clause as included in the bill would have taken effect "as if included in the enactment of the [MDA]," and would have "appl[ied] to any civil action pending or filed on or after the date of enactment of" the legislation. The language in H.R. 1346/S. 540 was incorporated in H.R. 4816, the Food and Drug Administration Improvement Act of 2010, in the 111th Congress, which was referred to committee but did not see further action. It appears that similar legislation has not been introduced in the 112th or 113th Congress.

Pharmaceutical Drugs and the FDCA

Having discussed the various ways the FDCA has been interpreted to preempt state tort claims with respect to medical devices, the report turns to the issue of FDCA preemption and prescription drugs.

¹⁸⁷ *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013).

¹⁸⁸ *Id.* at 1226.

¹⁸⁹ *Id.* at 1231-34.

¹⁹⁰ *Id.* at 1233.

¹⁹¹ *See, e.g., Hughes*, 631 F.3d at 782 (plaintiff's failure-to-warn claim following injury from a device receiving premarket approval neither expressly or impliedly preempted by federal law); *cf. Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic, Inc.* 623 F.3d 1200, 1205 (8th Cir. 2010) (court finds failure-to-warn and similar claims preempted under MDA preemption provision).

¹⁹² *See Stengel v. Medtronic*, No.12-1351 (petition filed May 10, 2013).

Premarket Approval of Drugs

Since 1938, there has been a federal system of premarket approval for drugs in the United States.¹⁹³ The Kefauver-Harris Drug Amendments of 1962 (Drug Amendments), enacted in the wake of the thalidomide crisis of the early 1960s, revamped the preapproval process for drugs to require that a manufacturer demonstrate that a new drug be both safe and effective for its intended use before the product can be marketed.¹⁹⁴ Under current law, in order to market a new drug, a manufacturer must file a New Drug Application (NDA) with the FDA, which must, among other things, include full reports of investigations into the drug's safety and effectiveness; a list of the drug's components; a full statement of the drug's composition; a description of the manufacturing methods, processing and packing; and "specimens of the labeling proposed to be used for such drug."¹⁹⁵ The FDA will not approve the NDA if it finds, for example, that the reports of testing show that the drug is unsafe or ineffective or if the "proposed labeling" does not make the drug "safe for use under the conditions, prescribed, recommended, or suggested."¹⁹⁶

With respect to the proposed labeling for a drug, the FDA must find that the labeling "contain a summary of the essential scientific information needed for the safe and effective use of the drug" and is neither "promotional in tone nor false or misleading ..."¹⁹⁷ For all prescription drugs, the label must include, among other information, details regarding how the drug should be administered, the proper dosage of the drug, and any contraindications, warnings, or adverse reactions related to the drug.¹⁹⁸ A label describing the contraindications would include descriptions of situations where the drug should not be used because the "risk clearly outweighs any possible benefit."¹⁹⁹

Once the FDA has approved a NDA, the agency places the drug at issue on a public list of approved drugs.²⁰⁰ The drugs on this list are known as "listed drugs,"²⁰¹ and the list is required to be updated every 30 days.²⁰² The law requires post-market surveillance of the drug by the government, necessitating the FDA to withdraw approval of a new drug if it finds that the drug is

¹⁹³ See Pub. L. No. 75-717, 52 Stat. 1040. Under the FDCA, a new drug could not be marketed unless it was shown to be "safe" for its intended use, see *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612-13 (1973), and the FDA could reject a new drug if the agency could demonstrate that the drug was not safe for use as labeled. See *Levine*, 555 U.S. at 566. Moreover, under the original 1938 law, if the FDA failed to act, an application became effective sixty days after the filing by a manufacturer. *Id.*; see also FDCA § 505(c).

¹⁹⁴ Pub. L. No. 87-781, 76 Stat. 780 (1962) (current version as amended at 21 U.S.C. §§ 301-392). The Drug Amendments also did away with the automatic approval of a new drug application after sixty days, requiring that the FDA take affirmative action in approving any drug application. *Id.* § 104(b) (current version as amended at 21 U.S.C. § 355(c), providing that the agency, within 180 days, either approve an application or give the applicant the notice of an opportunity for a hearing before the Secretary of Health and Human Services).

¹⁹⁵ 21 U.S.C. § 355(b)(1).

¹⁹⁶ *Id.*

¹⁹⁷ 21 C.F.R. § 201.56(a).

¹⁹⁸ See 21 C.F.R. § 201.56(d)-(e).

¹⁹⁹ See 21 C.F.R. § 201.80(d). The regulations provide as an example of contraindications descriptions regarding the "use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it." *Id.*

²⁰⁰ 21 U.S.C. § 355(j)(7).

²⁰¹ 21 U.S.C. § 355(j)(2)(A)(i).

²⁰² 21 U.S.C. § 355(j)(7)(A)(ii).

unsafe, or there is a lack of substantial evidence that the drug is effective.²⁰³ Likewise, a manufacturer is not absolved of all responsibility once a drug has been approved by the FDA, as a manufacturer must comply with the FDCA's Good Manufacturing Practices,²⁰⁴ report any "adverse events" to the FDA,²⁰⁵ and periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling of the drug.²⁰⁶ Nonetheless, the manufacturer generally may not make changes to the drug, including "[c]hanges in labeling," without first submitting a supplemental application to the FDA and securing the agency's prior approval for the change.²⁰⁷ Importantly, however, under the FDA's so called "changes being effected" or CBE regulation, a manufacturer can add or strengthen a warning without prior approval by the FDA,²⁰⁸ a "narrow" exception to the general rule that labeling changes require the FDA's prior approval.²⁰⁹

Approval of Generic Drugs

Generally, when a drug manufacturer invents a drug, the manufacturer obtains a patent which provides the "pioneer" drug maker with a limited period of time to exclusively manufacture or use the invention.²¹⁰ The *quid pro quo* for the exclusivity period created by patent law is that the manufacturer is required to disclose the invention so that others can one day make and use the underlying product.²¹¹ Normally, when a patent expires, anyone is free to make and use the invention. However, with respect to drugs, the FDCA requires the FDA to grant premarket approval to a particular manufacturer before a drug can be marketed.²¹² Following the passage of the Drug Amendments, the only way a drug manufacturer who wanted to market a copy of a drug approved after 1962 whose patent had expired was to submit a NDA and repeat the costly clinical trials that the inventor of the original drug had already undertaken. As a consequence, the FDCA's NDA process could functionally prohibit manufacturers from entering a market and competing with the pioneer manufacturer.²¹³

To alleviate the problems created by the Drug Amendments, the Drug Price Competition and Patent Term Restoration Act of 1984, or as it is more commonly known, the Hatch-Waxman Act,²¹⁴ created the modern generic drug infrastructure. The act created a new type of application for drug marketing approval, the abbreviated new drug application (ANDA), which allows a third party or "generic" manufacturer to show that its drug formulation is a therapeutically equivalent

²⁰³ *Id.* § 355(e).

²⁰⁴ 21 U.S.C. § 351(a)(1)(B).

²⁰⁵ 21 C.F.R. § 314.80.

²⁰⁶ *See* 21 U.S.C. § 355(k).

²⁰⁷ *See* 21 C.F.R. § 314.70(b)(1)-(2).

²⁰⁸ 21 C.F.R. § 314.70(c).

²⁰⁹ "CBE supplements were intended as a narrow exception to the general rule that labeling changes require FDA's prior approval ..." *See* 73 Fed. Reg. 2848, 2850 (Jan. 16, 2008) (citing 50 Fed. Reg. 7470).

²¹⁰ 35 U.S.C. § 154.

²¹¹ 35 U.S.C. § 112.

²¹² 21 U.S.C. § 355.

²¹³ H.R. Rep. No. 98-857(I) at 14.

²¹⁴ *See* Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417, 98 Stat. 1585 (enacted in 1984; codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

copy of the one being marketed by the originator.²¹⁵ An ANDA generally must include “information to show that the new drug is bioequivalent to the listed drug,”²¹⁶ and “information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug.”²¹⁷ The generic applicant is not required to conduct its own safety and effectiveness testing, but is permitted to rely upon the safety and effectiveness evidence presented in the NDA for the listed drug.²¹⁸ The FDA may withdraw approval of an ANDA for a generic drug if it finds that the labeling for the generic drug “is no longer consistent with that for the listed drug.”²¹⁹ The current NDA holder of a brand-name drug may change a drug’s labeling, but a generic drug manufacturer cannot and must ensure that its labeling remains the same as the labeling for the listed drug.²²⁰

Preemption and Prescription Drugs

In contrast to its provisions on medical devices, the FDCA does not contain an express preemption clause with respect to its prescription drug mandates. Nonetheless, the elaborate premarket approval scheme for drugs created by the FDCA has the potential to clash with state tort law, raising questions as to whether federal drug law preempts state tort law. On one hand, as discussed above, state tort law, depending on the specific theory pursued, could result in a manufacturer paying damages for marketing a prescription drug that has been approved by the FDA on the theory that the underlying product is unreasonably dangerous or has an insufficient warning or was fraudulently marketed. After all, common law tort doctrines typically do not treat compliance with a regulation as a bar to liability.²²¹ Moreover, the Supreme Court, in both *Lohr* and *Riegel*, has acknowledged that a jury’s verdict in a tort lawsuit can function just like a law passed by a state legislature or an administrative order issued by a governor in creating obligations that a manufacturer must obey.²²² On the other hand, the FDCA with its premarket approval process generally requires the FDA to approve a drug’s chemical makeup and warnings before the product can be marketed to the public, and presumably a drug that has been approved by the FDA is both safe and effective within the meaning of the FDCA and has the appropriate warnings to ensure the product is not misbranded in violation of the FDCA. Accordingly, state tort law has the potential to second guess the determinations made by the FDA, by allowing a jury to impose liability for manufacturing a drug whose composition and warnings have been approved by the federal agency.

²¹⁵ 21 U.S.C. § 355(j).

²¹⁶ 21 U.S.C. § 355(j)(2)(A)(iv).

²¹⁷ 21 U.S.C. § 355(j)(2)(A)(v).

²¹⁸ See *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc.*, 211 F.3d 21, 26 (2d Cir. 2000).

²¹⁹ 21 C.F.R. § 314.150(b)(10).

²²⁰ 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7).

²²¹ See Restatement (Third) of Torts: Liab. for Physical and Emotional Harm § 16 (“An actor’s compliance with a pertinent statute, while evidence of nonnegligence, does not preclude a finding that the actor is negligent under § 3 for failing to adopt precautions in addition to those mandated by the statute.”); see also Restatement (Third) of Torts: Product Liability § 4(b); Restatement (Second) of Torts § 288C (1965). The logic of this doctrine is that statutes and regulations typically provide “inadequate levels of safety” and the lawmaking process “can sometimes be insufficiently attentive to the interests of potential victims.” See Restatement (Third) of Torts: Liab. for Physical and Emotional Harm § 16 cmt. b; see also Dan B. Dobbs, *The Law of Torts* § 224 (2000) (“When it comes to technological standards, they are quickly outdated with no guarantee that the legislature or regulators will have time or information necessary to update them.”).

²²² See *Lohr*, 518 U.S. at 512; *Riegel*, 552 U.S. at 321-22.

Despite the potential for conflict between the FDCA's premarket approval process for drugs and state tort law, for much of the FDA's history the issue of federal drug law's preemptive effect on state tort claims was unresolved, and more exacting state tort law standards of care were generally seen by the courts as operating concurrently with federal requirements.²²³ However, beginning in 2004, the FDA began arguing that its prescription drug labeling regulations preempted injured plaintiffs' common law tort claims.²²⁴ In 2006, the FDA, in a lengthy preamble to regulations on drug labeling, stated its belief that under "existing preemption principles" product liability claims challenging the safety and efficacy of a FDA-approved label "would be preempted."²²⁵ Specifically, the FDA argued while the FDCA "contains no express preemption provision for drugs," the act, in giving the agency "comprehensive authority over drug safety, effectiveness, and labeling," implicitly preempted tort claims that functionally regulated the field of drug labeling.²²⁶ Moreover, the FDA, in the 2006 preamble, argued that the state tort laws challenging the adequacy of a drug label that had been approved by the agency both stood as "an obstacle to the achievement of the full objectives and purposes" of federal law and made it impossible for manufacturers to simultaneously comply with the FDCA's rules against mislabeling and adjusting a product's label and the duty imposed by state tort law to make the label safer.²²⁷ With the FDA asserting the position that the agency's labeling requirements for drugs established optimal, as opposed to minimal, standards from which state law could not deviate, the position was ripe for a challenge to the Supreme Court. The Court, beginning in 2009, handed down three landmark rulings that clarified when the FDCA's drug requirements preempt state tort law.²²⁸

Wyeth v. Levine

In 2009, *Wyeth v. Levine* became the first Supreme Court case to explore whether the FDCA's drug requirements preempted state tort law, ultimately finding the state tort claim at issue not preempted.²²⁹ The underlying facts of *Levine* were these: Diana Levine—a bass, guitar and piano player and author of children's music—visited a clinic to receive treatment for severe headache-related nausea and was given the brand name drug Phenergan.²³⁰ According to the federally approved label for Phenergan, the drug could be administered in one of three ways: (1) intramuscularly; (2) through an intravenous (IV) drip, where it is mixed with saline and descends slowly through a catheter into the patient's vein; or (3) through what is called an IV push, where

²²³ See, e.g., *Hill v. Searle Pharmaceuticals, Inc.*, 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA approval is not a shield to liability."); see also *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *Salmon v. Parke-Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975).

²²⁴ See Mary Ellen Egan, "Tort Turf," *Forbes* Apr. 26, 2004, at 48; see generally *Mason v. Smithkline Beecham Corp.*, 596 F.3d 387, 390-91 (7th Cir. 2010) ("Interestingly enough, the idea of conflict preemption in prescription drug cases is relatively new. Until the early 2000s, prescription drug companies infrequently invoked the preemption defense, and when they did, it rarely succeeded ... This changed in 2001 when district courts were inundated with preemption motions in prescription drug cases. In a number of these cases, the FDA filed *amicus* briefs in support of the pharmaceutical industry. In 2006, the FDA also released statements and revised its regulations in an attempt to bolster the drug manufacturers' preemption defense. Not surprisingly, courts began to issue contradicting opinions, which led the Supreme Court to grant certiorari in *Levine* to decide the issue.") (Evans, J.).

²²⁵ See 71 Fed. Reg. 3922, 3933 (Jan. 24, 2006).

²²⁶ *Id.* at 3935-36.

²²⁷ *Id.* at 3935.

²²⁸ See *Levine*, 555 U.S. at 555; *Mensing*, 131 S. Ct. at 2567; *Bartlett*, 133 S. Ct. at 2466.

²²⁹ *Levine*, 555 U.S. at 555.

²³⁰ See Alicia Mundy and Shirley S. Wang, *In Drug Case, Justices to Weigh Right to Sue*, Wall Street Journal, October 27, 2008, <http://online.wsj.com/article/SB122506300017470355.html>.

the drug is injected directly into the patient's vein.²³¹ The latter method of administration poses significant risks in that if the drug is injected into an artery, the corrosive nature of the drug can cause severe chemical irritation and damage to the tissue, risking irreversible gangrene.²³² The FDA was aware of the risks posed by the IV push method of administering Phenergan, but instead of prohibiting the IV push method, the FDA opted to require that the drug's label merely warn of the danger of gangrene and amputation following an inadvertent intra-arterial injection.²³³ The IV push method was used to administer Phenergan to Ms. Levine, and an error in administration resulted in the musician developing gangrene, ultimately forcing doctors to amputate her hand and forearm.²³⁴ Ms. Levine, after suing the clinic and the physician's assistant who administered Phenergan, received a \$700,000 settlement.²³⁵ Ms. Levine also sued the maker of Phenergan, Wyeth Pharmaceuticals, in a Vermont state court, arguing that the warning labels on the product were insufficient under common law negligence and strict-liability theories.²³⁶ Wyeth defended the suit by arguing that the state tort claims were preempted by federal law.²³⁷ The state courts rejected Wyeth's preemption argument, and after Ms. Levine won a jury verdict of \$6.7 million against Wyeth, the pharmaceutical giant appealed.²³⁸ The Supreme Court granted certiorari to hear the case in 2008 and issued its ruling in March 2009.

In a 6-3 ruling, the Supreme Court, with Justice Stevens the author, held that none of Ms. Levine's state tort claims were preempted by federal law. At the Supreme Court, Wyeth focused on a conflict preemption argument—that is, that the state tort duty was both (1) impossible to comply with simultaneously with the federal law and (2) an obstacle to the objects and purposes of federal drug law.²³⁹ With respect to Wyeth's first argument, the Supreme Court found that the FDA's CBE regulation precluded any preemption based on impossibility. According to Justice Stevens's opinion, the CBE regulation allowed a brand name drug manufacturer when presented

²³¹ *Levine*, 555 U.S. at 559.

²³² *Id.*

²³³ *Id.* at 559-60. The record regarding the FDA's rationale for allowing the IV push method to be used for administering Phenergan was scant, *id.* at 561, but industry publications do indicate there were some advantages for allowing the IV push method to continue. See Richard Rosenfeld, *Clinical and Economical Considerations for IV Push Drug Delivery: An Overview of the Historical Background for IV Push and Model for Implementation of a Successful Program* 3-4 (2007), <http://www.expert411.com/sitebuildercontent/sitebuilderfiles/IVPushRosenfeld.pdf> (noting the several advantages of IV push, including quick patient response time, cost and time savings, decreased fluid load, and increased nurse monitoring).

²³⁴ *Levine*, 555 U.S. at 559.

²³⁵ See Mark Herrmann, *The tragedy of Diana Levine*, Chicago Tribune, March 12, 2009, http://articles.chicagotribune.com/2009-03-12/news/0903120091_1_diana-levine-labeling-phenergan.

²³⁶ *Levine*, 555 U.S. at 559 – 60 (“Levine alleged that the labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug's therapeutic benefits.”).

²³⁷ *Id.* at 560.

²³⁸ See Mundy and Wang, *supra* footnote 230.

²³⁹ *Id.* Wyeth had abandoned the argument that federal law occupied the field with respect to the regulation of prescription drugs by the time the case reached the Supreme Court. *Id.* However, based on the comments made by the Court in *Wyeth* it appears that a field preemption argument would not have been persuasive. Specifically, the Court recognized that when Congress first enacted the FDCA, Congress “supplemented the protection for consumers already provided by state regulation and common-law liability.” *Id.* at 566. Moreover, the revamped premarket review process created by the Drug Amendments “took care to preserve state law.” *Id.* at 567. In other words, federal drug law is not “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,” the hallmark of field preemption. See *Rice*, 331 U.S. at 230.

with “newly acquired information” about a drug, including “new analyses of previously submitted data,” to make “changes to its label before receiving the agency’s approval,” including adding to or strengthening a warning.²⁴⁰ The *Levine* opinion noted that Wyeth had received evidence of 20 incidents resulting from IV push administration of Phenergan before Ms. Levine’s injury, giving them the basis to unilaterally strengthen the warning and making it *possible* for the drug manufacturer to both comply with the duty imposed by state tort law to strengthen Phenergan’s warning and to comply with federal drug law.²⁴¹ The Court noted that while the FDA retains the authority to reject any labeling changes made pursuant to the CBE regulation, barring any “clear evidence that the FDA would not have approved a change to Phenergan’s label,” the Court could not conclude that it was impossible for Wyeth to comply with both federal and state requirements.²⁴²

The Court likewise rejected Wyeth’s argument that requiring compliance with a state-law duty to provide a stronger warning about IV push administration would obstruct the “purposes and objectives of federal drug labeling regulation.”²⁴³ For Wyeth, Congress’s purpose in crafting the federal pre-market approval process for drugs was to “entrust an expert agency to make drug labeling decisions that strike the balance between competing objectives,” making the FDCA both the floor and ceiling for drug regulation.²⁴⁴ Relying on *Geier*, Wyeth contended that a state tort claim based on the inadequacy of a label served as an obstacle to a federal regime trying to account for various competing interests.²⁴⁵ The Court rejected this argument, however, concluding that Congress, in crafting the FDCA, recognized that state tort law remedies “further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.”²⁴⁶ Additionally, the majority opinion reasoned that if Congress wanted to preempt state tort claims with the FDCA’s drug provisions, it could have done so with an express preemption clause, as Congress had done in the medical device context.²⁴⁷ Congress’s silence on the issue was “powerful evidence” to the Court that Congress did not intend FDA oversight to be “the exclusive means of ensuring drug safety and effectiveness.”²⁴⁸ Moreover, the Court distinguished *Geier*. Unlike in *Geier*, where the regulation in question went through formal rulemaking and was a consistent position of the agency, in *Levine* the only regulatory guidance indicating that federal drug law preempted state tort claims came in the form of the 2006 preamble, a position that not only contradicted earlier statements by the FDA, but also was not subject to notice and comment rulemaking before being issued.²⁴⁹ In other words, the Court did not find that the FDA’s recently adopted position deserved any deference, and the Court affirmed the decision of the lower state courts finding no preemption.

²⁴⁰ *Levine*, 555 U.S. at 569.

²⁴¹ *Id.* at 569-71.

²⁴² *Id.* at 571.

²⁴³ *Id.* at 573.

²⁴⁴ *Id.* at 573-74.

²⁴⁵ *Id.*

²⁴⁶ *Id.* at 574.

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.* at 580-81.

The Concurring Opinions in *Levine*

Two concurring opinions were issued in *Levine*, both of which have largely guided the case law in this area. Justice Breyer, following the approach of his majority opinion in *Geier*, wrote separately to note that it was possible for state tort law to “interfere with the FDA’s” objectives, and therefore be preempted.²⁵⁰ For Justice Breyer, the problem for the defendant in *Levine* was that the FDA had not issued “lawful specific regulations” describing why labeling requirements serve as both a floor and a ceiling creating a preemptive effect, but instead relied on the 2006 preamble.²⁵¹ In other words, Justice Breyer, relying on an obstacle preemption theory, signaled a clear approach for future administrations to, through the issuance of formal administrative rulemaking, bar state tort claims against manufacturers of FDA approved drugs.

Justice Thomas, on the other hand, took a far different approach than Justice Breyer. Thomas wrote separately, noting that while he agreed with the majority’s conclusion on the issue of impossibility preemption, he did not agree with the premise that there was a constitutional basis for Wyeth’s obstacle or “purposes and objectives” preemption argument.²⁵² For Thomas, under the Supremacy Clause only federal laws “made in pursuance of the Constitution” preempted state laws, meaning that the law must be passed by both houses of Congress and signed by the President.²⁵³ For Justice Thomas, the “purposes and objectives” preemption doctrine invites the Court to broadly look at “federal policy objectives, legislative history, or generalized notions of congressional purposes that are not contained in the text of the federal law” that was passed by Congress and signed by the President.²⁵⁴ Accordingly, the Court, by trying to divine the “purposes and objectives” of certain legislation to determine the preemptive effect of a law, strayed from text of the Supremacy Clause.²⁵⁵ In short, Justice Thomas, in his concurrence in *Levine*, announced that he would not join an opinion that relied on obstacle preemption because of the theory’s tendency to “facilitat[e] freewheeling, extratextual, and broad evaluations of the ‘purposes and objectives’ embodied within federal law.”²⁵⁶

PLIVA v. Mensing

The Court returned to the issue of preemption and prescription drugs two years after *Levine* in *PLIVA v. Mensing*.²⁵⁷ In the wake of *Levine*, a majority of lower courts reasoned that *Levine*, which was concerned with a brand name or listed drug, was equally applicable to generic drugs and that failure-to-warn claims were not preempted absent “clear evidence” that the FDA would have rejected a stronger warning.²⁵⁸ In *Mensing*, the Supreme Court rejected how the lower courts

²⁵⁰ *Levine*, 555 U.S. at 581-82 (Breyer, J., concurring).

²⁵¹ *Id.* at 582.

²⁵² *Levine*, 555 U.S. at 582-83 (Thomas, J., concurring).

²⁵³ *Id.* at 587.

²⁵⁴ *Id.* at 587-88.

²⁵⁵ *Id.* at 588.

²⁵⁶ *Id.* at 604. Justice Alito, for Justice Scalia and Chief Justice Roberts, dissented in *Levine*, arguing that *Geier* controlled and that state tort suits served as an obstacle to the FDA’s role in finding the proper “balance” between the costs and benefits of administering drugs. See 555 U.S. 555, 621 (Alito, J., dissenting).

²⁵⁷ 131 S. Ct. at 2567.

²⁵⁸ See, e.g., *Mensing v. Wyeth*, 588 F.3d 603 (8th Cir. 2009); see also *Demahy v. Actavis*, 593 F.3d 428 (5th Cir. 2010); *Gaeta v. Perrigo Pharmaceuticals Co.*, 630 F.3d 1225 (9th Cir. 2011).

had interpreted *Levine* with respect to generic drugs.²⁵⁹ *Mensing* involved the consolidation of two cases in which the plaintiffs were prescribed the brand name drug Reglan but were dispensed the generic drug metoclopramide by their pharmacists in order to treat a digestive track disorder.²⁶⁰ One of the side effects of long-term metoclopramide use is the development of tardive dyskinesia, a severe neurological disorder.²⁶¹ In light of this side effect, over the years, the FDA approved several changes to Reglan’s labeling to increase the strength of its warnings about tardive dyskinesia, culminating in 2009 with a “black box” warning that “[t]reatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.”²⁶² Prior to the development of the stronger labels, the plaintiffs in *Mensing* were dispensed the metoclopramide and each developed tardive dyskinesia after taking the drug for several years.²⁶³ The plaintiffs sued the manufacturers of the generic drug, arguing that the manufacturer had breached its duty of due care by failing to change its warning label “despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label.”²⁶⁴ The manufacturers defended on preemption grounds.

Justice Thomas, writing for a majority that included the three *Levine* dissenters and Justice Kennedy, held that the FDCA’s requirements for generic drugs implicitly preempted state failure-to-warn claims for impossibility reasons. Deferring to the FDA’s views, the Court held that FDA regulations prevented generic manufacturers from “independently changing” a generic drug’s safety label, and accordingly, a state tort duty requiring a generic manufacturer to strengthen the drug’s label was impossible to comply with while simultaneously adhering to the federal “sameness” requirement for generic drugs.²⁶⁵ In so concluding, the majority rejected the argument that the generic manufacturer had to prove that the FDA would have rejected a suggested change to make the generic label safer because imposing such a requirement could theoretically defeat any impossibility claim because Congress could always be petitioned to amend a law that conflicted with a state tort duty.²⁶⁶ Instead, *Mensing* concluded that “when a party cannot satisfy its state duties without the Federal Government’s special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.”²⁶⁷ Thus, for the five-Justice majority, *Mensing* was distinguishable from *Levine* in that federal law permitted manufacturers of *brand name* drugs to unilaterally strengthen the warning without advance approval from the FDA.²⁶⁸

²⁵⁹ 131 S. Ct. at 2572.

²⁶⁰ *Id.*

²⁶¹ *Id.* (noting that 29% of the patients who take metoclopramide for several years develop tardive dyskinesia).

²⁶² *Id.* at 2573.

²⁶³ *Id.*

²⁶⁴ *Mensing*, 588 F.3d at 605.

²⁶⁵ *Mensing*, 131 S. Ct. at 2577-78.

²⁶⁶ *Id.* at 2579.

²⁶⁷ *Id.* at 2581.

²⁶⁸ Justice Sotomayor, joined by Justices Ginsburg, Breyer, and Kagan, dissented and accused the majority of “dilut[ing] the impossibility standard.” 131 S. Ct. at 2582 (Sotomayor, J., dissenting). For the dissenters, the possibility that the FDA would not agree to the suggestion of a generic manufacturer to strengthen a label was insufficient for impossibility preemption to exist. *Id.* at 2588. Moreover, the *Mensing* dissent noted the seemingly anomalous result of *Levine* and *Mensing* that the ability of a consumer “harmed by inadequate warnings” on a prescription drug to obtain relief through state tort law depended on the “happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug.” *Id.* at 2583.

Mutual Pharmaceutical v. Bartlett

Two years after *Mensing*, the Supreme Court again revisited the topic of preemption and prescription drugs in *Mutual Pharmaceutical v. Bartlett*.²⁶⁹ The case involved Karen Bartlett, a 53-year-old New Hampshire woman, who, after taking sulindac, a generic drug non-steroidal anti-inflammatory drug (NSAID), to treat her shoulder pain, developed a hypersensitivity reaction called Stevens-Johnson Syndrome, a rare but known side-effect to taking a NSAID.²⁷⁰ At the time Ms. Bartlett was prescribed sulindac, the drug's label did not specifically warn about Stevens-Johnson syndrome.²⁷¹ Ultimately, Ms. Bartlett suffered severe burns, resulting in permanent near-blindness and extreme damage to her lungs.²⁷² As a consequence, Ms. Bartlett filed suit against the manufacturer of the generic drug in a New Hampshire court, arguing that the manufacturer failed to properly warn about the dangers of the drug and, under a strict liability theory, the drug was defectively designed.²⁷³ The trial judge dismissed the plaintiff's failure-to-warn claim, but the strict liability claim went to a jury, which ultimately awarded Ms. Bartlett over \$21 million in damages.²⁷⁴ The pharmaceutical company argued on appeal to the Supreme Court that Ms. Bartlett's strict liability claims, just like the failure-to-warn claims in *Mensing*, were preempted by the federal sameness requirement for generic drugs.²⁷⁵

The Supreme Court, in another 5-4 ruling, agreed with the generic manufacturer of sulindac and held that the strict liability claim at issue in *Bartlett* imposed a duty that would conflict with the federal sameness requirements.²⁷⁶ In so ruling, Justice Alito, writing for the Court, rejected two central arguments made by the plaintiff. First, the Court dismissed the argument that state strict liability law did not impose a duty on the manufacturer, but instead merely reallocated the risks imposed as a result of an "unreasonably dangerous" product from the consumer to the manufacturer.²⁷⁷ The Court examined the underlying state law from New Hampshire and concluded that the state law did indeed impose a "substantive duty" on the manufacturer not to produce an "unreasonably dangerous" product.²⁷⁸ Specifically, the Court noted that New Hampshire strict liability law, at least in the context of prescription drugs, ultimately mirrors the failure-to-warn claims at issue in *Mensing*.²⁷⁹ The reason for the similarity is because New Hampshire, like many states,²⁸⁰ employs a "risk utility approach" to determine whether a product is defectively designed and "unreasonably dangerous," an approach that requires an evaluation of the usefulness of the product and risk of danger posed by the product.²⁸¹ With respect to

²⁶⁹ 133 S. Ct. at 2466.

²⁷⁰ *Id.* at 2471-72.

²⁷¹ *Id.* at 2472.

²⁷² *Id.* (noting that "sixty to sixty-five percent of the surface of respondent's body deteriorated, was burned off, or turned into an open wound.").

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ *Id.*

²⁷⁶ *Id.* at 2473 ("In the instant case, it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is preempted.").

²⁷⁷ *Id.*

²⁷⁸ *Id.*

²⁷⁹ *Id.* at 2475.

²⁸⁰ See generally *supra* "Strict Liability."

²⁸¹ *Levine*, 133 S. Ct. at 2474 (citing *Vautour v. Body Masters Sports Industries, Inc.*, 147 N. H. 150, 153, 784 A. 2d (continued...))

prescription drugs, and especially with respect to sulindac, a one-molecule drug, redesigning the drug is impossible.²⁸² Recognizing this, New Hampshire, like the majority of other states, had adopted comment k to § 402A of the Restatement (Second) of Torts and allows prescription drug manufacturers to avoid liability when the drug was accompanied by an adequate warning.²⁸³ In other words, the underlying claim, despite being described as a strict liability claim, functioned just like an ordinary negligent failure-to-warn claim, making *Bartlett* indistinguishable from *Mensing*.²⁸⁴

Second, the Court rejected the argument that impossibility preemption was inapplicable because a generic drug manufacturer could either “stop selling” its product or pay monetary damages under state law, and by taking either action, comply with both the federal “sameness” requirement and the duty imposed by state tort law.²⁸⁵ For the Court, the “stop selling” rationale would make impossibility preemption “all but meaningless,” because the idea of it being impossible to abide by a state and federal law simultaneously usually presupposes some sort of affirmative conduct, such as selling a product.²⁸⁶ For example, in the *Florida Lime & Avocado Growers* hypothetical,²⁸⁷ if the stop selling rationale governed impossibility claims, it would have been possible for an avocado grower to simultaneously comply with a state’s mandate to sell high oil avocados and a federal mandate to produce only low oil avocados by simply not selling avocados in that state.²⁸⁸ The same stop selling logic would have likewise led to an opposite conclusion in *Mensing*.²⁸⁹

Two dissenting opinions were filed in *Bartlett*, one by Justice Breyer and one by Justice Sotomayor.²⁹⁰

(...continued)

1178, 1181 (2001)).

²⁸² Even if it was chemically possible to reengineer sulindac, it would still be illegal under federal law to do so without first obtaining a NDA. *See Bartlett*, 133 S. Ct. at 2475.

²⁸³ *See id.* at 2475-76 & n.2. Notably, however, the defendant in *Bartlett* abandoned a comment k affirmative defense at trial, *see* 133 S. Ct. at 2487 (Sotomayor, J., dissenting), but the majority opinion’s broader point remains that strict liability claims premised on a design defect under New Hampshire law turn on the adequacy of a product’s warning. *See Bartlett*, 133 S. Ct. at 2475-76.

²⁸⁴ Apart from the failure-to-warn aspect of the strict liability claim, the *Bartlett* Court more broadly recognized that strict liability claims differ from absolute liability claims, in that the former create a duty to design a product reasonably safely, whereas the latter merely spread risk. *Id.* at 2473-74. This aspect of the Court’s decision appears to be in line with the general principles of strict liability law discussed earlier in this report. *See* footnote 95.

²⁸⁵ *Bartlett*, 133 S. Ct. at 2477-78.

²⁸⁶ *Id.* at 2477 (“In every instance in which the Court has found impossibility pre-emption, the ‘direct conflict’ between federal and state law duties could easily have been avoided if the regulated actor had simply ceased acting.”).

²⁸⁷ *See* 373 U.S. at 143. For a discussion of the *Florida Lime & Avocado Growers*’ hypothetical, *see supra* “Conflict Preemption.”

²⁸⁸ *Id.* at 2477 n.3.

²⁸⁹ *Id.* (“And, of course, *PLIVA, Inc. v. Mensing* ... forecloses any argument that impossibility is defeated by the prospect that a manufacturer could ‘pa[y] the state penalty’ for violating a state-law duty; that prospect would have defeated impossibility in *PLIVA* as well.”)

²⁹⁰ Justice Breyer, writing for himself and Justice Kagan, argued that it was not physically impossible for the manufacturer to comply with both federal or state law because the generic manufacturer could either “not do[] business in the relevant state or ... pay[] the state penalty.” 133 S. Ct. at 2480-81 (Breyer, J., dissenting). Adhering to the position he staked out in *Geier* and *Levine*, Justice Breyer continued his dissent by noting that while he could envision an obstacle preemption argument being made because of the duties imposed by a strict liability claim, that he would not defer to the views of the FDA on the matter because the agency had “held no hearings on the matter or solicited the (continued...)”

Future of Preemption Issues and the Food, Drug, and Cosmetic Act

The Broad Principles of *Levine*, *Mensing*, and *Bartlett*

Having issued three opinions on preemption and prescription drugs in the last five terms, the Supreme Court appears to have limited two routes for federal drug law to impliedly preempt state tort law, while dramatically expanding another avenue for implied preemption. Specifically, *Levine* foreclosed field preemption as a viable theory for drug manufacturers to defeat state tort claims, as a six-member majority of the Court recognized that state tort law generally serves to complement federal drug law.²⁹¹ Moreover, Justice Breyer’s concurrence in *Levine* and dissent in *Bartlett* signal that there could be a majority on the Court that would find state tort law serves as an “obstacle to the purposes and objectives” of federal drug law only if the FDA issues a regulation worthy of deference.²⁹² However, in *Mensing* and *Bartlett*, the Court appears to have breathed new life into impossibility preemption, a theory previously reserved to hypothetical examples in the High Court’s opinions.²⁹³ After *Mensing*, when an entity cannot independently satisfy both a state law requirement and federal law requirement without receiving “special permission” from the federal government, the state law must yield.²⁹⁴ *Bartlett* further expanded the impossibility defense by rejecting a long-time²⁹⁵ defense to conflict preemption that no conflict exists when a defendant can choose not to act or pay a state law fine—that is, the stop-selling theory.²⁹⁶

Collectively, after *Levine*, *Mensing*, and *Bartlett*, state failure-to-warn claims against a manufacturer of a brand name prescription drug *are not* preempted by federal drug law, but state failure-to-warn and strict liability claims premised on complying with a state law duty against a generic drug manufacturer *are* preempted. This result alone is significant, as generic medicines reportedly account for nearly 80% of all prescriptions dispensed in the United States and are

(...continued)

opinions, arguments, and views of the public in other ways.” *Id.* at 2481. Without giving deference to the FDA’s views on the matter, Justice Breyer would have adhered to the general rule of *Levine* that state tort litigation can supplement the FDA’s regulatory and enforcement activities. *Id.* at 2482.

Justice Sotomayor, writing for herself and Justice Ginsburg, gave a more full-throated defense of Ms. Bartlett’s position, arguing that the majority both ignored Congressional intent in preventing state tort claims from complimenting federal drug regulation and eschewed the presumption against preemption. 133 S. Ct. at 2483 (Sotomayor, J., dissenting). Justice Sotomayor disagreed with the majority’s assessment of the underlying state tort law claim, arguing that a New Hampshire design defect claim merely created an incentive for drug manufacturers to make changes to its product, but did not amount to a legal mandate to take a specific action. *Id.* at 2488. Moreover, the second *Bartlett* dissent argued that even if New Hampshire law imposed a legal obligation on the drug manufacturer, the manufacturer “may still choose between exiting the market or continuing to sell while knowing it may have to pay compensation to consumers injured by its product.” *Id.* at 2491. Finally, Justice Sotomayor’s dissent lamented the potential of the *Bartlett* opinion to displace state tort law in other contexts in which federal premarket approval is needed before a product can be sold in the United States. *Id.* at 2495 (citing federal pesticide, food additives, animal drugs, medical device, and color additives laws).

²⁹¹ See *Levine*, 555 U.S. at 578.

²⁹² See *Wyeth*, 555 U.S. at 581-82 (Breyer, J., concurring); *Bartlett*, 133 S. Ct. at 2480-81 (Breyer, J., dissenting).

²⁹³ See *Florida Lime & Avocado Growers*, 373 U.S. at 143.

²⁹⁴ *Mensing*, 131 S. Ct. at 2581.

²⁹⁵ See, e.g., *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 627 (1st Cir. 1987) (rejecting the stop-selling argument).

²⁹⁶ *Bartlett*, 133 S. Ct. at 2470 (holding that the stop-selling rationale would render impossibility preemption a “dead letter” and work a “revolution in this Court’s pre-emption case law.”).

growing at a rapid pace.²⁹⁷ Additionally, the independence principle enunciated in *Mensing* and reaffirmed in *Bartlett* lends to the conclusion that tort claims predicated on the chemical makeup of an approved drug, regardless of whether the drug is generic or brand name, would be preempted by the FDCA. After all, under current law no drug manufacturer can unilaterally change a drug, as the “altered chemical would be a new drug that would require its own NDA to be marketed.”²⁹⁸ Even more broadly, the principles enunciated in *Mensing* and *Bartlett* could potentially be applied to other contexts in which the law requires approval by the government before a product can be marketed, including with respect to the § 510(k) approval of medical devices,²⁹⁹ or conceivably to any other area of federal law that similarly imposes a process where the government evaluates the safety or effectiveness of a product before it can be sold.³⁰⁰

Potential Changes to the Generic Sameness Requirement

While the broad principles of *Mensing* and *Bartlett* with respect to impossibility preemption may have immense implications to a host of different areas of law, the underlying rationale for impossibility preemption of failure-to-warn claims in the generic drug context—the federal sameness requirement—may be altered in the near future. A few weeks after *Bartlett* was issued, the FDA indicated that it plans to issue a “Notice of Proposed Rulemaking” with respect to the labeling of generic drugs.³⁰¹ Specifically, the FDA states that the proposed revisions, which may be issued as soon as September 2013, will “create parity between NDA holders and ANDA holders with respect to submission of CBE labeling requirements.”³⁰² In other words, the FDA intends to allow generic manufacturers the ability to unilaterally update the labeling of a generic drug, which in theory would eliminate the underlying rationale for *Mensing* by making it possible to simultaneously comply with state tort duties and federal drug law. Nonetheless, eliminating the federal sameness requirement may be difficult to legally accomplish through a change in regulation given the statutory requirement that proposed labeling for a generic drug generally be the “same as the labeling approved for” a listed drug.³⁰³ That statutory basis can be eliminated by

²⁹⁷ See Food and Drug Administration, “Facts About Generic Drugs,” September 19, 2012, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> (“Today, nearly 8 in 10 prescriptions filled in the United States are for generic drugs. The use of generic drugs is expected to grow over the next few years as a number of popular drugs come off patent through 2015.”)

²⁹⁸ *Bartlett*, 133 S. Ct. at 2471 (“Once a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making any major changes to the ‘qualitative or quantitative formulation of the drug product, including the active ingredients, or in the specifications provided in the approved application.’”) (quoting 21 C.F.R. § 314.70(b)(2)(i)). In the wake of *Bartlett*, lower courts seem to be following the lead of the Supreme Court in finding that all design defect claim—even those that are not predicated on label inadequacies—are preempted. See, e.g., *In re Fosamax Prod. Liab. Litigation*, No. 06-MD-1789, 2013 WL 4306434 at * 6 (S.D.N.Y. Aug. 15, 2013) (holding that the “Supreme Court’s logic [in *Bartlett*] applies with equal force” with respect to whether a drug manufacturer could have “changed the chemical composition” of a drug “without being subjected to FDA procedures for new drugs.”).

²⁹⁹ Notably, *Lohr* only dealt with express, and not implied, preemption, see 518 U.S. at 484 (explaining that the issue presented in the case is “interpreting a statutory provision that express pre-empts state law”), and, pursuant to *Buckman*, implied preemption principles apply to the context of the MDA. See 531 U.S. at 352.

³⁰⁰ See *Bartlett*, 133 S. Ct. at 2495 (Sotomayor, J., dissenting) (citing federal pesticide, food additives, animal drugs, medical device, and color additives laws as examples of where a premarket evaluation and approval process exists).

³⁰¹ Food and Drug Administration, “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” Spring 2013, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201304&RIN=0910-AG94>.

³⁰² *Id.*

³⁰³ See 21 U.S.C. § 355(j)(2)(A)(v). The generic manufacturer must use a label that is identical to the pioneer’s label except “for changes required” because either (1) the manufacturer has petitioned the FDA under 21 U.S.C. (continued...)

Congress, as some bills have proposed doing,³⁰⁴ but such legislation may raise policy questions as to the wisdom of requiring generic manufacturers, who by definition are relying on others' safety data in marketing their products, to make unilateral determinations that the FDA's original judgments regarding the labeling of the brand name product should be overridden.

Another legislative solution to those who are disappointed with the outcomes of *Mensing* and *Bartlett* was hinted at near the end of the majority opinion in *Bartlett*. Specifically, Justice Alito's opinion lamented the lack of any explicit guidance from Congress with respect to the preemptive effect of the FDCA's prescription drug provisions, going so far as to say the Court "would welcome Congress' 'explicit' resolution of the difficult pre-emption questions that arise in the prescription drug context."³⁰⁵ The Court cites the explicit preemption clauses found in the FDCA with respect to vaccines and so-called "express non-preemption" clauses found in the FDCA's over-the-counter drugs provisions as examples of explicit language that Congress could add to the statute.³⁰⁶ However, the addition of language that explicitly states that state tort claims are not preempted by the FDCA may do little to alter the results of *Mensing* and *Bartlett*, as the Court has held that the existence of an express preemption clause or a savings clause does not prevent the Court from examining whether a law impliedly preempts state law.³⁰⁷

Other Developing Areas Regarding Preemption and Prescription Drugs

Assuming *Mensing* and *Bartlett* remain good law, several areas of legal dispute may allow the Court to revisit the issue of preemption and prescription drugs in the near future. For example, a circuit split has developed on whether federal law preempts a tort claim that a generic drug manufacturer has a duty to update a drug's label to match the brand name drug.³⁰⁸ In the context of *Mensing* and *Bartlett*, the generic sameness requirement imposed a requirement of inaction on the manufacturer without prior federal approval of a labeling change, but the same logic requires the generic label to match the pioneer's label at all times.³⁰⁹ On one hand, state-law tort law could impose an independent duty on a manufacturer to update a generic's label which, unlike in

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§ 355(j)(2)(C) with respect to a specific generic or (2) the new drug and the listed drug are produced by different manufacturers. See 21 U.S.C. § 355(j)(2)(A)(v). Presumably the latter exception only extends to labeling with respect to the name of the manufacturer, because that would be the only "required" change under the law. See 21 U.S.C. § 355(j)(2)(A)(v); see also *Krelic v. Mut. Pharms. Co.*, No. GD-08-024513, 2013 Pa. Dist. & Cnty. Dec. LEXIS 89 at *7 (Pa. County Ct. April 11, 2013). Additionally, the FDCA provides that the FDA may not approve an ANDA unless the application demonstrates that the labeling "is the same" as the labeling approved for the listed drug. See 21 U.S.C. § 355(j)(4)(G). Moreover, even if there is statutory basis for a change in the FDA's position, because the FDA would be altering what has been its longstanding interpretation of federal law, see, e.g. 57 Fed. Reg. 17950, 17955 (April 28, 1992) ("Labeling (including the container label and package insert) proposed for the drug product must be the same as the labeling approved for the reference listed drug."), the agency would have to provide a "reasoned analysis for change" if challenged in litigation. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983). This ordinarily requires that the agency to "display awareness that it is changing position" and to show that "there are good reasons for the new policy." See *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2009).

³⁰⁴ See, e.g., "Patient Safety and Generic Labeling Improvement Act," S. 2295, 112th Cong. (2012).

³⁰⁵ See *Bartlett*, 133 S. Ct. at 2480.

³⁰⁶ *Id.*

³⁰⁷ See *Geier*, 529 U.S. at 865.

³⁰⁸ Compare *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586 (6th Cir. 2013) (finding no preemption of a failure to update claim), with *Morris v. Pliva, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (finding a failure to update claim preempted).

³⁰⁹ See 21 C.F.R. § 314.150(b)(10).

Mensing and *Bartlett*, would be possible to satisfy while simultaneously obeying the federal sameness requirement.³¹⁰ On the other hand, a state duty that mirrors a federal requirement sounds very similar to the claim that was preempted in *Buckman*,³¹¹ as Congress intended the FDCA and the requirements imposed by the law to be enforced “exclusively by the Federal Government.”³¹²

The specific issue of whether failure to update claims can proceed may ultimately be of little consequence, as a state claim based on a failure to update would have to prove that not updating the generic label during the time the sameness requirement was violated was the proximate cause of a plaintiff’s injuries, seemingly a difficult task for any plaintiff injured by a prescription drug.³¹³ Nonetheless, failure to update claims raises the specter of a broader issue—much like in the medical device context—as to whether state-law claims that are parallel to the duties imposed by the FDCA’s drug provisions or FDA drug regulations are implicitly preempted by federal law.³¹⁴

Beyond the issue of whether parallel state-law claims are preempted, another issue that the Court may need to resolve is whether state law allowing for punitive damages for a failure-to-warn claim against a brand-name manufacturer are preempted.³¹⁵ Courts have also split on whether a tort law claim alleging that a generic manufacturer has a duty to communicate with customers about dangers not on a drug label is preempted.³¹⁶ In other words, *Bartlett* will likely not be the last time the Supreme Court delves into the difficult issues prompted by state tort claims, federal drug law, and constitutional preemption.

³¹⁰ See *Fulgenzi*, 711 F.3d at 586-87.

³¹¹ See *Morris*, 713 F.3d at 777.

³¹² See *Buckman*, 531 U.S. at 352.

³¹³ See *Fulgenzi*, 711 F.3d at 588.

³¹⁴ Cf. *Lohr*, 518 U.S. at 495 (recognizing the role of parallel state-law claims are not preempted under the MDA’s express preemption clause).

³¹⁵ Compare *Fussman v. Novartis Pharms. Corp.*, 509 Fed. Appx. 215, 225 (4th Cir. 2013) (per curiam) (rejecting that punitive damages for a failure-to-warn claim are preempted) with *McDarby v. Merck & Co.*, 401 N.J. Super. 10, 94, 949 A.2d 223, 276 (2008) (holding that punitive damages are preempted pursuant to *Buckman*).

³¹⁶ Compare *Strayhorn v. Wyeth Pharm. Inc.*, 887 F. Supp. 2d 799, 819 (W.D. Tenn. 2012) (“Plaintiffs’ assertion that the Generic Defendants could have sent Dear Doctor letter or other communications to physicians or patients is also preempted.”) with *Cooper v. Wyeth, Inc.* No. 09-929-JJB, 2012 WL 733846 * 4 (“Thus, a ‘Dear Doctor’ letter notifying a prescribing physician of the newly-updated and strengthened FDA label the generic drug was tied to would not run afoul of any federal law, which therefore leaves state law free to impose such a burden on the generic manufacturer so long as the state law’s requirements would not purport to require the letter to breach the parameters for such correspondence set by the FDA.”).

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