DRUG LABELING WARS: THE EIGHTH CIRCUIT AND THE DUTY TO WARN

by

Penny Herickhoff[1] and Georgia L. Holmes[2]

Abstract: Over the past decade, the drug industry has questioned whether consumers are entitled to bringing product liability claims in state court. Struggles to interpret preemption restrictions accelerated when the FDA published a formal preamble on preemption in 2006 asserting exclusive jurisdiction over drug and vaccine labeling. Today, a phalanx of prescription drug liability cases is moving through state and federal courts to establish the reach of the preemption defense. This paper analyzes the impact of two 8th Circuit "duty to warn" product liability claims which, taken together, offer important insights on consumer rights and company exposure in drug labeling claims.

Introduction: A wide range of drug liability cases, over the past decade, have raised questions whether consumers are entitled to bringing product liability claims in state court. In these cases, the drug industry has often sought federal court rulings that federal pre-emption concepts block patients from bringing product liability claims in state court, citing the supremacy clause and the desirability of exclusive federal jurisdiction to regulate drug products. Essentially, industry claims assert that the drug manufacturers sole legal responsibility is to satisfy the mandates of federal regulators and that drugs which achieve federal regulatory compliance are protected by a state tort liability shield. Few could blame the industry for wanting to mimic the judicial "safe harbor protection" the Supreme Court granted to the medical device manufacturer Medtronic in the *Riegel*[3] case. Although legislative proposals in Congress have sought to roll back the Reigel precedent, they have not succeeded. In 2006, the FDA published a directive claiming preemption and exclusive jurisdiction in matters involving claims against drugs and vaccines. Today, a phalanx of prescription drug liability cases is moving through the state and federal court systems to clarify the scope of tort liabilities faced by drug companies and to discern the boundaries of liability exposure for generic drug manufacturers.

This paper discusses the FDA drug review process, the formal statement on preemption issued by the FDA in 2006, the U.S. Supreme Court struggle to agree on proper construction of federal preemption (as articulated in Riegel opinions regarding the MDA) and analyzes the impact of two recent 8th Circuit cases which involved state "duty to warn product liability claims" against drug makers. Taken together, these cases offer important guidance on when failure of warn drug labeling claims are likely to succeed in the future against drug manufacturers in the 8th Circuit.

Background: The preemption defense is grounded in the supremacy of federal legislative and administrative power, created by the Supremacy Clause of the U.S. Constitution. [4]Preemption has three distinct dimensions. Express preemption arises when Congress clearly declares its intention to preempt state law. Implied preemption arises when the "structure and purpose" of federal law shows Congress's intent to exercise exclusive control over an area of law. And, conflict preemption which arises when there is an actual conflict between state and federal law with the result that it is impossible for a person to obey both.[5]

Federal Drug Approval and Duty to Warn Labeling Standards: All prescription drugs require approval by the Food and Drug Administration (FDA) before they may be marketed. Manufacturers of new drugs submit a new drug application (NDA) to the FDA.[6] An NDA must include information about the drug's safety and efficiency gleaned from clinical trials.[7] It must also propose a label reflecting appropriate use, warnings, precautions, and adverse reactions.[8] Recognizing a need to bring more affordable generic drugs to market as quickly as possible after the patents of name brand drugs expire, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the Food, Drug, and Cosmetic Act (FDCA) and is therefore referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an abbreviated new drug application (ANDA) procedure for generic manufacturers.[9] Generic manufacturers do not need to repeat the clinical trials conducted by name brand manufacturers. ANDA's are approved based on the initial safety profile of the name brand drug, as well as any post marketing surveillance.

As a result, ANDA applicants must show the FDA that their drug is essentially the same as the name brand drug and that their proposed label is in relevant part identical to the name brand drug label.[10]

Drug labels are subject to change. New risks may become apparent only after the drug has been used more widely and for longer periods. When a manufacturer has "reasonable evidence of an association of a serious hazard with a drug[,]" the drug's label must be revised; "a causal relationship need not have been proved." [11]Manufacturers cannot distribute a "misbranded" drug, [12]including a drug whose "labeling is false or misleading in any particular."[13] The FDA has several enforcement mechanisms to ensure that drugs with misleading labels are taken off the market. [14]

There are several procedures in 21 C.F.R. § 314.70 by which a manufacturer may supplement its application and propose changes to the drug or its label. "Major changes" require the FDA's prior approval through a prior approval supplement. [15]Manufacturers may implement "moderate changes," including changing a label to strengthen a warning based on newly acquired information, through a Changes Being Effected (CBE) supplement. [16]Manufacturers may implement CBE changes before the FDA formally approves them.

Beginning in 1992, preemption was raised as a defense in product liability litigation involving FDA regulated products [17][product was cigarettes). In Cipollone a 5-4 vote the Supreme Court held that a statutory preemption clause pre-empted common law rules. This was a clear case of express preemption. In 1976, Congress passed the Medical Device Act which governed FDA approval processes. The statute contained express preemption language for medical devices. The Lohr (1996) case and the Reigel (2008) case involved medical devices manufactured by Medtronic. Both were split decisions and reflect fragmentation of views on the court. However, taken together, the two decisions have established the principle that that the rigor of the device approval process affects whether product liability claims by users of the devices are allowed or preempted. For example, Reigel recognized a broad preemption with respect to pre-market approved devices (PMA), in recognition of the rigorous regulatory review prior to sale.

In 2006, the FDA published a formal position, called a "Preamble" in the Federal Register asserting exclusive FDA rights to regulate drugs, vaccines and medical devices. The majority in the *Levine*[18] case, discussed later in this paper, disregards the FDA proclamation saying "the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight."

Expansive and Conservative Judicial Views on Construction of Preemption: *The Reigel v. Medtronic* and *Warner Lambert v. Kent* cases offer fascinating chronicles of the current court's struggle with competing judicial views of "narrow construction" versus "normal interpretation" of language in the arena of preemption. In Reigel, Justice Ginzburg is the lone voice for narrow construction of federal preemption language. She urges the court to reconcile, to the extent reasonable, preservation of parallel enforcement of federal standards and state common law – each in their respective domains. Nevertheless, the majority in Reigel, appear eager to embrace broad construction of preemption doctrine and thereby limit liability of the private sector business interests, understanding, as they must, that their decision leaves injured consumers with no meaningful remedy for harm resulting from medical device failures, short of a malpractice claim against their medical provider.

In Reigel, the issue before the court was whether the express pre-emption language contained in the Medical Device Amendments of 1976, [19] barred state common-law claims of a consumer (which challenged the safety and effectiveness of a medical device) given premarket approval of that device by the Food and Drug Administration (FDA). In 1996, Charles Riegel underwent coronary angioplasty, shortly after suffering a myocardial infarction. Medical records indicate his right coronary artery was diffusely diseased and heavily calcified. Riegel's doctor inserted the Evergreen Balloon Catheter (manufactured by Medtronic) into his patient's coronary artery in an attempt to dilate the artery, although the device's labeling stated that use was contraindicated for patients with diffuse or calcified stenoses. The product label also warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres. Riegel's doctor inflated the catheter five times, to a pressure of 10 atmospheres. On its fifth inflation, the catheter ruptured.

Charles Riegel and his wife, Donna Riegel, brought suit against Medtronic in April 1999, in the United States District Court for the Northern District of New York. Their complaint alleged that Medtronic's catheter was

designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries. The plaintiffs alleged violations of New York state law including claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter, and negligent manufacturing.

MDA Section § 360k(a) prohibits imposition of "requirements" that are either different from or in addition to those established by the federal government. The Court first considered, whether the FDA pre-market approval (PMA) process for medical devices establishes "requirements." Distinguishing *Medtronic v. Lohr*, the Court found that the PMA process constitutes a "rigorous" review "specific to individual devices," thereby imposing federal "requirements" on the devices so approved. The Court then considered whether the Riegels' common-law tort claims drew on "any requirement" that was different from or in addition to the PMA requirements.

The MDA calls for federal oversight of medical devices that varies with the type of device at issue. The most extensive oversight is reserved for Class III devices that undergo the premarket approval process. These devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness. Manufacturers may not make changes to such devices that would affect safety or effectiveness unless they first seek and obtain permission from the FDA.

The Evergreen Balloon Catheter is a Class III device, under FDA rules. It received premarket approval from the FDA in 1994. Changes to the catheter's label received supplemental FDA approvals in 1995 and 1996. Medtronic argued that they are protected from the petitioner's state tort claims due to federal preemption of medical device regulation. Specifically, Medtronic argued that the Medical Device Amendments of 1976 (MDA) created a scheme of federal safety oversight for medical devices that effectively eliminated co-existing state oversight schemes. MDA's language, as amended, provides that a State shall not

> *"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 [federal law] 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" relevant federal law.*[20]

Medtronic argued this language clearly establishes that this is a case of express preemption which should be broadly construed to prevent state tort claims, such as those asserted by the plaintiffs.

The Reigel decision: It's instructive to review the distinct judicial perspectives on consumers rights to sue medical device makers articulated in Reigel and compare them to the Court's 2009 ruling in Levine, which involved a consumer claim against the maker of a prescription drug. The District Court in Reigel ruled that MDA language pre-empted the Riegels' claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter, and their claim of negligent manufacturing insofar as the claim was not premised on the theory that Medtronic had violated federal law. The court also concluded that the MDA pre-empted Donna Riegels' claim for loss of consortium to the extent it was derivative of the pre-empted claims. [21]

The United States Court of Appeals for the Second Circuit affirmed the trial court's dismissals,[22] holding that the MDA's pre-emption clause bars common-law claims challenging the safety or effectiveness of a medical device marketed in a form that received premarket approval from the FDA. The court ruled that Riegels' claims were pre-empted because they "would, if successful, impose state requirements that differed from, or added to" the device-specific federal requirements. [23]

On February 20, 2008, the U.S. Supreme Court affirmed the Second Circuit's ruling. Justice Scalia, wrote the opinion on behalf of the majority and was joined in full by six other justices. Justice Stevens joined the majority opinion except with respect to two parts, and also filed an opinion concurring in part and concurring in the judgment. Justice Ginsburg filed a dissenting opinion. Scalia points to the fact that the FDA requires a device that

has received premarket approval be marketed without significant deviations from the specifications in the device's approval application, for the reason that the FDA has determined that those specifications provide a reasonable assurance of safety and effectiveness. Pp. 8–10. Scalia and the majority appear to believe that consumers have on-going federal protection under the MDA derived from the fact that following premarket approval, the FDA is required to maintain continuing oversight of medical devices, including recall authority:

> "After premarket approval, the devices are subject to reporting requirements. [MDA]§360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR §814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, §803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. §360e(e)(1); see also§360h(e) (recall authority)."

The majority, in Reigel, held that the Petitioner's common-law claims are pre-empted because they are based upon New York "requirement[s]" with respect to Medtronic's catheter that are "different from, or in addition to" the federal ones, and that relate to safety and effectiveness, §360k(a). Pp. 10–17. They rejected the petitioner's contention that the duties underlying her state-law tort claims are not pre-empted because general common-law duties are not requirements maintained "with respect to devices." Scalia cites *Medtronic, Inc.* v. *Lohr*[24], as a case which must be distinguished from the Reigel case.

In Lohr, Scaliia says the Court interpreted the MDA's pre-emption provision in a manner "substantially informed" by an FDA regulation[25]which says that state requirements are pre-empted only when the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device" under federal law. FN What follows, in Scalia's opinion, is a somewhat tortured explanation of the majority's interpretation of the Lohr precedent. Scalia and the majority argue that the MDA's mandated FDA premarket approval of medical devices provide the "requirements" missing in the Lohr case and therefore justify broad federal preemption in Reigel.

> *"Premarket approval, in contrast, imposes "requirements" under the MDA as we interpreted it in Lohr. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it is federal safety review. Thus, the attributes that Lohr found lacking in §510(k) review are present here."*

Further, the majority argues that issues of safety and effectiveness are the driving forces behind the Riegels' common-law claims thereby conflicting with the MDA's purpose to impose federal regulation of the safety and effectiveness of Class III medical devices. So the court considers whether New York's tort duties constitute "requirements" under the MDA. Scalia's offers this interpretation and cites two other cases involving express statutory preemption in support:

> In *Lohr,* five Justices concluded that common-law causes of action for negligence and strict liability do impose "requirement[s]" and would be pre-empted by federal requirements specific to a medical device. See 518 U. S., at 512 (opinion of O'Connor, J., joined by Rehnquist, C. J., and SCALIA and THOMAS, JJ.); *id.,* at 503–505 (opinion of BREYER, J.). We adhere to that view. In interpreting two other statutes we have likewise held that a provision pre-empting state "requirements" pre-empted common-law duties. *Bates* v. *Dow Agrosciences LLC*, 544 U. S. 431 (2005) , found common-law actions to be pre-empted by a provision of the Federal Insecticide, Fungicide, and Rodenticide Act that said certain States " 'shall not impose or continue in effect *any requirements* for labeling or packaging in addition to or different from those required under this subchapter.' " *Id.,* at 443(discussing 7 U. S. C. §136v(b); emphasis added). *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504(1992) , held common-law actions pre-empted by a provision of the Public Health Cigarette Smoking Act of 1969, 15 U. S. C. §1334(b), which said that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to

the advertising or promotion of any cigarettes" whose packages were labeled in accordance with federal law.[26]

The Reigel dissent: Justice Ginzburg's dissent directly challenges the notion that MDA preemption language and mandated premarket approval should result in a judicial finding of exclusive federal regulation of medical devices, abolishing state common law claims by injured consumers. Ginzburg cites statements of the former chief counsel to the FDA in support of her view that under the MDA, medical devices should be subject to shared state and federal regulation:

"The former chief counsel to the FDA explained:

> *FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection … .*[27]

In her dissent, Justice Ginsburg challenges the majority's interpretation of Lohr and argues the court should narrow the pre-emptive scope of the term "requirement". Ginzburg argues, it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for consumers injured by FDA-approved devices. Rather, Ginzburg asserts the court should adopt a far more conservative position in applying preemption doctrine, which would maximize the preservation of state common law and honor Congressional intent at the time of passage of the MDA.

Ginzburg argues in favor of the "conservation of law position" that, "whenever possible, courts should seek to preserve the duality of state and federal regulation." She points to the centrality of Congressional intent when interpreting preemption language. Ginzburg also cites the traditional primacy of state regulation in matters of health and safety as a further reason for the court to exercise restraint and discretion in using preemption as grounds to nullify state law. Justice Ginzburg holds up the fundamental principle (most recently articulated in Bates (2005) FN) that "where the text of a preemption clause is open to more than one plausible reading, courts should ordinarily accept the reading that disfavors pre-emption." In her analysis, Ginzburg offers a very different interpretation of Medtronic v Lohr.

> The "purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504, 516 (1992) (internal quotation marks omitted). Courts have "long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 485 (1996) .[2] Preemption analysis starts with the assumption that "the historic police powers of the States [a]re not to be superseded … unless that was the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947). "This assumption provides assurance that 'the federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones* v. *Rath Packing Co.*, 430 U. S. 519, 525 (1977)
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> The presumption against preemption is heightened "where federal law is said to bar state action in fields of traditional state regulation." *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U. S. 645, 655 (1995) . Given the traditional "primacy of state regulation of matters of health and safety," *Lohr*, 518 U. S., at 485, courts assume "that state and local regulation related to [those] matters … can normally coexist with federal regulations," *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U. S. 707, 718 (1985) .

> Federal laws containing a preemption clause do not automatically escape the presumption against preemption. See *Bates* v. *Dow Agrosciences LLC*, 544 U. S. 431, 449 (2005); *Lohr*, 518 U. S., at 485. A preemption clause tells us that Congress intended to supersede or modify state law to some extent. In the absence of legislative precision, however, courts may face the task of determining the substance and scope of Congress' displacement of state law. Where the text of a preemption clause is open to more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption." *Bates*, 544 U. S., at 449.

The majority opinion ignores the 2005 Bates case and offers minimual responses to Ginzburg's "conservation of law" view of the proper scope of judicial alteration of state law in applying the preemption doctrine. Although the majority differs with Ginzberg's analysis, Justice Scalia and the majority hold open the question of whether parallel state regulation would offer injured plaintiffs a legal cause of action against Medtronics. In the concluding paragraph of the majority opinion Scalia states:

> *"State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. §360k(a)(1). Thus, §360k 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. Lohr, 518 U. S., at 495; see also id., at 513 (O'Connor, J., concurring in part and dissenting in part). The District Court in this case recognized that parallel claims would not be pre-empted,* see App. to Pet. for Cert. 70a–71a, but it interpreted the claims here to assert that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements.[28]

Justice Ginzburg challenges the logic of the majority's broad view of MDA preemption and their disregard of Congressional intent. She notes that the MDA offers no clear remedy for consumers and argues that the majority position ignores essential legislative history and established legal precedents, including Silkwood, which favor giving effect to state law wherever it would be reasonable to do so. Ginzburg appears deeply troubled by the court's departures from past practice and the judicial "tort reform" resulting from the majority's decision.

> *The Court recognizes that "§360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." Ante, at 17. That remedy, although important, does not help consumers injured by devices that receive FDA approval but nevertheless prove unsafe. The MDA's failure to create any federal compensatory remedy for such consumers further suggests that Congress did not intend broadly to preempt state common-law suits grounded on allegations independent of FDA requirements. It is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for large numbers of consumers injured by defective medical devices. Silkwood v. Kerr-McGee Corp., 464 U. S. 238, 251 (1984).*

In support of her argument, Ginsburg traces the history of state and federal regulation of drugs and medical devices. She concludes that MDA legislative history documents the presence of pervasive state premarket regulation of medical devices prior to MDA passage. Ginzburg asserts, it is this factor, not any design to suppress tort suits, that motivated Congress' inclusion of preemption language in the MDA.

> Congress enacted the MDA after decades of regulating drugs and food and color additives under the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U. S. C. §301 *et seq*. The FDCA contains no preemption clause, and thus the Court's interpretation of §360k(a) has no bearing on tort suits involving drugs and additives. But §360k(a)'s confinement to medical devices hardly renders irrelevant to the proper construction of the MDA's preemption provision the long

> history of federal and state controls over drugs and additives in the interest of public health and welfare. Congress' experience regulating drugs and additives informed, and in part provided the model for, its regulation of medical devices. I therefore turn to an examination of that experience.
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> Starting in 1938, the FDCA required that new drugs undergo preclearance by the FDA before they could be marketed. See §505, 52 Stat. 1052. Nothing in the FDCA's text or legislative history suggested that FDA preclearance would immunize drug manufacturers from common-law tort suits.[10]

Ginzburg points to the context in which the MDA became law; the fact that in the early 1970's a series of high-profile medical device failures caused extensive injuries and loss of life. The Dalkon Shield was one such failure which raised public concern and influenced Congressional adoption of the MDA.[5] [FN By early 1976, injuries and deaths caused by the Dalkon Shield had spawned more than 500 lawsuits seeking compensatory and punitive damages totaling more than $400 million.] Ginzburg argues that Congress' intention in passing the MDA was to protect consumers from malfunctioning medical devices by imposing more comprehensive federal regulation of the industry, including premarket approval, as a substitute for the crazy quilt of state regulation. Based upon her review of the legislative history, Ginzburg concludes that the record of MDA passage contains no evidence of a legislative design to preempt state common-law tort actions brought by parties who may be injured by medical devices.[7]

In seeking to evaluate the broader pattern of federal preemption of state regulation of medical products, Ginzburg looks beyond the MDA and concludes there is no pattern or tradition of federal preemption clauses in earlier federal laws regulating drugs and additives. Ginzburg concludes that, unlike medical devices, States had not installed comparable regulatory control regimes for the sale of drugs or additives.

> By the time Congress enacted the MDA in 1976, state common-law claims for drug labeling and design defects had continued unabated despite nearly four decades of FDA regulation.[11] Congress' inclusion of a preemption clause in the MDA was not motivated by concern that similar state tort actions could be mounted regarding medical devices.[12] Rather, Congress included §360k(a) and (b) to empower the FDA to exercise control over state premarket approval systems installed at a time when there was no preclearance at the federal level. See *supra*, at 3, and n. 3; *infra*, at 10–11, and n. 14.
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> Between 1938 and 1976, Congress enacted a series of premarket approval requirements, first for drugs, then for additives. Premarket control, as already noted, commenced with drugs in 1938. In 1958, Congress required premarket approval for food additives [Food Additives Amendment, §3, 72 Stat. 1785, as amended, 21 U. S. C. §348]. In 1960, it required premarket approval for color additives [Color Additive Amendments, §103(b), 74 Stat. 399, as amended, 21 U. S. C. §379e]. In 1962, it expanded the premarket approval process for new drugs to include review for effectiveness [Drug Amendments, §101, 76 Stat. 781, as amended, 21 U. S. C. §321 *et seq]*. And in 1968, it required premarket approval for new animal drugs [Animal Drug Amendments, §101(b), 82 Stat. 343, as amended, 21 U. S. C. §360b]. None of these Acts contained a preemption clause.
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> The measures just listed, like the MDA, were all enacted with common-law personal injury litigation over defective products a prominent part of the legal landscape. At the time of each enactment, no state regulations required premarket approval of the drugs or additives in question, so no preemption clause was needed as

> a check against potentially conflicting state regulatory regimes. See Brief for Sen. Edward M. Kennedy et al. as *Amici Curiae* 10.

Ginzburg notes that, when Congress wrote and passed the MDA, a very different situation existed, as to medical devices. She chronicles the facts that in the years pre-dating the MDA, several states had developed a comprehensive rubric of rules which required state regulators' premarket approval of medical devices. Ginzburg argues, it was this reality, and the potential conflict between state and federal premarket approval processes, not the prospect of conflicting state common law tort claims, that was the intended focus of the preemption language adopted by Congress in passage of the MDA and its amendments.

Ginzburg believes the court is obligated to honor Congressional intent (as discerned through study of legislative history). As a consequence, State laws establishing pre-market approval processes for medical devices should be the only state laws preempted by express MDA preemption language. Ginzburg looks to legislative history of the MDA to document Congressional intent:

As the House Report [on the MDA] observed:

> "In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the *requirement* that intrauterine devices are subject to premarket clearance in California." H. R. Rep. No. 94–853, p. 45 (emphasis added).[14]

In summary, state premarket regulation of medical devices, not any design to suppress tort suits, accounted for Congress' inclusion of a preemption clause in the MDA. No such clause figures in earlier federal laws regulating drugs and additives because States had not installed comparable control regimes in those areas.

Ginzburg argues in favor of a "conservation of law" approach, to uphold concurrent regulation of medical devices wherever direct conflict of laws is absent. She cites MDA statutory language in Section 360h(d) as further evidence of Congressional intent. Section 360h(d) states that "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law." This language clearly articulates a Congressional expectation that medical device manufacturers will face liability under state and other federal laws outside the MDA, and the statute expressly directs that the MDA is not to be construed to restrict or relieve manufacturers from those "other" liabilities.

> The MDA does grant the FDA authority to order certain remedial action if, *inter alia*, it concludes that a device "presents an unreasonable risk of substantial harm to the public health" and that notice of the defect "would not by itself be sufficient to eliminate the unreasonable risk." 21 U. S. C. §360h(b)(1)(A). Thus the FDA may order the manufacturer to repair the device, replace it, refund the purchase price, cease distribution, or recall the device. §360h(b)(2), (e). The prospect of ameliorative action by the FDA, however, lends no support to the conclusion that Congress intended largely to preempt state common-law suits. Quite the opposite: Section 360h(d) states that "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law." That provision anticipates "[court-awarded] damages for economic loss" from which the value of any FDA-ordered remedy would be subtracted. Ibid.[9]

Justice Scalia, writing for the majority, references the contradictory statutory language of Section 360h(d) in a cursory and dismissive fashion in Note 4, at the end of the majority opinion, saying,

> The Court regards §360h(d) as unenlightening because it "could not possibly mean that all state-law claims are not pre-empted" and "provides no guidance as to which state-law claims are pre-empted and which are not." Ante, at 12, n. 4.

Ginzburg responds in Note 8 of the dissent, saying, "Given the presumption against preemption operative even in construing a preemption clause, see supra, at [Notes] 2–3, the perceived lack of "guidance" should cut against Medtronic, not in its favor. Scalia has made clear that he places little weight on arguments that the court should give legal form to clear expressions of Congressional intent. Justices Roberts, Kennedy, Souter, Thomas, Breyer and Alito joined Scalia in the majority opinion. Justice Stevens filed a concurring opinion.

Justice Ginsburg dissented from what she viewed as a "constriction of state authority" that Congress never intended. Discussing at length the history of the Medical Device Amendments (MDA) and their purpose to "protect consumer safety," she found both the failure of the MDA to establish a federal compensatory remedy and the lack of a similar preemption provision in federal pharmaceutical regulation to indicate that Congress did not intend to bar state tort claims for medical devices. Finally, Justice Ginsburg pointed out that failing to find preemption here would not render the FDA PMA process irrelevant - it would still be relevant to the question of possible conflict preemption as well as other affirmative defenses.

Legislative Initiatives to Nullify *Reigel*. The *Riegel* majority effectively prohibited lawsuits against the manufacturers of medical devices. However, the tension of views in *Reigel* has been reflected in legislative action. U.S. Reps. Frank Pallone, D-N.J., and Henry Waxman, D-Calif. disagree with the Supreme Court's interpretation in Riegel, and want to clarify the law in broader terms. They introduced the "Medical Device Safety Act" in 2008 and 2009. The Act states that existing federal law governing medical device approvals does not "modify or otherwise affect" lawsuits brought in state courts. The bill would apply to any civil action pending or filed on or after the date of enactment. The language of the proposed Acts calls for it to be effective as if it were included in the Medical Device Amendments of 1976 and applicable to any civil action pending or filed on or after the date of enactment of the Act. Both years the Acts were sidelined in the legislative process. It is unclear if a 2010 Act will be proposed and whether it would receive any different treatment. For the present, the *Reigel* decision governing preemption in claims against medical device manufacturers remains good law.

Wyeth v. Levine case.[29] In March, 2009, approximately one year after the *Reigel* case, the United States Supreme Court decided the case of *Wyeth v. Levine*. Whereas the *Riege*l case involved an FDA approved medical device, the Levine case involved an FDA approved pharmaceutical. Virtually every product liability case involving a pharmaceutical depended upon what happened in this case. The majority ruled that Food and Drug Administration approval of a drug and the drug company's labeling of it do not protect the pharmaceutical company from product liability suits based upon state law. The specific issues addressed by the court in *Wyeth v. Levine* were: (1) When FDA regulations forbid a pharmaceutical company from changing its label without FDA approval, does that make it impossible for the company to comply with state common law and statutory duties as well as federal labeling regulations? And (2) Does allowing a lay jury to rule on drug labeling issues in a product liability suit by requiring stronger warnings on the label present a direct conflict between state and federal law that becomes an obstacle to the accomplishment of Congress's objectives?

In the *Levine* case, the plaintiff developed gangrene, resulting in amputation, when a physician's assistant injected her artery with the antinausea drug Phenergan by using the "IV-push" method of injection. She sued Wyeth, the manufacturer of Phenergan, for failing to provide an adequate warning about the different risks involved with the various methods of administering the drug. A jury concluded that Wyeth had failed to provide an adequate warning about these risks arguing that the plaintiff's state law failure-to-warn claims were pre-empted because it was impossible for the manufacturer to comply with both state law duties and federal labeling obligations. Wyeth also argued that the state law suits would undermine Congress's intent to trust labeling decisions to the expertise of the FDA. The Supreme Court held that there was no preemption in either instance and held that state law claims are an

important complement to the FDA's Herculean task of regulating the safety and effectiveness of all prescription drugs. In addition, in Levine, the Supreme Court held that there could be preemption if the manufacturer met the stringent standard of proving that there was clear evidence the FDA would have rejected the proposed change in the drug's label. Clearly, the evidence presented in Levine did not meet this exacting standard.[2]

Diane Levine, the plaintiff in the case, was a guitarist who went to the hospital for treatment of a migraine headache and ended up losing her right hand and forearm when she developed gangrene following the administration of the antinausea drug Phenergan by means of an "IV push." Administration of the drug by this method caused an immediate and irreversible gangrene when the drug came into contact with arterial blood. The FDA-approved label for the drug did not forbid intravenous injection, but instead cautioned that "extreme care should be exercised" in administering the drug intravenously and that "resultant gangrene requiring amputation" was "likely" if the drug hit an artery. In addition to her pain and suffering, Levine incurred substantial medical expenses and the loss of her livelihood as a professional musician.

Following the incident she brought claims under state law against the health center and the clinician, which she eventually settled. After settlement of these claims, she brought suit against Wyeth, relying on common-law and strict liability theories.[30] Although Phenergan's label warned of the danger of gangrene and amputation following intra-arterial injection, Levin argued the labeling was defective under state law, because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. She argued that the drug was not reasonably safe for intravenous administration because the foreseeable risk of gangrene and the loss of a limb are great in relation to the drug's therapeutic benefit. Wyeth filed a motion for summary judgment, arguing that Levine's failure-to-warn claims were pre-empted by federal law[31].

Following a 5-day trial, the jury found that Wyeth was negligent, that Phenergan was a defective product as a result of inadequate warning and instructions. After the verdict, the trial court filed a comprehensive opinion denying Wyeth's motion for judgment as a matter of law. The court also found that state tort liability in this case would not obstruct the FDA's work because the agency had paid no more than passing attention to the question of whether to warn against IV-push administration of Phenergan. The trial court also noted that state law serves a compensatory function distinct from federal regulation. (*Id.*, at 249-252). The Vermont Supreme Court found no evidence that Wyeth had "earnestly attempted" to strengthen the intra-arterial injection warning or that the FDA had "specifically disallowed" stronger language. (*Id.* at 23). It held that the jury's verdict "did not conflict with FDA's labeling requirement ."

In its appeal to the United States Supreme Court, Wyeth made two separate preemption arguments. The first was that it would be impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law. The second was that the recognition of Levine's state tort action created an unacceptable "obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Justice John Paul Stevens, writing on behalf of a 6-3 majority, rejected both of Wyeth's pre-emption arguments. Justice Stevens found that Wyeth was wrong in its first argument that relabeling the drug to conform to Vermont law would necessarily violate federal labeling regulations. In his analysis of federal labeling law, he concludes that although a manufacturer in general needs to receive FDA approval before changing a drug label, the agency's regulation permits unilateral labeling changes that improve drug safety. Stevens' interpretation of the Food, Drug and Cosmetic Act and of the FDA's regulations pursuant to it is that the manufacturer bears primary responsibility for drug labeling. He contends that it is a central premise of the FDCA that the manufacturer bear responsibility for the content of its label at all times. [32]

On Wyeth's second argument, Stevens found that Wyeth was incorrect in stating that permitting states to require stronger label warnings would interfere with Congress' purpose of entrusting the FDA with drug labeling decisions. Stevens found that it was not Congress's intent in writing the Food, Drug, and Cosmetic Act, to preempt state law failure to warn product liability actions. Wyeth maintained that Levine's tort claims were preempted because they interfered with Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives. The majority found no merit in this argument saying it relied "on an untenable interpretation of congressional intent and an overbroad view of an agency's power to preempt state law." (*Id*. at 1199).

> Wyeth contends that the FDCA establishes both a floor and a ceiling for drug regulation: Once the F DA has approved the drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue. The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary. . . .Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1939 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law re3medies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings. [33]

Stevens then goes on to suggest that "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision. (*Id*. at 1200). The court majority thus accepted the argument that preemption of state-law tort claims based on FDA regulation of a drug is unwarranted because the civil justice system complements the FDA's regulation of drugs. It does so by setting up a system to compensate people who are injured, something that FDA regulation of drugs was never intended to do. It does so by spreading the losses and deterring future injuries. The jurisprudential justification for imposing strict liability is that placing liability on those parties in the distribution chain places the risk on those who are best able to both bear the cost and at the same time protect the consumer from defective products. The manufacturer of a product is in the best position to make a cost-benefit analysis between accident costs and accident avoidance costs and to act on that analysis once it is made.

There were two concurrences to the opinion written by Justice Stevens. One written by Justice Breyer specifically noted that the FDA may create regulations that preempt state law tort claims. A second concurrence by Justice Thomas stated that he could not "join the majority's implicit endorsement of the far-reaching implied pre-emption doctrines." [34]. He stated that he was "increasingly skeptical of the Court's 'purposes and objectives' pre-emption jurisprudence' . . . under which the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law." [35] He expresses his belief that implied preemption doctrines not linked to specific statutory text are inconsistent with the Constitution. He is not inclined to expland federal statutes beyond their terms through doctrines of implied pre-emption.

Justices Samuel Alito wrote a dissent that was joined by Chief Justice John Roberts and Justice Antonin Scalia. The three of them disagreed with the Court's holding that a state jury ruling on tort law may countermand the FDA-mandated warning label for an FDA approved drug. In this sense, the minority opinion sees the issue, not as a narrow one, but as a broad one.

Recent 8th Circuit Duty to Warn decisions: *Scroggin v. Wyeth: In re Prempro Products Liability Litigation*,[36]: Although the United States Supreme Court found no preemption in *Wyeth v. Levine*, it left the door open for such a finding in subsequent cases if the facts so warrant. Subsequent cases have begun to arise and to be heard by the various Courts of Appeal. The Scroggin case was submitted to the Eighth Circuit Court of Appeals just two months after the decision in Wyeth v. Levine and was decided about nine months after Levine. The case is also known as In Re Prempro Products Liability Litigation, in part because of the large number of Amici briefs filed on behalf of the plaintiff/appellant in the case. A total of nineteen states, including all of the states in the Eighth Circuit, were among the parties filing friend of the court briefs opposing preemption. In the case, the court found no preemption of the plaintiffs warning claims in a case involving hormone therapy. There was no evidence that defendants could not change their warnings in the fashion demanded by plaintiffs. In rejecting preemption in less than half a page, the Eighth Circuit said, "The Supreme Court's recent decision in [*Levine*] has foreclosed this preemption argument."

Donna Scroggin took estrogen and progestin drugs manufactured by defendants for eleven years, and then was diagnosed with breast cancer. She sued Wyeth and Pharmacia & Upjohn Co. (a division of Wyeth) in 2004 for failure to warn of the risk of breast cancer from combination hormone therapy. The trial was bifurcated, with liability determined first and punitive damages determined second. A jury returned a verdict finding Wyeth and Upjohn liable and awarding Scroggin compensatory damages. In the second phase of the trial, the jury awarded Scroggin punitive damages. Wyeth and Upjohn then appealed from the entry of judgment against them on liability. Scroggin appealed from an order of the district court striking her expert evidence and vacating the jury's punitive damages award.

On appeal Wyeth and Upjohn argued that Scroggin's state law claim for failure to warn was preempted by federal law, and that there could be no heightened duty under state law. They further argued that they could not comply with state law without violating FDA requirements. The Eighth Circuit three judge panel gave short shrift to these arguments by citing the Supreme Court's decision in Levine, particularly the finding that federal regulations do not prohibit drug manufacturer's from strengthening their warnings prior to FDEA approval to reflect new developments and to comply with state laws. [37]The judges then said that as in Levine, there was no evidence that the FDA would not have permitted the strengthening of the labels of the drugs in question in a manner consistent with state law. [38] Nothing in the information submitted by Wyeth and Upjohn proved that any state requirements obstructed the purposes of federal drug regulation. The judges further stated that "Congress is aware of the potential for conflict and has enacted an express preemption provision for medical devices, but there is no such enactment for prescription drugs. It then declined to imply any such preemption. [39]

Mensing v. Wyeth, Inc., [40] In the *Mensing* case, the Minnesota plaintiff was a patient who had used the prescription drug metoclopramide from 2001 – 2005 under her doctor's prescription in treatment of a gastrointestinal disorder called diabetic gastroparesis. Wyeth, the brand name manufacturer, sells the drug under the name Raglan. Plaintiff's pharmacist filled her prescription with the generic drug MCP. Both Actavis and Pliva manufacture MCP, a generic bioequivalent of Raglan. The FDA approved Reglan in 1980. Manufacturers began seeking approval for generic versions of metoclopramide five years later. The generic metoclopramide labels have always been in relevant part the same as the Reglan label. The label warnings about tardive dyskinesia, and other similar but less severe extrapyramidal symptoms, did not change from 1985 through the time Mensing discontinued use of the drug in March, 2005.

By March, 2005, the plaintiff had developed a severe neurological movement disorder called tardive dyskinesia and discontinued use of the drug. She sued in state court claiming tort liability of the brand name and generic manufacturers' of the drug, claiming failure to adequately warn of the link between long term ingestion of the active ingredient in the drug and movement disorders. Mensing argued that despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than indicated on the label, no metoclopramide manufacturer took steps to change the label warnings. According to her allegations, metoclopramide manufacturers in fact promoted the drug for long term use.

The federal preemption defense was asserted by the defendants on grounds that drug labeling is exclusively regulated by the FDA. Based upon FDA regulations which prohibit a generic drug manufacturer from unilaterally strengthening drug label warnings without prior FDA approval, the trial court dismissed the plaintiff's claims against the generic manufacturers of the drug. The court ruled that under the federal statutory schemes, the labeling for generic drugs must always remain the same as that of the brand name drug. Further, the Court ruled that generic manufacturers have no independent duty to send "Dear Doctor" letters based upon the provisions of the Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act of 1984 (21 USC Sec. 355(j). The primary purpose of this act was to increase the availability of low-cost generic drugs by establishing a generic drug approval procedures labeling and which requires 1) a showing that the generic drug has the same active ingredients and is the "bioequivalent" of the listed drug (21 USC Sec. 355(j)(2)(A) and the applicant must submit a side by side comparison of the drug's proposed labeling [which in most cases must be the same as the labeling approved for the listed brand name drug]. 21 USC Sec. 314,94(a)(8)(iv).

The court held that any duty by generic manufacturers to issue label warnings different than those on the brand name drug they emulate would interfere with the purpose and objectives of the Hatch-Waxman Act. The Trial court dismissed the plaintiff's claims against the brand name drug Raglan on the basis that the plaintiff had not taken this product. The plaintiff appealed to the 8th Circuit. The 8th Circuit affirmed dismissal of the brand name manufacturer on the grounds that state law does not permit suit against a party whose product has not been used. However, the Court reversed the trial court's dismissal of the generic manufacturer's on grounds of preemption.

> In considering a preemption defense we must be attuned to Congressional intent and the presumption against preemption. *Wyeth v. Levine*, ___ U.S. ___, 129 S.Ct. 1187, 1194-95, 173 L.Ed.2d 51 (2009) (quotation omitted) (courts must assume "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."). In *Wyeth*, the Supreme Court ruled that failure to warn claims against name brand manufacturers are not preempted by the FDCA. The Court noted the historic coexistence of state tort remedies and federal regulation of prescription drugs:
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> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices,. . . Congress has not enacted such a provision for prescription drugs. . . . Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.
>
> The Hatch-Waxman Amendments are part of this 70 year history and they do not explicitly preempt suits against generic manufacturers. Congress could have crafted a preemption provision for generic drugs in its 1984 amendments, having done so for medical devices less than 10 years earlier. It chose not to do that. Seven in ten prescriptions filled in this country are now for generic drugs [Susan Okie, Multinational Medicines-Ensuring Drug Quality in an Era of Global Manufacturing, 361 New Eng. J. Med. 737, 738 (2009)].

The court reasoned that evidence in the case supported claims that 1) generic manufacturers did not fulfill their duties to the FDA to notify them of findings suggesting greater dangers from long term drug use and 2) that state common law could impose a duty to provide a stronger warning on drug labels than required by federal law.

> . In this case we need not decide whether generic manufacturers may unilaterally enhance a label warning through the CBE procedure [4] because the generic defendants could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved.
>
> The regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug. Generic manufacturers are subject to the requirement that their labeling 609*609 "shall be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug[.]" 21 C.F.R. § 201.57(e). The generic defendants argue that they comply with this statute by simply ensuring that their labels match the name brand label. Mensing alleges that the Reglan manufacturers did nothing to strengthen the label despite reasonable evidence of the drug's association with a serious hazard. In these circumstances, § 201.57(e) does not permit generic manufacturers passively to accept the inadequacy of their drug's label as they market and profit from it. *See Wyeth*, 129 S.Ct. at 1202 ("The FDA has limited resources to monitor the 11,000 drugs on the market[.] . . . [Manufacturers, not the FDA, bear primary responsibility for their drug labeling[.]"). The statute itself empowers the FDA to withdraw approval for a drug that is "misbranded" due to an insufficient label. 21 U.S.C. §§ 331(a)-(b), 352(a).

The court takes stock of the fact that generic manufacturers, like brand name manufacturers, are obligated to maintain detailed record keeping of patient outcomes and are obligated to share significant information with the FDA.

> 21 C.F.R. § 314.98 requires that generic manufacturers follow the same record keeping and reporting of adverse drug experiences post marketing that name brand manufacturers must undertake. In discussing this provision, the FDA noted that "ANDA applicants [must] submit a periodic report of adverse drug experiences even if the ANDA applicant has not received any adverse drug experience reports *or initiated any labeling changes.*" 57 Fed. Rep. 17950, 17965 cmt 53 (Apr. 28, 1992) . . .

> Implicit in these comments is the FDA's expectation that generic manufacturers will initiate label changes other than those made to mirror changes to the name brand label and that the agency will attempt to approve such proposals quickly.

This characterization creates the expectation that generic manufacturers are a co-equal partner in the patient outcomes reporting and drug-labeling process following FDA approval to sell, not a secondary and dependent player.

> In addition to proposing a label change, the generic manufacturers could have suggested that the FDA send out a warning letter to health care professionals. When the FDA first adopted its labeling regulations, well before the Hatch-Waxman Amendments, it stated that the requirements "do not prohibit a manufacturer . . . from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered." 44 Fed.Reg. 37434, 37447 (June 26, 1979); *see also* CDER, Manual of Policies and Procedures (MAPP) 6020.10, NDAs: "Dear Health Care Professional" Letters (July 2, 2003) (guidance document to name brand manufacturers stating that the letters may be ordered by the FDA or sent by manufacturers without FDA involvement).

In summary, the 8th Circuit ruled that the common law could impose a duty upon generic drug manufacturers to alert the FDA and to seek a stronger warning for both generic and brand name labeling or to have the agency issue a "Dear Doctor" letter, in light of evolving knowledge. Nothing in Hatch-Waxman evinces a congressional intent to preempt state law.

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If Mensing's injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable.

It is noteworthy that on February 26, 2009, the FDA, acting on its own initiative, pursuant to the Food and Drug Administration Amendments Act of 2007, Pub.L. No. 110-85, 121 Stat. 823 (FDAAA), ordered manufacturers of Reglan and generic metoclopramide to add a boxed warning to their labels about the increased risks of tardive dyskinesia from long term metoclopramide usage.

Conclusion: In recent years the medical device and pharmaceutical industries have been vigorously asserting the defense of federal preemption of state product liability law. As the law of preemption now stands a medical device manufacturer who has received FDA approval of its product is generally no longer susceptible to product liability claims under state products liability law. On the other hand, a pharmaceutical manufacturer who has received FDA approval of its product may in most cases be sued under state product liability law. The medical device and pharmaceutical industries have had some success in arguing that state common law is no different from state statutory law when the doctrine of preemption is applied to both express preemption brought about by a specific statutory provision in federal statute and implied preemption based on an actual conflict between state and federal law, even when the state law involved is the state common law of torts. Although the state common law of torts has historically not been susceptible to preemption by federal regulatory law, because it is judicially administered on a case by case basis, the current United States Supreme Court approach is to consider all forms of state law subject to preemption.

In *Riegel* a divided U.S. Supreme Court found that the language of the FDA statute expressly preempted state common law tort claims. When the same argument was made with regard to pharmaceuticals in the *Levine* case, an equally divided U.S. Supreme Court found there was no express preemption. However, this decision left open the possibility of implied preemption particularly when state Supreme Court decisions impose common law notice and labeling restrictions that may conflict with federal labeling requirements. In such cases state tort duties may be seen by federal courts as interrupting or interfering with the federal regulatory scheme. In its decisions so far, the Eighth Circuit Court of Appeals has held that when label changes require FDA approval, preemption is more

difficult to prove. This viewpoint holds that if Congress had intended to deprive plaintiffs of common law claims involving matters of health and safety, it would have expressed this intent more clearly.

Much remains unclear with regard to preemption claims involving medical devices and pharmaceuticals, and many are concerned about too cozy a relationship between FDA regulators and the medical industry. The fact remains that great harm could result to consumers from the curtailment of private state based product liability lawsuits. The area presents a direct conflict between (1) the right of states to use their governmental police powers to regulate statutorily and through common law to protect the health and safety of their citizens, and (2) the right of the federal government to regulate interstate commerce. Congress is considering legislation that would preserve individual product liability claims based on state law. The proposals under consideration would reverse the *Riegel* ruling, which was based upon express preemption. However, they would have no effect on implied preemption claims raised by defendants as a result of the FDA regulatory scheme.

Footnotes

[1] Professor of Business Law, Minnesota State University, Mankato.
[2] Professor of Business Law, Minnesota State University, Mankato.
[3] *Riegel v. Medtronic*, 552 U.S. _____.
[4] U.S. Const. Art VI, cl 2.
[5] See *English v. Gen. Elec. Co.*, 496 U.S. 72, 79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990).
[6] 21 U.S.C. § 355(a)-(b).
[7] *Id.* at §§ 355(b), (d).
[8] 21 C.F.R. § 201.56.
[9] 21 U.S.C. § 355(j).
[10]. 21 C.F.R. § 314.94(a) (8).
[11] 21 C.F.R. § 201.57(e) (redesignated as 21 C.F.R. § 201.80(e) in 2006, after the conduct at issue here).
[12] 21 U.S.C. §§ 331(a)-(b).
[13] *Id.* at § 352(a).
[14] *See, e.g., id.* at § 333, 355(e).
[15] 21 C.F.R. § 314.70(b).
[16] 21 *C.F.R. § 314.70(c)(6)(iii)(A)-(D).*
[17] *Cipollone v. Liggett Group, Inc*., 505 U.S. 504 (1992).
[18] *Wyeth v. Levine*, 555 U.S. _____ (2009), 129 S. Ct. 1187, 173 L.Ed. 2d 51.
[19] 21 U. S. C. §360k.
[20] *21 U. S. C. §360 k(a)*.
[21] *Id.*, at 68a; see also *id.*, at 75a.
[22] 451 F. 3d 104 (2006).
[23] *Id.*, at 121.
[24] 518 U. S. 470518 U. S. 470.
[25] 21 CFR §808.1(d).
[26] See 505 U. S., at 523.
[27] Porter, The Lohr Decision: FDA Perspective and Position, *52 Food & Drug L. J.* 7, 11 (1997).
[28] See *id.*, at 68a.
[29] 555 U.S.____(2009), 129 S.Ct. 1187, 173 L.Ed 2d 51.
[30] 183 Vt. 76, 944 A.2d 179 (2006).
[31] *Id.* at 21.
[32] 129 S. Ct.1187 at 1194 to 1196.
[33]*Id.* at 1199-1200.
[34] *Id.* at 1204.
[35] *Id.* at 1205.
[36] 586 F.3d 547 (8th Cir. Nov. 2, 2009).
[37] *Id.* at 563.

[38] *Id.*
[39] *Id.*
[40] 588 F.3d 603 (8th Cir. Nov. 27, 2009).