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FDA PREEMPTION AFTER THE FOOD AND DRUG AMENDMENTS ACT OF 2007

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ABSTRACT

Opposing the explosive rise in tort litigation in the last two decades has been a corresponding rise in federal preemption claims. In the FDA context, the controversy has largely surrounded the issue of whether federal law preempts state common-law “failure-to-warn” claims against drug and medical-device manufacturers. During the current Bush Administration, FDA changed its position regarding preemption of state tort law claims and for the first time asserted that that compliance with FDA-mandated labeling provisions preempts common law failure-to-warn claims. The changed position attracted considerable attention in the academic and legal community, and the preemption debate has consequently become one of fiercest battles in products liability litigation today. Indeed, the Supreme Court is scheduled to hear a case next Term addressing preemption of products liability claims against drug manufacturers.

Any decision addressing preemption of drug-based products liability claims will have to consider the impact of the recent Food and Drug Amendments Administration Amendments Act of 2007 (“FDAAA”). This Act significantly expands FDA’s enforcement and surveillance powers, provides a framework for post-market risk identification, and expands the requirements for clinical trials registration and disclosure of results, among other provisions. This Paper therefore examines the impact of the FDAAA on FDA’s preemption claims and concludes that by strengthening FDA’s powers, the FDAAA may also have strengthened FDA’s claim for preemption. By increasing the FDA’s ability to effectively regulate drug efficacy and safety, the FDAAA put the agency on stronger ground when claiming ultimate authority over drug labeling.

I. INTRODUCTION

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

— U.S. CONSTITUTION article VI, clause 2

Ever since the founding of the Food and Drug Administration (“FDA”), public health crises have played a prominent role in defining the scope of FDA’s drug regulation authority.¹ In its early days, FDA had little power to ensure that drugs on the market were safe and effective; modern day drug regulation was ushered in by the sulfanilamide² crisis of the 1930s. After over one hundred people died from consuming toxic Elixir Sulfanilamide,³ Congress passed the Food Drug and Cosmetic Act of 1938⁴ (“FDCA”). For the first time, FDA was given jurisdiction to ensure that drugs were safe before they were marketed. For over two decades, FDA’s power to regulate drugs remained largely unchanged until yet another drug tragedy rocked the country. In the late 1950s and early 1960s, thousands of infants were born in Europe with terrible deformities after their mothers had taken the new sedative thalidomide. This tragedy focused

¹ See KAREN F. GREIF & JOHN F. MERZ, CURRENT CONTROVERSIES IN THE BIOLOGICAL SCIENCES 119 (2007) (arguing that a “pattern of regulation following seminal, even tragic, events and public outcries typifies the evolution of federal regulations of drugs and devices as well as the use of humans and animals in research”).

² See Paul M. Wax, *Elixers, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 ANNALS INTERNAL MED. 456, 456 (1995) (“The relationship between the government and the pharmaceutical manufacturers was profoundly changed by this event.”).

³ Thirty-four children and seventy-one adults died after receiving Elixir Sulfanilamide. Wax, *supra* note 2, at 458.

⁴ Ch. 675, 52 Stat. 1040.

public attention on pending legislation in Congress that would strengthen the FDCA.⁵ In 1962, Congress passed a set of amendments to the FDCA, which gave FDA the power to ensure drugs were both safe and effective.⁶ Among the many provisions of the Act, drug manufacturers were required to send adverse event reports to FDA, and drug advertising in medical journals was required to provide doctors with complete information about the risks and benefits of drugs.⁷

After decades without such significant drug legislation, Vioxx may well prove to be the thalidomide of the new millennium. The pain-reliever Vioxx was widely marketed in the United States to treat acute pain, dysmenorrhea, and osteoarthritis.⁸ However, the product was withdrawn by its manufacturer, Merck, in September 2004 after a new study found a higher rate of heart attacks and strokes in patients taking the drug than in those taking a placebo.⁹ The withdrawal shocked the public in light of the fact that Vioxx had been marketed in more than 80 countries, with worldwide sales totaling \$2.5 billion in 2003, and had been sold in the United States for more than five years.¹⁰ Post-withdrawal studies revealed that Vioxx may have caused an estimated 140,000 heart-related injuries and 56,000 deaths in the United States in the five

⁵ FDA Consumer, *The Story of the Laws Behind the Labels: Part III, 1962 Drug Amendments* (June 1981), <http://www.cfsan.fda.gov/~lrd/histor1b.html>.

⁶ Kefauver-Harris Amendment, Pub L. No. 87-781, 76 Stat. 780 (1962). Under these amendments drug sponsors were required to provide “substantial evidence” of safety and efficacy as part of the New Drug Application. *See* 21 U.S.C. § 355(d).

⁷ FDA Consumer, *supra* note 5.

⁸ FDA, *Sequence of Events with Vioxx, Since Opening of IND*, http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4090B1_04_E-FDA-TAB-C.htm.

⁹ Rita Rubin, *How did the Vioxx debacle happen?*, USA TODAY, Oct. 12, 2004, *available at* http://www.usatoday.com/news/health/2004-10-12-vioxx-cover_x.htm.

¹⁰ *Id.*

years it was marketed.¹¹ The scandal was only compounded by reports that Vioxx's manufacturer, Merck, had been alerted to the possible cardiovascular risks of Vioxx as early as 2000, but had downplayed the drug's risk and dismissed outside research confirming such risks.¹² Furthermore, although FDA was notified about the possible risks of Vioxx as early as 2000, it took over fourteen months of intense negotiation between FDA and the manufacturer before new warning language to be added to the product label.¹³ The fact that the drug's serious risks had not been discovered until after marketing, combined with the considerable time it took for a warning to be added to the product label, led to a public sense that many of the Vioxx-related injuries could have been prevented and that FDA had fallen short in its tasks of ensuring drug safety.¹⁴ One author articulated the general outrage when he concluded that the information revealed in the unfolding Vioxx scandal "points to astonishing failures in Merck's internal systems of post-marketing surveillance, as well as to lethal weaknesses in the US Food and Drug

¹¹ Jonathan V. O'Steen & Van O'Steen, *The FDA Defense: Vioxx® and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 67 (2006).

¹² _ Alex Berenson et al., *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, N.Y. TIMES, Nov. 14, 2004 ("The data that first alerted Merck to the heart risks with Vioxx arrived in March 2000, derived from a study of 8,100 rheumatoid arthritis patients begun in January 1999. . . . Five times as many patients taking Vioxx had heart attacks as those taking [the pain reliever] naproxen."), available at <http://www.nytimes.com/2004/11/14/business/14merck.html?scp=1&sq=vioxx&st=cse>; Rubin, *supra* note 9 ("Merck continued to minimize unfavorable findings up to a month before withdrawing Vioxx. On Aug. 26, the company fired off a press release refuting Graham's [unfavorable] study.").

¹³ FDALegislativeWatch, FDA Bill Passes; Congress Adds \$225 Million to Industry User Fee Burden (Sept. 26, 2007), <http://www.fdalegislativewatch.com/2007/09/fda-bill-passes.html>.

¹⁴ For an excellent discussion of the regulatory failures surrounding Vioxx, see Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941, 941 (2007).

Administration's regulatory oversight.”¹⁵ Advocacy groups pressed Congress to better equip FDA to monitor drug safety, in an effort to avoid similar tragedies in the future. Congress held a set of hearings¹⁶ and issued several reports¹⁷ outlining deficiencies in FDA regulation. FDA also requested study of its regulatory system from the Institute of Medicine of the National Academy of Sciences (“IOM”). In 2006, the IOM issued a landmark report, which found the FDA drug oversight system to be inadequate and recommended a lifecycle approach to obtaining information about a drug's risks and benefits. To this end, the report suggested “increased enforcement authority and better enforcement tools directed at drug sponsors, which should include fines, injunctions, and withdrawal of drug approval.”¹⁸

In response to the Vioxx tragedy¹⁹ and the recommendations of the IOM,²⁰ in September 2007, Congress passed the Food and Drug Amendments Administration Amendments Act of

¹⁵ Richard Horton, *Vioxx, the Implosion of Merck, and Aftershocks at the FDA*, 364 LANCET 1995, 1995 (2004).

¹⁶ E.g., *The Adequacy of FDA to Assure the Safety of the Nation's Drug Supply: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007), available at <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110%5Fhouse%5Fhearings&docid=f:35502.pdf>; *FDA's Drug Approval Process: Up to the Challenge?: Hearing of the S. Comm. on Health, Education, Labor, and Pensions*, 109th Cong. (2005), available at <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109%5Fsenate%5Fhearings&docid=f:99761.pdf>.

¹⁷ See e.g., COMM. ON GOV'T REFORM—MINORITY STAFF, U.S. HOUSE OF REPS., *PRESCRIPTION FOR HARM: THE DECLINE IN FDA ENFORCEMENT ACTIVITY* (2006), available at <http://oversight.house.gov/documents/20060627101434-98349.pdf> (concluding that there has been a decline in FDA enforcement since 2000, which, in some cases, has resulted in a health risk to consumers).

¹⁸ INST. OF MED., NAT. ACAD. OF SCIENCES, *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 168-70 (2006) [hereinafter IOM REPORT].

¹⁹ See CONG. REC. H10596 (Sept 19, 2007) (statement of Rep. Pallone) (“The past several years have been marked by drug scandal after drug scandal. Vioxx, Ketek, Paxil and Avandia. These drugs have harmed families across the country and come to symbolize the urgent need for reform at the FDA.”); CONG. REC. H10598 (Sept 19, 2007) (statement of Rep. Waxman) (“This

2007²¹ (“FDAAA”). This Act is the most extensive revision of the FDCA since 1962; it significantly expands FDA’s enforcement and surveillance powers, provides a framework for post-market risk identification, and expands the requirements for clinical trials registration and disclosure of results, among other provisions.²² Experts have described the Amendments as a “mammoth” bill, and it is likely to take courts, commentators, and FDA many years to sort through it.²³ This Paper will focus on only one small aspect of the 156 page-bill: its impact on federal preemption of drug labeling claims.

Preemption doctrine has been in existence for well over a hundred years,²⁴ but it has reached prominence in the drug and device context only in the last couple decades. Opposing the explosive rise in tort litigation in the last two decades has been a corresponding rise in federal preemption—a doctrine holding that state laws that conflict with federal law are preempted.²⁵ In the FDA context, the controversy has largely surrounded the issue of whether federal law preempts state common-law “failure-to-warn” claims against drug and medical-device

legislation will provide FDA with the ability to require companies to update their drug label with new safety information. Our goal here is the address tragic situations like Vioxx.”).

²⁰ For a comparison of the IOM recommendations and the final FDCAA provisions, see Bruce M. Psaty & David Korn, *Congress Responds to the IOM Drug Safety Report—In Full*, 298 JAMA 2185 (2007).

²¹ Pub. L. No. 110-85, 121 Stat. 823 (to be codified as amended at 21 USC §§301 *et seq.*) [hereinafter FDAAA]. The bill passed the House by a vote of 405 to 7 on September 19, 2007, and the Senate by unanimous consent the following day.

²² The relevant provisions of the FDAAA will be explored in more detail *infra* Part III.

²³ See Gardiner Harris, *House Passes Bill Giving More Power to the F.D.A.*, N.Y. TIMES, Sept. 20, 2007, available at <http://www.nytimes.com/2007/09/20/washington/20fda.html> (referring to the House version of the bill).

²⁴ See *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824).

²⁵ Preemption doctrine is discussed in more detail in Part II.A, *infra*.

manufacturers.²⁶ During the current Bush Administration, FDA changed its position regarding preemption of state tort law claims and for the first time asserted that that compliance with FDA-mandated labeling provisions preempts common law failure-to-warn claims.

The preemption issue has garnered much attention lately in the academic and legal community and has been characterized as “the fiercest battle in products liability litigation today.”²⁷ Indeed, the Supreme Court has already decided two cases this term relating to preemption.²⁸ In *Warner-Lambert v. Kent*,²⁹ the Court reached a 4-4 deadlock (Chief Justice recused himself) on whether federal law preempted a Michigan law immunizing pharmaceutical companies from products liability claims except in cases of “fraud-on-the FDA.”³⁰ With respect to medical devices, however, the Supreme Court ruled 8-1 last February that some suits against device manufacturers are preempted.³¹ Arguably, this decision is the most recent in a line of

²⁶ The debates over preemption of state products liability claims against manufacturers of drugs and medical devices are closely related. However, the arguments are also distinguishable because the Medical Device Act explicitly preempts state tort actions. [[Cite]] Thus, this Paper will largely ignore preemption of medical device claims. However, the Supreme Court’s recent decision in *Medtronic* will be analyzed in Part x, *infra*, to the extent that its analysis sheds light on preemption claims against drug manufacturers.

²⁷ Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 450 (.2008).

²⁸ As a general matter, there has been a sharp increase in the number of preemption cases decided by the Supreme Court in the last two decades as compared to prior decades. JAMES T. O’REILLY, *FEDERAL PREEMPTION OF STATE AND LOCAL LAW* 2 (2006).

²⁹ 128 S. Ct. 1168 (2008) (per curiam).

³⁰ The Court issued only a one-line opinion: “The judgment is affirmed by an equally divided Court.” *Id.* at 1168.

³¹ See *Riegel v. Medtronic*, 128 S. Ct. 999 (2008). Note, however, that the preemption analysis for medical devices is distinguishable from that of prescription drugs because there is an express preemption clause in the Medical Device Amendments on 1976, which preempts state requirements that are “different from, or in addition to, any requirement applicable . . . to the device” under the Medical Device Amendments. 21 U.S.C. § 360k(a).

cases embodying “a pro-defense trend” among the Supreme Court’s preemption decisions,³² and some commentators have speculated that the Court would be inclined to rule similarly on the issue of drug-related tort claims.³³ The issue may be decided soon, as the Supreme Court will hear a case next Term addressing preemption of products liability claims against drug manufacturers.³⁴

The recent focus on this issue is hardly surprising. Preemption is extremely important for both plaintiffs and defendants. As one legal blog succinctly summarized, preemption matters for four reasons: it is potent, generic, legal, and severable.³⁵ A finding of preemption is potent in that it eliminates all of the plaintiff’s failure-to-warn claims based on alleged inadequacies in the drug’s package insert, including strict liability, negligence, warranty, and consumer protection act claims.³⁶ Because of the difficulty of proving manufacturing defect or design defect claims for drugs, such failure-to-warn claims are often the primary basis for a plaintiff’s tort suit.³⁷ Preemption is also generic—it extends beyond an individual plaintiff to preclude failure-to-warn

³² See Sharkey, *supra* note 27, at 455.

³³ See, e.g., Gardiner Harris & Alex Berenson, *Drug Makers Near Old Goal: A Legal Shield*, N.Y. TIMES, Apr. 6, 2008, available at http://www.nytimes.com/2008/04/06/washington/06patch.html?_r=1&partner=rssnyt&emc=rss&oref=slogin (“After decades of being dismissed by courts, [preemption] now appears to be on the verge of success, lawyers for plaintiffs and drug companies say.”).

³⁴ *Wyeth v. Levine*, 944 A.2d 179 (Vt. 2006), *cert. granted*, 128 S. Ct. 1118 (Jan 18, 2008) (No. 06-1249); see also *infra* notes 174-182 (discussing the *Wyeth* case in more detail).

³⁵ Drug and Device Law, *Why Does Preemption Matter?* (Apr. 15, 2007), <http://druganddevicelaw.blogspot.com/2007/04/why-does-preemption-matter.html>.

³⁶ *Id.*

³⁷ See *id.* (“In most pharma products cases, failure-to-warn is the whole ball game.”)

claims by *any* plaintiff based on a particular drug.³⁸ In some cases, a preemption holding can even extend beyond a particular drug to preempt claims against a whole class of products, such as antibiotics,³⁹ or even all drugs or medical devices.⁴⁰ Furthermore, defendants favor preemption because it is a purely legal question and may be decided on a motion to dismiss or on summary judgment, before the parties have incurred the enormous costs of discovery.⁴¹ Likewise, the factual issues underlying preemption are severable from the other issues in a case, again reducing the costs of litigation.⁴² Therefore, the preemption issue is of paramount importance for litigants. With settlement sums and jury verdicts in product liability suits sometimes running in the millions or billions of dollars,⁴³ manufacturers are advocating

³⁸ *See id.*

³⁹ *See, e.g.,* Feldman v. Lederle Labs., 516 A.2d 288 (1983) (holding that the labeling requirements for antibiotic drugs preempted a state failure to warn claim).

⁴⁰ In *Medtronic*, for example, the Supreme Court held that common law claims of “strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale” were preempted by the Medical Device Amendments of 1976. *Riegel v. Medtronic*, 128 S. Ct. 999, 1005-06 (2008). Likewise, the question in *Wyeth v. Levine* relates to whether the prescription drug labeling provisions of the FDCA broadly preempt “state law product liability claims.” Petition for a Writ of Certiorari, *Wyeth v. Levine*, No. 06-1249 (Mar. 12, 2007).

⁴¹ *See id.*

⁴² *See id.*

⁴³ *See* James Copland, *Leave It to the FDA*, WASHINGTON POST, Mar. 15, 2008, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/03/14/AR2008031402875.html> (“Merck spent upwards of \$1 billion defending against Vioxx claims before recently reaching a partial settlement agreement for more than \$5 billion, while the estimated tab for Wyeth over its recalled diet drug combination Fen-Phen is \$21 billion.”).

vigorously for preemption,⁴⁴ while plaintiffs and their lawyers⁴⁵ as advocating just as vigorously in the opposite direction.

Any decision addressing preemption of drug-based products liability claims will find it hard not to consider those claims in light of “the most comprehensive reform of prescription drug regulation in four decades”⁴⁶ — the FDAAA. The issue of preemption was very much on the mind of legislatures when the bill was passed. Congress considered various preemption-related provisions in successive versions of the bill, eventually settling on an obtuse “rule of construction” stating that the new FDA enforcement powers contained in the FDAAA shall not be construed to affect the responsibilities of a drug manufacturer to maintain its label in accordance with existing requirements.⁴⁷ Lawyers in the field have already begun speculating that plaintiffs will attempt to use the rule to undermine arguments for FDA preemption.⁴⁸

⁴⁴ Immunity from products liability would also dramatically reduce a manufacturer’s liability exposure and insurance costs. James T. O’Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 FOOD & DRUG L.J. 287, 289 (2003).

⁴⁵ See O’REILLY, *supra* note 34, at 3 (“Preemption has become a ‘dollars-and-cents’ issue for every lawyer whose livelihood depends on contingent fee portions of large jury verdicts awarded to injured persons.”).

⁴⁶ Covance, FDAAA Overview, <http://www.covance.com/fdaaa/> (last visited May 10, 2008).

⁴⁷ See Pub. L. No. 110-85, 121 Stat 823, 925-26 (to be codified at 21 U.S.C. § 355(o)(4)(I)). The rule of construction will be analyzed in greater detail in Part IV.A, *infra*.

⁴⁸ See ARNOLD & PORTER LLP, THE FDA AMENDMENTS ACT OF 2007, at 9 (2007) (arguing that the rule of construction is “undoubtedly a tool that will be used by plaintiffs seeking to undermine preemption in ‘failure to warn’ cases), available at http://arnoldporter.com/resources/documents/A&PCA_ExecutiveSummary-TheFDA_Oct107_V2.pdf; Drug and Device Law, The 2007 FDCA Amendments and Preemption (Oct. 18, 2007) (“[T]he ink’s hardly dry on the FDAAA before the plaintiffs are at it again, claiming that an obscure ‘rule of construction,’ facially applicable only to a single section of the new act, somehow undermines preemption as to the FDCA as a whole.”); see also Susan J. Pannell, *Claim Based on Deceptive Drug Ads is Preempted, Third Circuit Holds*, 43 TRIAL 16, 18 (quoting American Association for Justice regulatory counsel, Gerie Voss, as stating: “With the recent passage of the Food and Drug

However, the meaning of the rule is subject to considerable controversy and has yet to be resolved by the courts. In contrast, by strengthening the FDA's powers, the FDAAA may actually have strengthened FDA's claim for preemption. By increasing the FDA's ability to effectively regulate drug efficacy and safety, FDA is on stronger ground when asserting that "[t]he ultimate authority over drug, biologic, and medical device labeling, therefore, continues to rest with FDA."⁴⁹

This Paper makes an initial attempt to analyze the complex text and history of the FDAAA and evaluate the impact of the Act on drug-related preemption claims. Because preemption is heavily dependent on the federal regulatory scheme in place, Part II begins by providing background on the scope of drug regulation under the FDCA. Against this background, Part III summarizes the current preemption theories being advanced by litigants: Part III.A lays out the basics of preemption doctrine, in particular implied conflict preemption, which is the category of preemption most commonly at issue in drug-related products liability claims. Part III.B next discusses FDA's historical preemption position — one that eschewed agency preemption in favor of a more complementary relationship between state and federal regulations to ensure adequate regulation of drug safety. Part III.C then introduces FDA's more recent preemption position, which asserts that federal regulations constitute both a ceiling and a floor on drug labeling requirements, therefore preempting common law failure-to-warn claims. Due to the considerable opposition that has surrounded FDA's recently articulated pro-preemption view, Part IV then analyzes the strength of FDA's position in light of the new

Administration Amendments Act of 2007, Congress has stated its intent that FDA regulation should not preempt the field and that drug companies continue to have an independent obligation to promptly update a label to warn consumers of a drug's risks").

⁴⁹ FDA, Proposed Rule, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 (proposed Jan. 11, 2008).

surveillance and enforcement powers contained in the FDAAA. Part IV argues that though the text of the statute and the legislative history are not determinative on the issue of preemption, courts are likely to adopt the agency's pro-preemption interpretation of the FDCA in light of the fact that the agency is now better able to monitor drug safety. Lastly, Part V concludes.

II. FDA REGULATION OF DRUGS UNDER THE FOOD, DRUG AND COSMETIC ACT

Drugs are subject to pervasive regulation under the Food, Drug and Cosmetic Act, and are one of the most heavily regulated consumer products in the nation.⁵⁰ New drugs must obtain premarket approval from FDA, which requires a showing that the drug is safe and effective for its intended use. Manufacturers must submit a New Drug Application ("NDA") to receive premarket approval, and such an application must contain evidence of "adequate tests . . . to show whether or not [the] drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling."⁵¹ The proposed labeling itself is also subject to detailed requirements under the FDCA.⁵² These requirements are significant to the preemption debate, especially those relating to warnings for prescription drugs. This Part begins by summarizing the basic drug labeling requirements under the FDCA. Next, this Part discusses FDA's expanded authority under the FDAAA to ensure that drugs are safe and correctly labeled.

⁵⁰ See Daniel E. Troy, *The Case for Federal Preemption*, in *FEDERAL PREEMPTION* 81, 82 (Richard A. Epstein & Michael S. Greve eds. 2007).

⁵¹ 21 U.S.C. § 355(d).

⁵² The labeling requirements for prescription and over-the-counter drugs differ. This Paper will only address the labeling requirements for prescription drugs.

a. Drug Labeling Requirements Under the FDCA

Under 21 U.S.C. § 352(f)(2), a drug is misbranded unless, among other things, its labeling bears: “(1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users”⁵³ An applicant submitting an NDA must include a proposed physician package insert to be included with the product. This insert is intended to ensure that physicians are informed of the risks and benefits of a drug. In particular, the warning section of the insert must describe clinically significant adverse reactions or other potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.⁵⁴ The initial warnings supplied with a new prescription drug when it is first marketed are specifically prescribed by FDA.⁵⁵ Approval of an NDA is conditioned upon the applicant incorporating the specified labeling changes exactly as directed and submitting a copy of the final printed labeling to FDA prior to marketing.⁵⁶

However, information relating to drug safety that is discovered after a drug has been marketed may obligate the manufacturer to provide additional warnings or prompt FDA to require changes in the approved labeling.⁵⁷ The regulations mandate that “[i]n accordance with

⁵³ 21 U.S.C. § 352(f)(2).

⁵⁴ 21 C.F.R. § 201.57(c)(6)(1). The warning requirements are extremely detailed. For more on the required contents of the warning section, see *id.* § 201.57(c)(6).

⁵⁵ Peter BARTON HUTT & RICHARD A. MERRILL, *FOOD & DRUG LAW* 422 (2d ed. 1991).

⁵⁶ 21 C.F.R. 314.105(b).

⁵⁷ HUTT & MERRILL, *supra* note 55, at 422-23.

314.70 and 601.12 of this chapter, the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not be established.”⁵⁸ In general, however, these warnings cannot be added unilaterally by the manufacturer. Under 21 C.F.R. § 314.70, manufacturers must submit a supplemental application to FDA and obtain the agency’s advance approval for labeling changes.⁵⁹ If a manufacturer makes a labeling change prior to receiving approval, FDA may reject the change and order the manufacturer to cease distribution of the product.⁶⁰

There is a significant exception, however, to the prior approval requirement for labeling changes: manufacturers have authority the Changes Being Effectuated (“CBEs”) provisions to “add or strengthen a contradiction, warning, precaution, or adverse reaction” without first obtaining FDA approval, simply by providing notice to the agency.⁶¹ Likewise, the manufacturer does not need prior approval to add or strengthen statements about drug abuse, dependence, psychological effect, or overdose, or to add or strengthen instructions about dosage and administration intended to increase safe use of the drug.⁶²

Despite these detailed requirements, the Vioxx tragedy and other drug safety scandals exposed the agency to criticism that its regulatory system failed in practice.⁶³ Critics argued that

⁵⁸ 21 C.F.R. § 201.57(c)(6)(i).

⁵⁹ 21 C.F.R. § 314.70(b) (“The applicant must obtain approval of a supplement from FDA prior to distribution of a drug product made using a change under paragraph (b) of this section.”).

⁶⁰ 21 C.F.R. § 314.70(c)(7).

⁶¹ 21 C.F.R. § 314.70(c)(6)(iii)(A).

⁶² *Id.* §§ 314.70(c)(6)(iii)(B)-(C).

⁶³ *See, e.g.*, Horton, *supra* note 15, at 1995 (“In the case of Vioxx, FDA was urged to mandate further clinical safety testing It did not do so. This refusal to engage with an issue of grave

FDA had too little authority to monitor drugs once they have been approved, and too few enforcement mechanisms once risks were actually detected.⁶⁴ The IOM Report, for example, concluded that “FDA lacks the clear, unambiguous authority needed to enforce sponsor compliance with regulatory requirements and instead relies on the prospect of productive negotiations with industry. . . . FDA’s authorities must be clarified and strengthened to empower the agency to take rapid and decisive actions when necessary and appropriate.”⁶⁵ Therefore, with the passage of the FDAAA, Congress gave FDA significant new authority to ensure that drugs were safe and properly labeled.

b. The Food and Drug Administration Amendments Act of 2007

The FDAAA is an expansive piece of legislation spanning well over a hundred pages. Parts of the legislation consist of reauthorizing existing law — such as FDA’s prescription drug user fee program and the Best Pharmaceuticals for Children Act — but the Act also bestows important new powers upon the FDA. It would be impossible to adequately discuss all of the new provisions in a paper this short; therefore, I will focus only on the provisions that are most

clinical concern illustrates the agency’s in-built paralysis, a predicament that has to be addressed through fundamental organizational reform.”).

⁶⁴ See, e.g., Maurice Hinchey, *The Fight to Safeguard American Drug Safety in the Twenty-First Century*, 35 HOFSTRA L. REV. 685 (2006) (“Unlike its abilities on the drug approval front, the FDA’s options on the drug safety front are reduced to pleading for small changes . . . and is only able to enforce on major change: declaring a drug misbranded and yanking it from the market — an action that is rarely used.”).

⁶⁵ IOM REPORT, *supra* note 18, at 10-11.

relevant to the preemption debate.⁶⁶ The significant changes fall into three general categories: an active surveillance system, tools to detect drug risks, and greater authority to require warning and labeling.⁶⁷ The law also provides strengthened enforcement mechanisms.

Active Post-Market Surveillance System — The least well-defined of FDA's new duties and authorities is the post-market risk identification and analysis requirement. This provision was imposed due to the recommendations of the IOM report, which emphasized the importance of post-market surveillance for detecting risks not found during clinical trials.⁶⁸ FDAAA requires FDA to establish an active postmarket risk identification and analysis system within two years of enactment.⁶⁹ This system would provide access to federal and private medical records data and link and analyze data to provide, among other things, for active adverse event surveillance and reporting, identification of trends and patterns in the data, and the ability to export data for further aggregation, analysis and reporting.⁷⁰ The goal of this provision is to include at least 25 million patients by July 2010 and 100 million patients by July 2012.⁷¹ Within one year after developing methods to link and analyze these data, the Secretary must establish and actually

⁶⁶ For a more comprehensive discussion of the FDAAA provisions, see COVINGTON & BURLING LLP, FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007 (2007), *available at* <http://www.cov.com/files/Publication/2d3ce0d0-ec9e-4d8b-a376-3d79293d830f/Presentation/PublicationAttachment/a514e76e-029b-4f0e-b9e1-06e3ef3dc7ef/Food%20and%20Drug%20Administration%20Amendments%20Act%20of%202007.pdf>

⁶⁷ See CONG. REC. S11835 (Sept. 20, 2007) (statement of Sen. Hatch).

⁶⁸ See Margaret Gilhooley, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption, and the Drug Reform Legislation*, 59 S.C. L. REV. 347, 361, 363 (2008)

⁶⁹ FDCA § 505(k)(3)(B).

⁷⁰ *Id.* § 505(k)(3)(B)(i), (C)(i).

⁷¹ *Id.* § 505(k)(3)(B)(ii).

maintain procedures for the post-market risk identification and analysis system.⁷² Since this system is still in its nascent stages, however, it is difficult to measure the practical success of this system in detecting post-market drug risks.⁷³

Increased Risk-Detection Tools — The FDAAA increases FDA’s ability to detect safety risks. The Act authorizes the Secretary of Health and Human Services⁷⁴ to require the drug’s “responsible person” (defined as the holder of the approved or pending NDA)⁷⁵ to conduct post-market studies or clinical trials under certain circumstances. If the Secretary determines that the responsible person’s current reporting and post-market risk identification systems⁷⁶ are not sufficient to address a drug safety concern, the Secretary may require post-approval studies to assess a known serious risk or signals of a serious risk related to the use of the drug, or to identify an unexpected serious risk when available data indicates the potential for such risk.⁷⁷ If the Secretary makes a determination that a post-approval studies will not be sufficient to meet the purposes above, he or she may require the responsible person to conduct a clinical trial.⁷⁸

⁷² *Id.* § 505(k)(3)(C).

⁷³ See Gilhooly, *supra* note 68, at 364 (“[T]he agency would seem to need more experience with the system before an adequate assessment can be made of the potential for success.”).

⁷⁴ Determinations by the Secretary under FDCA § 505(o) must “be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).” FDCA § 505(o)(5).

⁷⁵ *Id.* § 505(o)(2)(A).

⁷⁶ The post-market risk-identification requirements are contained at FDCA § 505(k).

⁷⁷ *Id.* § 505(o)(3)(D)(i).

⁷⁸ *Id.* § 505(o)(3)(D)(ii).

However, if the product in question is already approved, the Secretary may not require a post-approval study or clinical trial unless he or she becomes aware of new safety information.⁷⁹

The Act also requires sponsors to submit a proposed “risk evaluation and mitigation strategy” (“REMS”) as part of an NDA or abbreviated NDA when the Secretary determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks.⁸⁰ Even if a REMS is not required when an application is approved, the Secretary may later require submission of a REMS proposal if he or she becomes aware of new safety information⁸¹ and makes a determination that a REMS is necessary to ensure that the benefits of the drug outweigh its risks.⁸² The holder of the approved application must then submit a proposed REMS within 120 days of notification, or within such other reasonable time as the Secretary requires to protect the public health.⁸³ If the Secretary makes the necessary finding, the proposed REMS may be required to include a medication guide, a patient package insert, or a plan for communication to healthcare providers.⁸⁴ The Secretary may also require that the REMS include “such elements as

⁷⁹ *Id.* § 505(o)(3)(C). Under § 505(o)(2)(C) “new safety information” is giving its meaning under FDCA § 505-1(b)(3) — information about a serious risk or an unexpected serious risk associated with use of the drug, or information about the effectiveness of the approved risk evaluation mitigation strategy of the drug. 21 U.S.C. § 355-1(b)(3).

⁸⁰ FDCA § 505-1(a)(1).

⁸¹ “New safety information” is defined as information derived from a clinical trial, an adverse event report, a post-approval study, peer-reviewed literature, the postmarket risk identification and analysis system, or other appropriate scientific data about: (1) a serious risk associated with use of the drug that the Secretary has become aware of since the drug was approved, since the REMS was required, or since the last assessment of the approved REMS; or (2) the effectiveness of the approved REMS since the last assessment of such strategy. FDCA § 505-1(b)(3).

⁸² *Id.* § 505-1(a)(2)(A).

⁸³ *Id.* § 505-1(a)(2)(B).

⁸⁴ *Id.* § 505-1(e).

are necessary to assure safe use of the drug,” if it is associated with a serious adverse drug experience and could be approved only if, or would be withdrawn unless, the elements are made part of the REMS.⁸⁵ Required elements may include that: (1) prescribers have particular training, experience, or certification; (2) drug dispensers are certified; (3) the drug be dispensed to patients only in certain settings; (4) that patients have evidence of “safe-use conditions; (5) patients be monitored; and (6) patients be enrolled in registries.⁸⁶ The drug holder must also conduct periodic assessments of the REMS, among other detailed requirements.⁸⁷ A drug may be deemed misbranded if the responsible person does not comply with a REMS requirement and the person may be subject to civil monetary penalties.⁸⁸

Authority to Require Warnings and Labeling — Finally, the FDCAA provides FDA with greater authority to require drug warnings and labeling. The Act does not alter the basic labeling scheme under the FDCA or the policy behind it.⁸⁹ However, the Act introduces provisions for imposing new labeling requirements when FDA becomes aware of new drug safety information. These changes are a response to the perceived inability of FDA to effectively impose labeling requirements—as illustrated by the fourteenth-month negotiation process between FDA and

⁸⁵ *Id.* § 505-1(f)(1).

⁸⁶ *Id.* § 505-1(f)(3).

⁸⁷ *Id.* § 505-1(g).

⁸⁸ *Id.* § 502(y), 303(f)(4).

⁸⁹ CONG. REC. S11835 (Sept. 20, 2007) (statement of Sen. Hatch) (“The provision does not affect the agency’s general policy on labeling or its current labeling rules and policy.”).

Merck to add relevant warnings to the Vioxx label.⁹⁰ The Act first imposes a mandatory duty on the FDA to act in the face of new safety information: “If the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person.”⁹¹ The Act then delineates a strict timetable for the process. Within 30 days of such notification, the responsible person must either (1) submit a supplement proposing labeling changes or (2) notify the Secretary that he or she does not believe labeling changes are warranted and submit a statement detailing why.⁹² If the Secretary disagrees with the proposed changes or the notification that labeling changes are not warranted, the Secretary must initiate discussions with the responsible party to reach an agreement on whether the labeling for the drug should be modified, and if so, what the contents of such labeling changes should be.⁹³ Significantly, such negotiation may not extend beyond thirty days unless the Secretary determines that an extension is warranted.⁹⁴ Within fifteen days of the conclusion of these discussions, the Secretary may issue an order direction the responsible person to make a labeling change, and the responsible person must submit a supplement with the labeling change within the next fifteen days.⁹⁵ Finally, the responsible person may appeal within

⁹⁰ FDALegislativeWatch, FDA Bill Passes; Congress Adds \$225 Million to Industry User Fee Burden (Sept. 26, 2007), <http://www.fdalegislativewatch.com/2007/09/fda-bill-passes.html> (“In response to complaints that patients continued to be exposed to *Vioxx* while FDA and Merck spent 18 months negotiating new warning language in the label, H.R. 3580 not only gives FDA authority to require label changes, but sets timelines for negotiations.”).

⁹¹ FDCA § 505(o)(4)(A).

⁹² *Id.* § 505(o)(4)(B).

⁹³ *Id.* § 505(o)(4)(C).

⁹⁴ *Id.* § 505(o)(4)(D).

⁹⁵ *Id.* § 505(o)(4)(E).

five days of receiving the order.⁹⁶ The above timetable may be accelerated if the labeling change is needed to protect public health.⁹⁷ In addition, the FDAAA requires dispute resolution procedures for labeling changes, but those these procedures are not specified in the law and must be implemented through agency “regulation and guidance.”⁹⁸ The new labeling provisions also strengthen the agency’s enforcement authority. FDA may order civil monetary penalties if a sponsor fails to comply with an order pursuant to a dispute resolution proceeding that orders post-approval testing or a safety labeling change.⁹⁹

Notably, the new labeling requirements raised concerns among trial lawyers and some members of Congress, who worried that the scheme would allow drug firms to argue that any state-based liability claims are pre-empted by FDA's labeling powers.¹⁰⁰ As a result, the bill now contains language stating that sponsors are still responsible for maintaining their labels in compliance with the governing regulations. This language, called a “rule of construction,” states:

This paragraph shall not be construed to affect the responsibilities or the responsible person or the holder of the approved application under section 505 (j) to maintain its label in accordance with existing requirements, including Subpart B or Part 201 and Section 314.70 and 601.12 of Title 21, Code of Federal Regulations (or any successor regulations).¹⁰¹

⁹⁶ *Id.* § 505(o)(4)(F).

⁹⁷ *Id.* § 505(o)(4)(H).

⁹⁸ *Id.* § 505(o)(4)(F).

⁹⁹ *Id.* §303(f)(4).

¹⁰⁰ FDALegislativeWatch, FDA Bill Passes; Congress Adds \$225 Million to Industry User Fee Burden (Sept. 26, 2007), <http://www.fdalegislativewatch.com/2007/09/fda-bill-passes.html>.

¹⁰¹ FDCA § 505(o)(4)(I).

Commentators immediately warned that the rule of construction is “product of lobbying by the plaintiffs’ bar” and is “undoubtedly a tool that will be used by plaintiffs seeking to undermine preemption in ‘failure to warn’ cases.”¹⁰² Already it appears such predications were correct. For example, in the briefings for *Wyeth v. Levine*, which will be heard by the Supreme Court later this Term, the respondent argues that “the rule of construction underscores Congress’s view that, in the future, state-law damages liability should continue to coexist with the FDA’s enhanced power to demand label changes.”¹⁰³ However, the text of the provision does not unequivocally indicate that it was meant to have an anti-preemption impact.¹⁰⁴ The issue is complex, and the impact of the rule of construction likely will depend significantly on its interpretation by the courts.¹⁰⁵ Nevertheless, an initial analysis of the implications of the rule of construction for the preemption debate is explored in further detail in Part IV. But first, I will provide some necessary background on the preemption conflict.

III. THE HISTORY OF THE PREEMPTION DEBATE

FDA’s position on preemption of drug claims has changed in the last decade, attracting considerable attention from scholars and litigants. Its early position was characterized by a generally anti-preemption position, in which state and federal law were complementary, and state law was seen as a necessary supplement to ensure drug safety. During the current Bush

¹⁰² ARNOLD & PORTER, *supra* note 48, at 9.

¹⁰³ Respondent’s Supplemental Brief in Response to Brief of the United States at 9, *Wyeth v. Levine*, No. 06-1249 (U.S. Jan. 2, 2008), 2008 WL 55106.

¹⁰⁴ *See infra* Part IV.A.

¹⁰⁵ *C.f.* Respondent’s Supplemental Brief, *supra* note 103, at 9 (predicting that the meaning of the rule of construction “will be fiercely debated in case after case”).

Administration, however, the agency reversed its position and began to assert in amicus briefs and rulemakings that the federal drug regulation scheme contained in the FDCA preempted common law product liability claims. Some commentators have blasted the new policy and attributed the change in position purely to a change in politics — claiming the current view is a result of pro-industry allegiances of the new administration.¹⁰⁶ For example, in 2004, Congressman Maurice Hinchey accused then-FDA Chief Counsel Daniel Troy of taking the agency “in a radical new direction,” and “wast[ing] taxpayer money on pursuits that are undermining FDA’s basic mission.”¹⁰⁷ He then went on to accuse the FDA of a “pattern of collusion” with drug companies and medical device manufacturers.¹⁰⁸ Other commentators, however, have defended the new policy as well supported by precedent,¹⁰⁹ and have asserted that it is necessary in light of the danger posed by an explosion in products liability litigation.¹¹⁰ This Part discusses the conflicting views on FDA preemption of product liability claims against drug manufacturers. But first, in order to help the reader understand the FDA’s varying positions on

¹⁰⁶ See, e.g., MARGARET H. CLUNE, CTR. FOR PROGRESSIVE REGULATION, STEALTH TORT REFORM: HOW THE BUS ADMINISTRATION’S AGGRESSIVE USE OF THE PREEMPTION DOCTRINE HURTS CONSUMERS (2004) (“[I]t appears that the primary motivating concept behind FDA’s pro-preemption briefs is the Bush Administration’s tort reform agenda.”).

¹⁰⁷ 150 CONG. REC. H5598 (July 13, 2004) (statement of Rep. Hinchey).

¹⁰⁸ *Id.* at H5599.

¹⁰⁹ See, e.g., Letter from Peter Barton Hutt, Richard A. Merrill, Richard M. Cooper, Nancy L. Buc and Thomas Scarlett to Hon. Henry Bonilla (July 15, 2004), 150 Cong. Rec. E1505-30 (July 22, 2004). The authors of this letter, five former FDA Chief Counsels, cited previous cases in which the FDA had submitted amicus briefs and argued that “there is ample precedent for the actions that Mr. Troy has recently been undertaking. His action is not radical or even novel.” *Id.* at E1506.

¹¹⁰ See, e.g., *id.* at E1506 (“There is a greater need for FDA intervention today because plaintiffs in courts are intruding more heavily on FDA’s primary jurisdiction than ever before.”); Troy, *supra* note 50, at 85-91 (identifying four risks of increased tort litigation: decreased investment in research, decreased availability of investigational or approved drugs, increased drug prices, and interference with rational prescribing).

the preemption conflict, this Part begins with a brief summary of the relevant preemption doctrine.

a. Background on Supreme Court Preemption Doctrine

Under the Supremacy Clause of article VI, federal law is the supreme law of the land.¹¹¹ This clause has long been interpreted to mean that state or local action that conflicts with congressional action is preempted and no longer has the force of law.¹¹² Likewise, it has long been accepted that regulations promulgated by a federal agency such as FDA, pursuant to a congressional delegation, have the same preemptive effect as federal statutes.¹¹³ But while the concept of preemption is uncontroversial, determining whether a state law conflicts with federal law proves to be a difficult matter in practice. This task is not made any easier by the fact that the Supreme Court has been inconsistent in its application of preemption doctrine.¹¹⁴ However, the Supreme Court has consistently held that Congressional intent to preempt is paramount to the

¹¹¹ U.S. CONST. art. VI, cl. 2.

¹¹² *See, e.g.,* Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824) (recognizing that in the case of “such acts of the State Legislatures as do not transcend their powers, but, though enacted in the execution of acknowledged State powers, interfere with, or are contrary to the laws of Congress, made in pursuance of the constitution, or some treaty made under the authority of the United States . . . the act of Congress, or the treaty, is supreme; and the law of the State, though enacted in the exercise of powers not controverted, must yield to it.”); Fidelity Federal Savings & Loan Ass’n v. de la Cuesta, 458 U.S. 141, 153 (1982) (“[S]tate law is nullified to the extent that it actually conflicts with federal law.”).

¹¹³ 1 LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW § 6-26, at 481 (2d ed. 1988) (citing Hillsborough County, Fla. v. Automated Med. Labs., 481 U.S. 707, 713 (1985) (“We have held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes.”)).

¹¹⁴ *See* Sharkey, *supra* note 27, at 454 (“It is exceedingly difficult to demonstrate that any consistent principle or explanatory variable emerges from the Supreme Court’s products liability preemption jurisprudence.”).

inquiry.¹¹⁵ A rule may only preempt to the extent intended by Congress.¹¹⁶ In its case law, the Court has created three categories of cases in which Congress's intention is sufficiently clear to preempt state law: express preemption, field preemption, and implied conflict preemption. In general, preemption of drug-related products liability claims falls under the conflict preemption category. To show why this is so, I will discuss each type of preemption in turn.

Express Preemption — Express preemption is preemption that exists as a matter of statute or as a matter of agency regulation. To fit within this category, the statute or regulation must contain a provision specifically referring to preemption and explaining which state laws are supplanted.¹¹⁷ For example, the Medical Device Amendments of 1976 contain a provision stating that “no 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.”¹¹⁸ However, Congress has never passed statutory language addressing preemption with respect to

¹¹⁵ See *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963) (“The purpose of Congress is the ultimate touchstone.”).

¹¹⁶ CHARLES ALAN WRIGHT & CHARLES H. KOCH, JR., *FEDERAL PRACTICE & PROCEDURE: JUDICIAL REVIEW OF ADMINISTRATIVE ACTION* § 8167 (2008).

¹¹⁷ STONE ET AL., *CONSTITUTIONAL LAW* 275 (5th ed. 2005).

¹¹⁸ Pub.L. No. 94-295, § 2, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k). The Supreme Court ruled last February that this provision preempted some suits against medical device manufacturers. See *Riegel v. Medtronic*, 128 S. Ct. 999 (2008).

the regulation of prescription drugs;¹¹⁹ thus, state-law tort claims against drug manufacturers are not expressly preempted.¹²⁰

Field Preemption — In the second category of preemption, field preemption, Congressional intent is inferred from the comprehensiveness of the federal regulatory scheme. Preemption occurs when the federal scheme created by Congress is so pervasive that it is understood as manifesting an attempt by Congress to control the field.¹²¹ Professor Tribe has described this category as one “within which states are deemed powerless to act because of a vacuum deliberately, even if not expressly, created by federal legislation.”¹²² After the passage of the FDAAA, some consumer advocacy groups worried that the expansive provisions in the Act would create a pervasive regulatory scheme adequate to create field preemption.¹²³

However, fears of field preemption in the drug context are likely unfounded for several reasons. First, the consequences of finding field preemption are significant: field preemption generally occurs where there is no federal law with which the state law conflicts (otherwise

¹¹⁹ In contrast, Congress has include express preemption provisions for the labeling of nonprescription drugs, 21 U.S.C. § 379r, and medical devices, *id.* § 360k.

¹²⁰ *See, e.g., In re Vioxx Products Liability Litigation*, 501 F. Supp. 2d 776, 784 (E.D. La. 2007) (“[T]he FDCA does not contain an express statement that Congress intended to displace state-law claims in the prescription drug context.”).

¹²¹ *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (“The scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.”).

¹²² 1 LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* § 6-25, at 479 (2d ed. 1988).

¹²³ *See, e.g., People Over Profits*, Information on the Rule of Construction Regarding Federal Preemption, http://www.peopleoverprofits.org/site/c.ntJWJ8MPIqE/b.2804449/k.BC2F/Federal_Preemption.htm (last visited April 15, 2008) (“The drug safety provisions in the PDUFA reauthorization create field preemption.”).

conflict preemption would occur), so a finding of field preemption means that the matter is left unregulated by either the state or the federal government.¹²⁴ Therefore, courts employ a strong presumption against field preemption, and proponents of preemption must show that Congress has expressed an intent that federal law be exclusive in the field. This is especially true in areas, such as tort law, that have traditionally been regulated by the states.¹²⁵ Second, state law still operates to control a number of prescription drug issues: states license drug manufacturers, determine prescription status, penalize pharmacists for mishandling prescription drugs, and oversee controlled substances.¹²⁶ Third, a specific preemption provision added as part of the Drug Amendments of 1962 specifies that the 1962 amendments, which include the basic labeling requirements, may not preempt state law unless there is direct and positive conflict between such amendments and the state law.¹²⁷ Therefore, though some scholars have advocated for field preemption as a policy matter,¹²⁸ in general, drug manufacturers have not pursued field preemption claims.¹²⁹

¹²⁴ STONE, *supra* note 117, at 276; *c.f.* Sharkey, *supra* note 27, at 480 (“The Supreme Court has set a high bar to imputing a congressional intent to preempt when such an interpretation would create what I would call a remedial or enforcement ‘void.’”).

¹²⁵ *See Rice*, 331 U.S. at 230 (“Congress legislated here in field which the States have traditionally occupied. So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” (internal citations omitted)).

¹²⁶ O’Reilly, *supra* note 44, at 291.

¹²⁷ Kefauver-Harris Amendment, Pub L. No. 87-781 § 202, 76 Stat. 780, 793 (1962).

¹²⁸ For arguments in favor of field preemption in the drug context see, for example, *David R. Geiger & Mark D. Rosen, Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 397 (1996).

¹²⁹ *See, e.g.,* AstraZeneca’s Response to Plaintiff’s Supplemental Briefing Regarding AstraZeneca’s Motion for Judgment on the Pleadings on the Basis of Federal Preemption at 4, *In*

Conflict Preemption — The final category of preemption is conflict preemption. This is the type of preemption most likely to implicate claims against tort manufacturers. Like field preemption, this category of preemption is implied — there is no express preemption provision and Congress’s intent to preempt state law is implicit. Implied preemption can be described as falling into two subcategories: actual preemption and obstacle preemption.¹³⁰ Actual preemption occurs when compliance with both the federal and state law is impossible.¹³¹ Object preemption occurs when it would be technically possible to comply with both state and federal law, but compliance with state law would frustrate the federal purpose.¹³² The distinction between these two types of conflict preemption may be more semantic than practical, however, as the Court has

re Seroquel Products Liab. Litig., MDL No. 1769 (M.D. Fla. Oct. 17, 2007) (“[Astrazeneca’s] motion is based on the doctrine of implied conflict preemption (not field preemption) arising from the authoritative federal actions of the FDA acting within the scope of its congressionally delegated authority.”).

¹³⁰ See Petition for a Writ of Certiorari at 23, *Wyeth v. Levine*, No. 06-1249 (Mar. 12, 2007) (“This Court has consistently made clear that conflict preemption analysis requires consideration both of whether it would be impossible to comply with federal and state law and of whether the state law would stand as an obstacle to the objectives of federal law.”). These subcategories of preemption may be referred to by varying names. The Supreme Court, for example, has sometimes called the “obstacle” type of conflict preemption “frustration of purpose” preemption. See *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 885 (2000).

¹³¹ See *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) (conflict preemption occurs where “compliance with both federal and state regulations is a physical impossibility”).

¹³² See *McDermott v. Wisconsin*, 228 U.S. 115, 132 (1913) (“[T]o the extent that state law interferes with or frustrates the operation of the acts of Congress, its provisions must yield to the superior Federal power . . .”).

previously conceptualized obstacle preemption as a form of actual preemption, where the conflict is simply more subtle.¹³³

On the other hand, the presumption that the Court chooses to employ when deciding an implied preemption case may have considerable practical significance. While the presumption against preemption is generally accepted in the field preemption context, the presumption in conflict preemption cases is less well-settled. Some courts and commentators have indicated that there is a presumption against preemption even in actual conflict cases, and that the presumption is particularly strong in cases involving areas of that that are traditionally occupied by the states.¹³⁴ Other commentators interpret the case law to establish that the presumption against preemption originated in field preemption cases should be limited to such cases.¹³⁵ The one thing that can be said for certain, however is that the Supreme Court has been inconsistent in its application of the presumption in conflict cases.¹³⁶

In light of the Supreme Court's recent line of pro-preemption decisions,¹³⁷ however, it may be fair to assume that the Court would not apply a presumption against preemption when

¹³³ See *Geier*, 529 U.S. at 873 (“The Court has not previously driven a legal wedge — only a terminological one — between ‘conflicts’ that prevent or frustrate the accomplishment of a federal objective and ‘conflicts’ that make it ‘impossible’ for private parties to comply with both state and federal law.”); see also 1 *TRIBE*, *supra* note 122, §6-26, at 482.

¹³⁴ See Sharkey, *supra* note 27, at 458 (citing cases).

¹³⁵ See Drug and Device Law, *The Presumption Against Preemption*, <http://druganddevicelaw.blogspot.com/2006/11/presumption-against-preemption.html> (Nov. 15, 2006) (With one arguable exception, the presumption against preemption hasn't been employed — by the Supreme Court, anyway — to take the edge off actual conflicts between federal and state law. That's not to say that the Court might not extend the presumption to every form of preemption, only that it has yet to do so, and that there are good reasons for not doing so.”).

¹³⁶ See Calvin Massey, “Joltin' Joe Has Left and Gone Away”: *The Vanishing Presumption Against Preemption*, 66 ALB. L. REV. 759 (2003).

¹³⁷ See *supra* note 32 and accompanying text.

conducting conflict preemption analysis. One could argue that if Congress intended not to preempt, it would have done so in equally unequivocal language as it has done in other statutes, such as ERISA.¹³⁸ Congress does not seem to have adopted such unequivocal anti-preemption language for prescription drug regulations. It is true that the 1962 Drug Amendments do contain a qualified “savings clause,” which states:

Section 202. Nothing in the amendments made by this Act to the Federal, Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.¹³⁹

However, it is not clear that this provision applies to failure to warn claims. The clause is limited by its text to the amendments made by the 1962 legislation, which required the agency to consider the efficacy, as well as the safety, of a drug.¹⁴⁰ It is not applicable to the entire FDCA. The provisions delineating the drug approval process, however, including the NDA labeling requirements, predated the 1962 Amendments. Furthermore, even if the clause does apply to the regulation of prescription drug warnings, the text of the provision indicates that it contemplates preemption in circumstances involving “a direct and positive conflict.”¹⁴¹ Therefore, it would not seem to displace ordinary conflict preemption principles.

¹³⁸ See 29 U.S.C. § 1144(b)(2)(A) (“Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.”).

¹³⁹ Kefauver-Harris Amendment, Pub L. No. 87-781 § 202, 76 Stat. 780, 793 (1962).

¹⁴⁰ See HUTT & MERRILL, *supra* note 53, at 1032 (describing the legislative history behind the clause).

¹⁴¹ Brief for the United States as Amicus Curiae, *Wyeth v. Levine*, No. 06-1249 (U.S. Dec. 21, 2007), 2007 WL 455760 (citing Pub L. No. 87-781 § 202, 76 Stat. at 793).

Some lower courts have nevertheless interpreted Section 202 to preclude object preemption claims, claiming that the provision allows preemption only in situations in which it would be impossible to comply with both federal and state law (actual preemption).¹⁴² However, this interpretation is likely incorrect for two reasons: First, as discussed above, the Court has recently equated actual preemption and conflict preemption in its analysis.¹⁴³ Second, even if Section 202 was treated as a savings clause proscribing conflict preemption, the Supreme Court has sometimes ignored express savings language and instead proceeded to consider language indicating whether state law should nonetheless be impliedly displaced. For example in *Geier v. American Honda Motor Co.*,¹⁴⁴ the plaintiff brought a tort suit claiming that Honda's automobile was defectively designed because it did not contain an airbag. The Federal Motor Vehicles Act contained a savings clause stating that "'compliance' with a federal safety standard 'does not exempt any person from any liability under common law.'"¹⁴⁵ The Court concluded, however, that the savings clause "does not bar the ordinary working of conflict pre-emption principles."¹⁴⁶ Again, this exception would seem to apply to both actual preemption and obstacle preemption cases, since *Geier* was a case in which compliance with both the state and federal scheme was not impossible.

¹⁴² See *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006).

¹⁴³ See *supra* note 133 and accompanying text.

¹⁴⁴ 529 U.S. 861 (2000).

¹⁴⁵ *Id.* at 868 (quoting 15 U.S.C. § 1397(k)).

¹⁴⁶ *Id.* at 869.

b. FDA's Traditional Preemption Position

Prior to 2002, FDA had not traditionally claimed that the provisions of the FDCA preempted common law failure to warn actions.¹⁴⁷ Instead, FDA took the view that federal and state law operated independently, each providing a “significant, yet distinct layer of consumer protection.”¹⁴⁸ FDA conceptualized the FDCA labeling requirements as a “floor” for regulation, and states were free to supplement or augment these requirements to provide greater protection for consumers.¹⁴⁹ Under this approach, a manufacturer’s compliance with FDA regulations was admissible as evidence that product labeling is adequate, but it was not dispositive on the issue.¹⁵⁰

¹⁴⁷ See James T. O’Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 FOOD & DRUG L.J. 287, 288 (2003) (“Until DHHS asserted prescription drug preemption in a brief to the Ninth Circuit in late 2002, FDA had remained aloof from preemption arguments that often had been made by prescription drug manufacturers in defense of individual products liability lawsuits.” (internal footnotes omitted)). FDA also articulated this position in an earlier product liability case against a prescription drug manufacturer, but that case was decided on other grounds. See *Bernhardt v. Pfizer, Inc.* No. 00 Civ. 4042 (LMM), 00 Civ. 4379 (LMM), 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000).

¹⁴⁸ Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997) (writing as FDA Chief Counsel).

¹⁴⁹ See FDA, Final Rule, New Drug Requirements for Labeling Directed at the Patient, 43 Fed. Reg. 4214, 4214 (1978) (addressing labeling requirements for oral contraceptives and noting that liability for manufacturers was dependent on the applicable state law, and “[t]he fact that patient labeling may have been required and drafted by FDA would not protect the manufacturer from an adverse jury determination on the issue of adequacy”); HUTT & MERRILL, *supra* note 53, at 426 (stating that a line of products-liability cases brought by women who had used oral contraceptives “enunciated a general rule that FDA-mandated warnings represent the minimum, and not necessarily the appropriate, warnings for a prescription drug”).

¹⁵⁰ *C.f.* David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L.J. 1003, 1015 (2004) (“[A] product seller’s compliance with a statutory or regulatory safety standard in a negligence action is proper evidence of a product’s nondefectiveness but is not conclusive of that issue.”).

Many of FDA's arguments underlying this position mimic those set forth by today's critics of preemption. For example, FDA warned that premarket approval of a product cannot anticipate or protect against all safety risks to consumers.¹⁵¹ Furthermore, FDA cited the fact that preemption would foreclose all possibility of recovery by plaintiffs as a factor supporting a presumption against preemption.¹⁵² Professor Mary Davis has summarized the reasoning underlying FDA's historical position as follows:

[G]overnmental regulations are based on narrowly defined goals, supported by limited information provided substantially by the regulated entity, and typically do not include setting optimal standards of care for all circumstances; rather, they set minimum standards not intended to prevent the operation of other remedial mechanism such as common law tort claims. Consequently, more exacting state tort law standards of care do not conflict, but operate concurrently with the federal requirements.¹⁵³

An example of FDA's previous view includes its position in *Medtronic, Inc. v. Lohr*,¹⁵⁴ a case examining the preemptive effect of the Medical Device Amendments of 1976. The United States filed an amicus brief in that case, arguing in part that the labeling provisions of the Act and the implementing regulations did not preempt the failure-to-warn claims in that case.¹⁵⁵

¹⁵¹ Compare *id.*, with Gilhooley, *supra* note 14, at 954 ("As has long been known, the risks drugs pose cannot be fully known from the testing done before approval.").

¹⁵² Compare *id.* at 9 ("Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe that Congress meant to effect so sweeping a change without even a comment."), with Sharkey, *supra* note 27, at 503-04 ("In my view, although existence of a remedial void should not lead inevitably to an anti-preemption position, it should take arguments for implied field preemption off the table.").

¹⁵³ Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1090-91 (2007) (internal footnotes omitted).

¹⁵⁴ 518 U.S. 470 (1996).

¹⁵⁵ See Brief for the United States as Amicus Curiae at 27-28, *Medtronic, Inc. v. Lohr*, Nos. 95-754, 95-886 (U.S. Mar. 13, 1996), 1996 WL 118035.

Furthermore, shortly after that decision, the then-Chief Counsel of the FDA, Margaret Jane Porter, stated that the agency's position in that case was consistent with its traditional presumption against preemption, particularly when state regulations provide greater consumer protection.¹⁵⁶ According to Porter, "FDA's position has always been that state and local requirements are not preempted and may be enforced until FDA establishes specific counterpart requirements. . . ."¹⁵⁷

In the context of product liability claims against drug manufacturers, FDA also traditionally adopted a presumption against preemption. For example, FDA included statements in a former drug labeling rule indicating that FDA favored labeling changes by manufacturers to increase information.¹⁵⁸ The 1979 rule addressing the form and content of prescription drug labeling, the Commissioner advised that "these labeling regulations do not prohibit a manufacturer, packer, relabeler, or distributor from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered."¹⁵⁹ The Commissioner also specifically addressed manufacturer liability, stating: "In considering these regulations in a product liability case, at least one court has held that an NDA holder may have a duty to add a warning before FDA approval of a supplemental application."¹⁶⁰ Under this

¹⁵⁶ Porter, *supra* note 148, at 7.

¹⁵⁷ *Id.*

¹⁵⁸ See FDA, Final Rule, Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434 (1979).

¹⁵⁹ *Id.* at 37,447.

¹⁶⁰ *Id.* (citing *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (Ore. 1974)).

framework, a line of cases established “a general rule that FDA-mandated warnings represent the minimum, and not necessarily the appropriate, warnings for a prescription drug.”¹⁶¹

c. FDA’s Current Preemption Position

Beginning in 2002, FDA began to take the position that compliance with FDA-mandated labeling preempts common law failure-to-warn claims. Former Chairman of the FDA under the Bush Administration, Daniel Troy, took the view that the FDCA labeling requirements are “central to the FDA’s mission” and argued that “without full control of the content of drug labeling, the FDA could not effectively convey its risk-benefit information to prescribers.”¹⁶² Critical to this position is the assertion that the FDCA labeling regulations establish the *optimal* standards for regulation — in a sense, both a ceiling *and* a floor on the requirements for manufacturers.¹⁶³ Such reasoning is necessary to a pro-preemption argument because the contrary view interprets the CBE provisions in the FDCA to mean that “[t]he position of the FDA is that a manufacturer can, and should, provide stronger warnings as soon as such a

¹⁶¹ HUTT & MERRILL, *supra* note 55, at 436.

¹⁶² Troy, *supra* note 50, at 85. Troy also argues that the new position is a much-needed response to the threat of state tort claims. However, this reasoning does not appear in FDA amicus briefs or rulemaking. *See id.* at 82 (“[T]he FDA’s increasingly explicit assertion that the [FDCA] and its accompanying regulations preempt state law cannot be viewed as a unilateral change of direction. Rather, it is best viewed as a response to protect the FDA’s mission and objectives, as defined by Congress, against independent threats emanating from state tort law, especially failure-to-warn suits.”).

¹⁶³ *See* Troy, *supra* note 50, at 84 (“When the FDA approves a new drug, it does not set a minimum safety standard: rather, it balances the risks associated with the drug against the competing risks associated with not having the drugs available and sets what it sees as an *optimal* standard. Manufacturers can fail to meet that optimal standard by including less or more than the FDA requires.”) (internal footnote omitted).

warning is warranted.”¹⁶⁴ Thus, the CBE requirements are used by plaintiffs to rebut the argument that FDA requires full control of the content of drug labeling.¹⁶⁵ For example, in *Levine v. Wyeth*,¹⁶⁶ the Vermont Supreme Court case granted certiorari by the Supreme Court, the CBE provisions were crucial to the court’s preemption analysis. The court reasoned: “While specific federal labeling requirements and state common-law duties might otherwise leave drug manufacturers with conflicting obligations, § 314.70(c) allows manufacturers to avoid state failure-to-warn claims without violating federal law.”¹⁶⁷ Therefore, in recent years, FDA has repeatedly asserted its view that the CBE provisions do not transform the federal labeling requirements into a minimum standard or allow drug manufacturers to unilaterally amend the labeling for a product without limitation. FDA has articulated this position, and explained the reasoning behind it, in a number of amicus briefs, in the preamble to a 2006 drug labeling rule, and in a recently proposed rule.

¹⁶⁴ MICHAEL E. CLARK, PHARMACEUTICAL LAW: REGULATION OF RESEARCH, DEVELOPMENT, AND MARKETING 105 (2007); *see also* *Levine v. Wyeth* 944 A.2d 179, 187 (Vt. 2006) (determining 21 C.F.R. § 314.70(c) “appears to allow unilateral changes to drug labels whenever the manufacturer believes it will make the product safer, and places no limit on the duration of pre-approval warnings unless the FDA disapproves of the change”).

¹⁶⁵ *See, e.g.*, Respondent’s Brief in Opposition at 24, *Wyeth v. Levine*, No. 06-1249 (U.S. Jan. 2, 2008), 2008 WL 55106 (“[I]t would not have been impossible to comply with a state-law duty to warn [requirements] . . . and federal labeling requirements because those requirements expressly give manufacturers the right to revise labels to include contraindications, warnings, and instructions that enhance patient safety without prior FDA approval.”) (citing 21 C.F.R. § 314.70(c)(6) and 21 C.F.R. § 201.80(e)); *see also* Jonathan V. O’Steen & Van O’Steen, *The FDA Defense: Vioxx® and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 82 -83 (2006) (“The availability of [the CBE provisions] undercuts popular arguments made by drug manufacturers that labeling is within the exclusive control of the FDA.”).

¹⁶⁶ 944 A.2d 179 (Vt. 2006)

¹⁶⁷ *Id.* at 187.

FDA first asserted its new position in an amicus brief submitted to the Ninth Circuit in *Motus v. Pfizer, Inc.*¹⁶⁸ In *Motus*, the widow of a man who committed suicide while taking the antidepressant Zoloft brought a common law failure-to-warn claim against the drug manufacturer Pfizer, alleging that Pfizer failed to provide adequate warnings to doctors of the alleged suicide risk associated with Zoloft.¹⁶⁹ In considering, and approving, the Zoloft NDA, FDA had previously determined that there was no credible evidence “to support a conclusion that antidepressant drugs cause the emergence and/or intensification of suicidality and/or other violent behaviors.”¹⁷⁰ Therefore, FDA did not require that such warnings appear on the product label. The issue on appeal was whether Pfizer’s compliance with the labeling provisions of the FDCA and the applicable regulations preempted the plaintiff’s failure-to warn claim. According to FDA, compliance with state law would obstruct the purposes and objectives of the FDCA for two main reasons: First, imposing liability would thwart FDA’s objective of ensuring optimal use of a drug because disseminating an unnecessary warning would curtail the beneficial use of a drug.¹⁷¹ Second, excess warnings required under state law could detract from the FDA-approved warnings. As FDA stated in its amicus brief in *Motus*:

Under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly life-saving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug’s scientifically demonstrable adverse effects. Further, allowing unsubstantiated warnings may

¹⁶⁸ 358 F.3d 659 (9th Cir. 2004), rev’g 127 F. Supp. 2d 1085 (C.D. Cal 2000).

¹⁶⁹ *See id.* at 660.

¹⁷⁰ Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant at 9, *Motus v. Pfizer, Inc.*, Nos. 02-55372, 02-55498 (9th Cir. Sept. 19, 2002), 2002 WL 32303084 [hereinafter *Motus Brief*].

¹⁷¹ *Id.* at 15.

also diminish the impact of valid warnings by creating an unnecessary distraction and making even valid warnings less credible.¹⁷²

Since its amicus brief in *Motus*, FDA has repeated this pro-preemption position in a number of other amicus briefs before state and federal courts.¹⁷³ The most recent articulation is in a supplemental brief for certiorari in *Wyeth v. Levine*,¹⁷⁴ which was recently granted certiorari by the Supreme Court.¹⁷⁵ In *Levine*, the plaintiff's hand and forearm were amputated after the anti-nausea medication Phenergan was injected directly into her artery.¹⁷⁶ The plaintiff brought a common law failure-to-warn claim against the manufacturer, Wyeth, alleging that Wyeth's failure to warn of the known dangers of direct intravenous injection of Phenergan caused her injuries.¹⁷⁷ Although the Phenergan label was FDA approved, the plaintiff argued that additional warnings could and should have been added under the CBE provisions of the FDCA. The Supreme Court of Vermont held that the claim was not preempted by federal law because it did "not impose conflicting obligations on defendant or present an obstacle to the objectives of Congress."¹⁷⁸ FDA filed an amicus brief supporting certiorari on behalf of the defendants.¹⁷⁹ In

¹⁷² *Id.* at 23-24. *Motus* was eventually decided on grounds other than preemption. *See Motus*, 358 F.3d at 661.

¹⁷³ *See Davis, supra* note 153, at 1095 n.34 (citing cases in which FDA submitted amicus briefs advocating the position that approved prescription drug labeling preempts state product liability claims).

¹⁷⁴ No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006).

¹⁷⁵ Brief for the United States as Amicus Curiae, *Wyeth v. Levine*, No. 06-1249 (U.S. Dec. 21, 2007), 2007 WL 455760.

¹⁷⁶ *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006).

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 194.

the brief, FDA argued that that the plaintiff's claims "are impliedly preempted by the FDCA because they challenge labeling that FDA approved . . . based on its expert weighing of the risks and benefits requiring additional or different warnings."¹⁸⁰ As in *Motus*, FDA emphasized that unnecessary warnings and exaggeration of risk could discourage appropriate uses of a beneficial drug or detract from more meaningful risk information.¹⁸¹ The agency concluded that "[f]or these reasons, 'FDA interprets the FDCA to establish both a "floor" and a "ceiling"' with respect to drug labeling."¹⁸²

FDA also formalized its pro-preemption position in the preamble of a 2006 rule updating the format and labeling requirements for prescription drugs. The preamble supports the position previously articulated in amicus briefs that full control over drug labeling is essential for FDA to convey its risk-benefit mission.¹⁸³ The provision emphasizes that labeling is "[t]he centerpiece of risk management," as it "communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively."¹⁸⁴ The preamble furthermore states in relevant part:

FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has

¹⁷⁹ Petition for a Writ of Certiorari, *Wyeth v. Levine*, No. 06-1249 (U.S. Mar. 12, 2007), 2007 WL 4555760.

¹⁸⁰ *Id.* at 7.

¹⁸¹ *Id.* at 10-11 ("A warning in a drug's labeling must strike a balance between notifying users of potential dangers and not unnecessarily deterring beneficial uses.").

¹⁸² *Id.* at 11 (quoting 71 Fed. Reg. 3922, 3935 (2006)).

¹⁸³ See Troy, *supra* note 50, at 85.

¹⁸⁴ 71 Fed. Reg. at 3934 (quoted in Brief for the United States as Amicus Curiae at 9, *Wyeth v. Levine*, No. 06-1249 (U.S. Dec. 21, 2007)).

considered and found scientifically unsubstantiated. . . . The agency believes that State law conflicts with and stands as an obstacle to achievement of the full objectives and purposes of Federal law if it purports to preclude a firm from including in labeling or advertising a statement that is included in prescription drug labeling. By complying with the State law in such a case and removing the statement from labeling, the firm would be omitting a statement required under § 201.100(c)(1) as a condition on the exemption from the requirement of adequate directions for use, and the omission would misbrand the drug¹⁸⁵

In sum, the text of the provision reiterates the position that FDCA sets both a ceiling and a floor on the labeling requirements for manufacturers.¹⁸⁶ It therefore serves as a powerful tool for opposing claims that manufacturers may provide warnings over and above those approved by FDA. Though the level of deference that courts should give to agency views expressed in a preamble of a rule is a subject of fierce debate among scholars,¹⁸⁷ in practice courts have given considerable weight to agency views expressed through more informal procedures.¹⁸⁸

FDA recently added an even more powerful weapon to its pro-preemption arsenal, however. On January 16, 2008 FDA brought its preemption position into even sharper focus when it issued a proposed rule that would reaffirm “the agency’s longstanding view on when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency’s review and approval of such change.”¹⁸⁹ Under the proposed rule, FDA would amend the CBE provisions to reaffirm that a changes may be made according

¹⁸⁵ FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (2006) (internal citations omitted).

¹⁸⁶ *See id.*

¹⁸⁷ FDA, Proposed Rule, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2848 (proposed Jan. 11, 2008).

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

the CBE provisions only under narrow circumstances: to show newly acquired information or to “add or strengthen a contraindication, warning, precaution, or adverse reaction . . . if there is sufficient evidence of a causal association with the drug, biologic, or device.”¹⁹⁰ For example, a CBE supplement may be appropriate if a postmarket study suggests a more severe and significant adverse reaction, but one would not be appropriate merely to provide additional data on a known adverse reaction.¹⁹¹

In explaining the reasoning behind this clarification, the proposed rule reiterates the policy arguments advanced by FDA in earlier amicus briefs. For example, the proposed rule explains that allowing sponsors to unilaterally amend labeling without limitation would undermine the FDA approval process.¹⁹² It also reiterates the policy reasons for preemption that the agency articulated in numerous amicus briefs: permitting a manufacturer to unilaterally add warnings “would disrupt FDA’s careful balancing of how the risks and benefits of the product should be communicated.”¹⁹³

The proposed rule could have significant consequences for preemption of state tort claims because it provides a more formalized expression of FDA’s view that the federal rules are supposed to be both a floor and a ceiling for labeling requirements. Commentators have already noted that “the proposed rule, if finalized, could give significant support to firms that invoke an FDA preemption defense in product liability cases where plaintiffs argue that firms should revise

¹⁹⁰ *Id.* at 2849.

¹⁹¹ FDA Law Blog, FDA Proposes to Codify Longstanding Policy for Making Labeling Changes for Approved Drugs, Biologics, and Medical Devices; Change Could Significantly Affect Preemption Defense (Jan. 23, 2008), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/01/fda-proposes-to.html.

¹⁹² *Id.*

¹⁹³ *Id.*

their own labeling in accordance with state law.”¹⁹⁴ The implications of this proposed rule for federal preemption of state tort claims will be discussed in more detail in Part IV. In the meantime, let it suffice to say that the proposed rule has invoked outrage among many commentators and members of Congress. On January 23, 2008, for example, several members of Congress sent a letter to FDA Commissioner Andrew von Eschenbach expressing their opposition to the proposed rule. In particular, the Congresspersons accused the FDA of abandoning its mission and instead attempting to protect pharmaceutical companies from being held liable for marketing products that they know are unsafe. In some of the sharpest language, the letter argued that “[t]he issuance of the proposed CBE rule is not an isolated case, but part of a pattern of actions in the Bush Administration’s final months to permanently insulate the drug and device industry from liability.”¹⁹⁵ In response, FDA continued to stay true to its preemption message — Stephen Mason, FDA’s acting assistant commissioner for legislation insisted that the proposals modifying the CBE proposals has become a high public health priority.¹⁹⁶

¹⁹⁴ FDA Law Blog, U.S. House and Senate Democrats Pen Letter to FDA Expressing “Profound Regret” Over FDA’s Proposed Labeling Rule (Jan. 28, 2008), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/01/us-house-and-se.html.

¹⁹⁵ Letter from Henry A. Waxman et al. to the Hon. Andrew C. von Eschenbach, M.D., Commissioner, U.S. Food & Drug Admin. 1 (Jan. 23, 2008), *available at* <http://oversight.house.gov/documents/20080123120931.pdf>. Numerous commentators have echoed the Congressmen’s accusation that FDA has been subject to industry capture. *See, e.g.* David Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 100 (2005) (“[B]y working hand-in-glove with industry to change the law on preemption, the Administration has given the public legitimate reason to question whether the FDA is serving the interests of the public or the industry it regulates.”).

¹⁹⁶ *See* Pete Mansell, *CBE Labeling Rule Does Not Let Manufacturers off the Hook, FDA Insists*, IN-PARMA TECHNOLOGIST.COM, Feb. 04, 2008, <http://www.in-pharmatechnologist.com/news/ng.asp?id=84385-fda-labelling-cbe> (quoting Stephen Mason).

One of the interesting aspects of the proposed CBE rule is the fact that both FDA and opponents of the rule have invoked the FDAAA to support their position. In the proposed rule, FDA explicitly argues that its understanding of the CBE provisions is supported by its enhanced authority to control drug labeling under the FDAAA.¹⁹⁷ Several members of Congress, on the other hand, have argued that FDA's proposed CBE rule contradicts Congress's intent when passing the rule of construction. According to Congressmen Spulak and others, Congress included the rule of construction to strike a balance between giving FDA authority to protect consumers from adverse reactions and "preserving the ability of Americans to pursue common law remedies."¹⁹⁸ The proposed rule, however, "directly contradicts this language by reversing a drug manufacturer's obligation to warn of new risks and hazards and, instead, allowing these companies to claim immunity from liability because they had no duty to warn."¹⁹⁹

IV. THE EFFECT OF THE FDAAA ON FDA PREEMPTION CLAIMS

In light of the opposing views on preemption and the lack of direct Supreme Court precedent on the issue, it is not surprising that lower court decisions concerning preemption of drug-related common law tort claims are split on whether FDA's authority over new drug approvals impliedly preempts some state law tort claims.²⁰⁰ In attempting to predict the holding

¹⁹⁷ FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (2006); *see also infra* Part IV (discussing the impact of the FDAAA on FDA preemption claims).

¹⁹⁸ Mansell, *supra* note 196 (quoting the Spulak letter).

¹⁹⁹ *Id.*

²⁰⁰ For example, *compare In re Bextra & Celebrex Marketing Sales Practices & Prod. Liability Litigation*, No. M:05-1699 CRB, 2006 WL 2374742 (N.D. Cal., Aug. 16, 2006); *Colacicco v.*

of the Supreme Court in a case like *Wyeth v. Levine*, it is important to consider the reasoning behind these cases, but it is also necessary to consider how the recent passage of the FDAAA changes the preemption landscape. As is true with any preemption analysis, in order to determine the preemption impact of the FDAAA, it is necessary to ascertain the intent of Congress.²⁰¹ As the Supreme Court has noted, the “purpose of Congress is the ultimate touchstone of pre-emption analysis.”²⁰² Courts divine the intent of Congress primarily through three sources: the plain text of the statute, the legislative history, and agency interpretations of the statute. This Part therefore analyzes each of these sources in the context of the FDAAA. Section A concludes that the text of the statute, in particular the rule of construction, is subject to varying interpretations, and is not likely to be conclusive. Section B likewise determines that the legislative history of the Act contains only conflicting statements by individual Congresspersons, none of which is dispositive on the issue of congressional intent. Section C argues that courts should instead give deference to FDA’s interpretation of the Act as contained in amicus briefs, the preamble to the 2006 format and content rule, and in the proposed CBE rule. Lastly, Section D concludes that as a policy matter, the increased surveillance and enforcement mechanisms contained in the FDAAA mitigate many of the concerns advanced by scholars against preemption of state product liability claims.

Apotex, Inc., 432 F.Supp.2d 514 (E.D.Pa.2006); *Needleman v. Pfizer Inc.*, No. Civ. A. 3:03-CV-3074-N, 2004 WL 1773697 (N.D. Tex., Aug.6, 2004); *Dusek v. Pfizer Inc.*, No. Civ. A. H-02-3559, 2004 WL 2191804 (S.D.Tex., Feb.20, 2004), with *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776 (E.D. La. 2007); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230 (E.D.N.Y. 2007); *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 676 (E.D. Ky. 2006); *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 685-87 (E.D. Pa. 2006).

²⁰¹ See *supra* Part III.A.

²⁰² *Cipollone v. Liggett Group, Inc.* 505 U.S. 504, 516 (1992) (internal quotation marks omitted).

a. The Text of the Rule of Construction

In recent years, the Supreme Court has emphasized that the plain text of the statute is the authoritative source for statutory interpretation, and is the appropriate place to begin when conducting such an analysis.²⁰³ The FDAAA text that most impacts the preemption analysis is the rule of construction.²⁰⁴ On one hand, the text of the provision seems to indicate that it does little to alter the preemption debate. The rule states that “This paragraph shall not be construed to affect the responsibilities or the responsible person. . . ,” therefore it only applies only to the provisions of FDAAA § 901, which merely describe the new authority for FDA to order manufacturers to conduct post market studies and clinical trials.²⁰⁵ Placed in the context of § 901, the rule of construction therefore emphasizes that the section does not displace existing FDA labeling rules, including the CBE rule.²⁰⁶ The text of the FDAAA, therefore, would not support arguments for or against preemption — instead, the previous provisions delineating manufacturer responsibilities must inform the debate.²⁰⁷

²⁰³ See, e.g., *Riegel v. Medtronic*, 128 S. Ct. 999, 1009 (2008) (“We have found it unnecessary to rely upon that agency view because we think the statute itself speaks clearly to the point at issue.”).

²⁰⁴ See FDCA § 505(o)(4)(I); see also *supra* notes 101-105 and accompanying text (discussing the rule of construction).

²⁰⁵ See *supra* notes 75-79 and accompanying text.

²⁰⁶ Astrazeneca’s Response to Plaintiff’s Supplemental Briefing Regarding AstraZeneca’s Motion for Judgment on the Pleadings on the Basis of Federal Preemption, *In re Seroquel Products Liab. Litig.*, MDL No. 1769 (M.D. Fla. Oct. 17, 2007).

²⁰⁷ *C.f.* CONG. REC. S11839 (Sept. 20, 2007) (statement of Sen. Coburn) (arguing that nothing in the rule of construction changes “FDA’s ultimate authority over drug labeling; nor is it intended to change the legal landscape in this area”).

However, the rule of construction has thus far been subject to widely varying interpretations in briefs and in the literature. Some scholars and commentators have taken the position that the rule of construction is a “savings clause” meant to indicate that the FDAAA provisions were not intended to have a preemptive effect. For example, David Kessler and David Vladeck have argued that, by codifying the manufacturer’s obligation to maintain its label in accordance with the existing CBE requirements, the rule of construction “undercuts the key pro-preemption argument the FDA and manufacturers make – namely, that the FDA alone decides the content of drug labels.”²⁰⁸ This view seems contradicted however, by the fact that Congress chose to drop a provision in the House version of the bill that would have expressly barred preemption claims.²⁰⁹

In light of the considerable uncertainty surrounding the rule of construction, the interpretation of the rule that is probably most correct is the one that holds that the issue of preemption should be left to the courts to decide in light of other provisions.²¹⁰ In light of the likelihood that courts may look beyond the plain text of the statute to determine congressional intent, I next examine the legislative history of the statute.

b. The Legislative History of the FDAAA

The legislative history is a natural starting place for ascertaining the congressional intent behind federal law, and litigants on both sides have already looked to the history of the FDAAA

²⁰⁸ David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 468-69.

²⁰⁹ See *infra* note 216 and accompanying text.

²¹⁰ ARNOLD & PORTER, *supra* note 48, at 8 (describing the rule of construct as an attempt “to leave it to the courts to address the preemptive effects of labeling actions.”).

to gain insight into Congress's intent and support their preemption arguments. For this reason, I spend some time reviewing the legislative history of the FDAAA with respect to the rule of construction and preemption of state tort law claims. However, I ultimately determine that the legislative history is inconclusive, and provides little compelling authority to support either side of the preemption debate.

The original House and Senate versions differ markedly in their positions toward preemption. The Senate version took a generally pro-preemption position, adopting language that “would have also implied that if a company was already in discussions with the FDA about the labeling issue, and attempting to determine if the labeling change was necessary, then a future lawsuit would have to argue how the company was acting in an improper way.”²¹¹ The House version, in contrast, initially contained savings-clause-like language asserting that the nothing in the new legislation would preempt state law products liability claims. The provision stated: “Nothing in this Act or the amendments made by this Act may be construed as having any legal effect on any cause of action for damages under the law of any State (including statutes, regulations, and common law).”²¹² The language tracked the anti-preemption language of the Occupational Health and Safety Act (“OSHA”),²¹³ which has been interpreted by several lower

²¹¹ See also CONG. REC. S11836 (Sept. 20, 2007) (statement of Sen. Allard) (arguing that “the FDA regulation would have ‘occupied the field’ with respect to liability for failure to warn”).

²¹² People Over Profits, Information on the Rule of Construction Regarding Federal Preemption, http://www.peopleoverprofits.org/site/c.ntJWJ8MPIqE/b.2804449/k.BC2F/Federal_Preemption.htm (reporting the text of the proposed savings clause).

²¹³ 29 U.S.C. § 653(b)(4). The savings clause in OSHA states: “Nothing in this chapter shall be construed. . .to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment.” *Id.*

courts to restrict the preemptive effects of OSHA regulations in tort suits.²¹⁴ Former FDA chief counsel Daniel Troy said that under at least one interpretation, the provision “would completely undercut FDA’s authority.”²¹⁵ At a hearing of the House Energy and Commerce Committee’s Health Subcommittee, panel Republicans and representatives of the FDA and drug and device manufacturers objected to the anti-preemption language,²¹⁶ and industry threatened to pull their support for the bill. A compromise was reached in the final version: the current rule of construction.

Determining the congressional intent behind the rule of construction is no easy task, however. Unfortunately, the legislative history available in the case of the FDAAA is particularly non-authoritative. Committee reports are “the authoritative source for legislative intent,”²¹⁷ but the House Report says nothing about the rule of construction, and there is no Senate Report or Conference Report. Therefore, the primary information about Congress’s intent when passing the Bill comes from the statements of individual speakers in the Congressional Record. These statements are by no means dispositive, however. The Supreme Court has

²¹⁴ See, e.g., *Lindsey v. Caterpillar, Inc.*, 480 F.3d 202, 209 (3d Cir. 2007); *Pedraza v. Shell Oil Co.*, 942 F.2d 48, 53 (1st Cir. 1991); *In re Welding Fume Products Liability Litigation*, 364 F. Supp. 2d 669, 686 (N.D. Ohio 2005).

²¹⁵ David Filmore, *Federal Preemption Defense Under Fire in Draft House Bills*, MEDICAL DEVICES TODAY, June 11, 2007, http://www.medicaldevicestoday.com/2007/06/federal_preempt.html (quoting Daniel Troy).

²¹⁶ Jeffrey Young, *Trial Lawyers’ Win on Suit Provision Threatens FDA Bill*, THE HILL.COM, June 15, 2007, <http://thehill.com/the-executive/trial-lawyers-win-on-suit-provision-threatens-fda-bill-2007-06-15.html>.

²¹⁷ *Thornburg v. Gingles*, 478 U.S. 30, 44 (1986).

recognized many times that “[f]loor debates reflect at best the understandings of individual Congressmen,”²¹⁸ and therefore are not controlling when analyzing the text of a statute.²¹⁹

Numerous litigants and commentators have nevertheless argued that the legislative history of the FDAAA indicates that the Act was not intended to preempt state tort claims.²²⁰ Indeed, the legislative history does contain some statements to support this view. For example, Senator Gene Green stated:

There is no question that the labeling and liability language prompted a great deal of debate during conference negotiations, but one thing is clear: the Congress in no way intends to limit the ability of a patient injured by a drug to seek redress from our Nation’s justice system. FDA should have the ability to require labeling changes, but that additional authority does not absolve the drug manufacturer of any duty to initiate labeling changes on their own when new data bears out the need for a change.²²¹

This sentiment was echoed in the House by Representative Waxman, who observed that “this legislation will make clear that, in giving FDA this labeling change authority, Congress does not intend to impact, in any way, a drug company’s responsibility to promptly update its label with safety information on its own accord.”²²²

However, some pro-preemption commentators have noted that many of the anti-preemption statements by Congresspersons relate to field preemption—not conflict preemption,

²¹⁸ *Zuber v. Allen*, 396 U.S. 168, 186 (1969).

²¹⁹ *See, e.g., Chrysler Corp. v. Brown*, 441 U.S. 281, 311 (1979) (“the remarks of a single legislator, even the sponsor, are not controlling in analyzing legislative history”); *accord* *General Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 599 (2004).

²²⁰ *See, e.g., Kessler & Vladeck, supra* note 208, at 468-69 (“The codification of this obligation undercuts the key pro-preemption argument the FDA and manufacturers make — namely, that the FDA alone decides the content of drug labels.”).

²²¹ CONG. REC. H10598 (Sept. 19, 2007) (statement of Rep. Green).

²²² CONG. REC. H10598 (Sept. 19, 2007) (statement of Rep. Waxman).

as is typically asserted in drug liability cases. Take, for example, Senator Kennedy's statement made when introducing the Senate version of the bill:

By enacting this legislation, we do not intend to alter existing state law duties imposed on a drug manufacturer to obtain and disclose information regarding drug safety hazards either before or after a drug receives FDA approval or labeling. We do not believe that the regulatory scheme embodied in this act is comprehensive enough to preempt the field or every aspect of state law. FDA's approval label has always been understood to be the minimum requirement necessary for approval. In providing the FDA with new tools and enhanced authority to determine drug safety, we do not intend to convert this minimum requirement into a maximum.²²³

Furthermore, some comments in the legislative history indicate that the Act was not intended to alter the current preemption standard. Take, for example, Senator Alexander's statement:

[T]his legislation reinforces FDA's broad authority over prescription drug labels. Under current law, States are preempted from substituting their judgment for the FDA's scientific decisions based on exhaustive reviews of clinical data. If this weren't the case, medicine labels would become so overwhelmed with warnings designed to avert lawsuits that most Americans will simply stop paying attention to them.

Additionally, Congress has decided to give FDA the authority to make expedited labeling changes, so that when prescription drug safety problems are identified the FDA and drug manufacturers can work together to quickly update product labels to ensure that the American people have the latest safety information. If a drug manufacturer comes to the FDA in good faith to discuss the possible need for an expedited labeling change—and if the FDA does not respond in a timely manner or decides that the science does not require a labeling change—then that drug manufacturer should not be subject to frivolous lawsuits.²²⁴

²²³ CONG. REC. S11832 (Sept. 20, 2007) (statement of Sen. Kennedy).

²²⁴ CONG. REC. S12050 (Sept. 25, 2007) (statement of Sen. Alexander).

Likewise, Senator Coburn argued that the Act stood to preempt state tort law claims.²²⁵ In contrast Senator Kennedy's contention that the FDCA established a floor for prescription drug labeling requirements, Senator Coburn stated: "I want to be clear that the FDA's labeling requirements establish both a 'floor' and a 'ceiling.'"²²⁶

Thus, culling a clear congressional intent from the legislative history is quite difficult. This not necessarily surprising, considering that Congress is often intentionally vague in passing laws, in order to obtain the necessary votes needed for the statute's passage.²²⁷ Indeed, although several Senators and Congresspersons indicated that Congress "clearly" objected to preemption in the legislation,²²⁸ ostensibly through the rule of construction, others recognized that the language of the provision is anything but clear. For example, Senator Enzi warned: "I am deeply concerned about the provisions related to labeling changes and liability, given that we do not fully understand the implications of that language. This new rule of construction was part of the House-passed

²²⁵ CONG. REC. S11839 (Sept. 20, 2007) (statement of Sen. Coburn) ("It is clear that Congress relies on the scientists at the FDA to assess safety risks and drug labeling and this should be squarely and solely the FDA's role. . . . The newly expanded role of the FDA does and should preempt State law when it comes to drug safety and labeling. In order to ensure scientific drug safety the last thing that we need is the regulatory nightmare of every State court being a mini-FDA.").

²²⁶ *Id.* at S11840.

²²⁷ See Copland, *supra* note 43 (discussing statements of NYU law professor Catherine Sharkey).

²²⁸ See CONG. REC. S11833 (Sept. 20, 2007) (statement of Sen. Kennedy) ("Congress has stated very clearly in the legislation that we do not intend the new authority being given to FDA to preempt common law liability for a drug company's failure to warn its customers of health risks."); *id.* at S.11834 ("The legislation we are set to pass today contains a rule of construction making clear that Congress has again decided that we are not preempting State law regarding the responsibility of drug manufacturers to immediately notify consumers of dangers without waiting for the FDA to act."); *id.* at S11835 ("The drug labeling provisions in today's legislation include a rule of construction that makes clear that Congress does not intend to preempt state requirements regarding drug companies' responsibilities.").

language as not something the Senate fully debated.”²²⁹ Thus, the legislative history of the FDAAA is unlikely to provide any definitive guidance to courts in conducting their preemption analysis.

c. Deference to FDA’s Interpretation of the FDAAA

In contrast to the text of the statute or the legislative history, FDA’s interpretation of the pro-preemption impact of the FDAAA is likely to be relevant to courts’ analysis. In fact, the agency’s position may be one of the more reliable predictors of how the Supreme Court is likely to rule on a preemption case. Professor Catherine Sharkey has argued that a trend towards agency deference has emerged in the Supreme Court’s recent products liability cases.²³⁰ She notes that “from *Cipollone* in 1992 to *Riegel* in 2008, the Supreme Court's position in every products liability preemption case (save one — *Bates*) aligned with the relevant underlying federal agency's take on preemption.”²³¹ A number of Supreme Court opinions have also emphasized that an agency’s intent to preempt state regulation will usually be decisive.²³²

An agency’s intent to preempt state regulation may take a variety of forms, however, from articulation in formal notice-and-comment rulemaking to less formal interpretive statements and rule preambles. FDA has generally adopted an informal tactic of expressing its

²²⁹ CONG. REC. S11833 (Sept. 20, 2007) (statement of Senator Enzi).

²³⁰ Sharkey, *supra* note 27, at 455.

²³¹ *Id.* at 471.

²³² See, e.g., *United States v. Shimer*, 367 U.S. 374 (1961); *City of New York v. FCC*, 486 U.S. 57, 64 (1988); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-700 (1984); *Fidelity Federal Savings & Loan Assoc. v. de la Cuesta*, 458 U.S. 141, 152-54 (1983).

preemption views in amicus briefs before courts deciding preemption questions. It also expressed its position in the preamble to the 2006 rule revising the format and content requirements for prescription drug labels.²³³ The use of these informal statements raises an interesting question of what level of deference that should be given to such statements. In the seminal case of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,²³⁴ the Supreme Court held that courts must grant deference to agency interpretations of statutes they administer if: (1) Congress has not “directly spoken to the precise question at issue,” and (2) the agency’s interpretation “is based on a permissible construction of the statute.”²³⁵ However, in the subsequent case of *United States v. Mead Corporation*,²³⁶ the Court clarified that such mandatory deference is only required when there is an “indication that Congress intended such a ruling to carry the force of law.”²³⁷ However, where an agency interpretation is not accorded Chevron deference, it may still be granted deference under the standard announced in *Skidmore v. Swift & Co.*²³⁸ The *Skidmore* standard is rather amorphous — though the agency interpretation is not controlling upon the courts under this standard, that courts has stated that such interpretations nevertheless “constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.”²³⁹ The court may accord the agency’s judgment the amount of deference it deems

²³³ See *supra* notes 183-188.

²³⁴ 467 U.S. 837 (1984).

²³⁵ *Id.* at 842-43.

²³⁶ 533 U.S. 218 (2001).

²³⁷ *Id.* at 221.

²³⁸ 323 U.S. 134 (1944).

²³⁹ *Id.* at 140.

appropriate based on the thoroughness of the agency's consideration, the validity of its reasoning, its consistency with other pronouncements, and "all those factors which give it power to persuade."²⁴⁰

Though some lower courts have accorded Chevron deference to FDA's preemption views as articulated in amicus briefs and the preamble to the 2006 format and content rule,²⁴¹ dicta in the recent case of *Riegel v. Medtronic, Inc.* indicates that the Supreme Court would be unlikely to adopt this view. The court indicated that had the relevant statute been ambiguous in that case, "Skidmore deference would seemingly be at issue" when considering the statements in FDA's amicus brief.²⁴² The Court also implied that under *Skidmore*, "the degree of deference might be reduced by the fact that the agency's earlier position was different."²⁴³ However, the Court seems to recede from this position, stating: "But of course the agency's earlier position . . . is even more compromised, indeed deprived of all claim to deference, by the fact that it is no longer the agency's position."²⁴⁴ Thus, it is somewhat difficult to predict what deference, if any, the Court would accord FDA's position in its amicus brief in *Wyeth v. Levine*. The opinion in *Medtronic* seems to imply that this position would receive some deference, though the degree would be reduced because of the FDA's changed preemption position.

Fortunately, this particular issue may become less relevant when analyzing the agency's interpretation of the rule of construction, because the agency has set forth its interpretation of

²⁴⁰ *Id.*

²⁴¹ See Sharkey, *supra* note 27, at 513 n.304 (citing cases).

²⁴² *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1009 (2008) (citing *United States v. Mead Corp.*, 533 U.S. 218, 229-233 (2001)).

²⁴³ *Id.*

²⁴⁴ *Id.*

that provision in a proposed rule. If the rule is finalized, it will constitute a formalized expression of FDA’s pro-preemption position, deserving of *Chevron* deference. Under *Chevron* deference, courts will defer to the agency’s view if it is “reasonable.”²⁴⁵ Especially in light of the Supreme Court’s recent decision in *Medtronic*, it is unlikely that a court would determine that FDA’s pro-preemption position is unreasonable. Thus, the FDAAA, combined with the 2008 proposed rule, constitutes a powerful tool supporting the agency’s preemption agenda.

d. The Impact of Other FDAAA Enforcement Provisions

As a policy matter, deferring to the agency’s position may also be a wise decision. Professor Catherine Sharkey has argued that “with respect to answering the key regulatory policy issue at the heart of the preemption query — namely, whether there in fact should be a uniform federal regulatory policy — federal agencies emerge as the institutional actor best equipped to provide the answer.”²⁴⁶ In the context of prescription drug labeling and warnings, FDA has repeatedly argued that the agency possesses the necessary expertise to determine the optimal regulatory strategy. Previous cases indicate that the Court would be receptive to recognizing the agency’s relevant expertise: In *Geier*, for example, the Court found it appropriate to defer to agency views in light of the fact that “the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is ‘uniquely qualified’ to comprehend the likely impact

²⁴⁵ *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984).

²⁴⁶ Sharkey, *supra* note 27, at 477.

of state requirements.”²⁴⁷ Similarly, Justice Breyer, who wrote the *Geier* opinion, expressed this view in a concurring opinion in an earlier case, *Bates v. Dow Agrosciences LLC*,²⁴⁸ when he argued that “the federal agency charged with administering the statute is often better able than are courts to determine the extent to which state liability rules mirror or distort federal requirements.”²⁴⁹ This line of cases indicates that the Court may be positioned to accord deference to FDA’s views on preemption in upcoming cases.

Furthermore, the additional enforcement provisions in the FDAAA may also help rebut several of the key objections leveled against this sort of argument. Former FDA Commissioner Dr. David Kessler and Professor David Vladeck, for example, argue that FDA’s pro-preemption arguments are based on “an unrealistic assessment of the agency’s practical ability – once it has approved the marketing of a drug – to detect unforeseen adverse effects of the drug and to take prompt and effective remedial action.”²⁵⁰ The expansive surveillance and enforcement provisions of the FDAAA discussed in detail in Part III, however, provide FDA with new ability to detect drug risks and adverse effects. Thus, on the eve of *Wyeth v. Levine*, FDA is on stronger ground than ever in asserting its preemption claims.

V. CONCLUSION

In light of the billions of dollars potentially at stake for litigants in drug-related products liability claims, it is not surprised that the preemption debate has captured the

²⁴⁷ *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996)).

²⁴⁸ 544 U.S. 431 (2005).

²⁴⁹ *Id.* at 455 (Breyer, J., concurring).

²⁵⁰ Kessler & Vladeck, *supra* note 208, at 465.

legal community. Nevertheless, despite the fierce debate, little consensus has emerged among either commentators or the courts on whether the labeling provisions of the FDCA preempt common law products liability claims. The recent and extremely significant legislation embodied in the FDAAA adds only additional uncertainty to the legal landscape for preemption.

The upcoming Supreme Court case of *Wyeth v. Levine* makes it imperative that scholars and commentators continue to dissect the numerous provisions of the FDAAA to try and assess the impact of this extremely complex bill on drug-related preemption claims. What is the significance of the FDA's expanded enforcement and surveillance powers, post-market risk identification system, or clinical trials database, for example? This Paper represents an initial attempt to answer this question and analyze the complex text and history of the FDAAA in the preemption context. In light of the unclear "rule of construction" in the Act, and the equally obscure legislative history, this Paper concludes that by strengthening FDA's powers, the FDAAA may also have strengthened FDA's claim for preemption. By increasing the FDA's ability to effectively regulate drug efficacy and safety, the FDAAA put the agency on stronger ground when claiming ultimate authority over drug labeling.