

THE CASE FOR FIELD PREEMPTION OF STATE LAWS IN DRUG CASES[†]

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INTRODUCTION: PREEMPTION IN FLUX

Catherine Sharkey's essay, *What Riegel Portends for FDA Preemption of State Law Product Liability Claims*, represents an ingenious effort to work between the horns of the most pressing dilemma in today's law of federal preemption with her "agency reference model" of preemption.¹ This issue is hot today because the Supreme Court recently held in *Riegel v. Medtronic, Inc.* that the Medical Devices Act preempted a plaintiff's state product liability claims alleging defective design of a balloon catheter after plaintiff suffered grievous injuries when the device ruptured inside his right coronary artery.² It is worthy of note that here the treating physician made two controversial decisions: (1) he used the catheter on a patient whom FDA warnings classified as unfit for the treatment, and (2) he overinflated the catheter.³

The problem of FDA preemption also arises in the context of a drug manufacturer's duty to warn in a closely watched case recently argued before the Supreme Court, *Wyeth v. Levine*.⁴ In that case, the Vermont Supreme Court upheld a damage award on the ground that Wyeth should have warned the plaintiff against using its drug, Phenergan, in a risky procedure that the FDA had explicitly authorized. More specifically, the FDA-approved warning label allowed Phenergan to be injected intravenously by a so-called "IV push," or rapid injection into a vein by syringe, so long as

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¹ Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437 (2008) [hereinafter Sharkey, *What Riegel Portends*].

² *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

³ *Id.* at 1005.

⁴ *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006) (sustaining jury verdict), *cert. granted*, 128 S. Ct. 1118 (U.S. Jan. 18, 2008) (No. 06-1249).

physicians were alert of the risk of hitting an artery instead of a vein. The plaintiff suffered gangrene and consequent loss of a limb when the IV needle mistakenly punctured the artery. Plaintiff argued that Wyeth's label "should not have allowed IV push"—*period*.⁵

To understand the legal issues raised by these two cases, it is useful to set the background with a thumbnail sketch of the modern law of preemption. All parties agree that some principles of interpretation are needed to work out the interrelationships between federal and state law, broadly conceived, that covers the same sphere of action. It is understood as well that the law of preemption divides itself into two halves. The first half deals with *express* preemption, which holds that if the federal government makes it clear—itsself a term that turns out often to be unclear—that its statute preempts the state law, then the issue is over. Under the Supremacy Clause⁶ of the United States Constitution, the lowliest federal action trumps the most grandiose state pronouncement. Conversely, if the federal statute makes it clear that the state law may peacefully coexist with it, a system of dual enforcement is appropriate.

In many cases, of course, the question of preemption is not resolved by *express* preemption, at which point the common view holds that there are three possible grounds for *implied* preemption. The strictest standard allows for preemption only in cases of *actual conflict*, such that there must be a clear inconsistency between what the federal government and the state government each allow or require. Second, it is often stated that the preemption in question only arises in those cases where the imposition of the state liability will *frustrate* the ends of the federal statute. Finally, a third form of preemption argues that preemption does not require this form of explicit conflict, but is satisfied if it appears that the federal statute has *occupied the field*, blocking state efforts to impose sanctions within that field even if there is no explicit conflict. For our purposes, the first and third forms of preemption are the most relevant ones. Drug cases are more problematic than device cases because the Medical Devices Act does contain an explicit preemption provisions for medical devices, in contrast to drug cases, which are subject to no explicit form of preemption.⁷

Professor Sharkey's distinctive contribution to this debate is her careful elaboration of the "agency reference model" of preemption, which enriches the debate over preemption by consciously incorporating administrative law

⁵ *Id.* at 182.

⁶ U.S. CONST. art. VI, cl. 2.

⁷ See Medical Device Amendments of 1976 § 521, 21 U.S.C. § 360k (2006):

(a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter 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 chapter.

principles resting on the twin pillars of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*⁸ and *Skidmore v. Swift & Co.*⁹ Sharkey's "agency reference model" treats *Chevron* and *Skidmore* as defining an administrative universe in which the level of deference given an administrative action increases with thoroughness and formality of the processes that generate the disputed ruling.¹⁰ Sharkey's proposal, elaborated with her customary vigor and clarity in her article on *Riegel*, explains how the key interpretive tools of the administrative state can shed light on the preemption question.

This brief Essay renews my defense of strong field preemption for FDA regulation. In Part I, I shall set out the emergence of modern preemption law in light of the vast expansion of federal power after the New Deal with special reference to two cases of great current concern, *Riegel*¹¹ and *Levine*.¹² Thereafter, in Part II, I shall comment first not on Professor Sharkey's article, but on a recent essay by David Kessler and David Vladeck that takes the strong view that the doctrine of implied preemption should not be applied in duty-to-warn drug cases.¹³ Then, in Part III, I address Professor Sharkey's agency model, and, lastly, in Part IV I offer a brief capitulation of my field preemption position.

I. PREEMPTION AFTER THE NEW DEAL

Historically, the consolidation of the New Deal administrative state meant the federal government faced few, if any, limitations on the scope of its power given the expansive reading of the Commerce Clause.¹⁴ This rapid expansion of federal power took place in an environment highly sympathetic to regulation at both the national and the state levels. State powers of regulation have never been constrained by the federal constitutional doctrine of enumerated powers. But post-1937, the broad construction of the Commerce Clause gave the federal government total power to regulate in areas formerly reserved to the states, except in the most marginal of cases.¹⁵

⁸ 467 U.S. 837 (1984).

⁹ 323 U.S. 134 (1944).

¹⁰ For a discussion of the various ins and outs of judicial deference to administrative decisions, see Kristin E. Hickman & Matthew D. Kreuger, *In Search of the Modern Skidmore Standard*, 107 COLUM. L. REV. 1235 (2007), and Thomas W. Merrill, *The Mead Doctrine: Rules and Standards, Meta-Rules and Meta-Standards*, 54 ADMIN. L. REV. 807 (2002).

¹¹ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

¹² *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006) (sustaining jury verdict), *cert. granted*, 128 S. Ct. 1118 (U.S. Jan. 18, 2008) (No. 06-1249).

¹³ 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 (2008).

¹⁴ U.S. CONST. art. I, § 8, cl. 3. For the classic defense of the expansive view of the Commerce Clause, see Robert Stern, *The Commerce Clause and the National Economy*, 59 HARV. L. REV. 645 (1946).

¹⁵ See Richard A. Epstein, *The Federalism Decisions of Justices Rehnquist and O'Connor: Is Half a*

Riegel and *Levine* offer an effective window around which to organize a discussion of preemption in the modern regulatory debate. What should be done to ease the tension that arises when state and federal governments regulate concurrently, arguably in inconsistent ways? We should not work ourselves into a deep philosophical funk that regards the federal government as congenitally unable to speak with a clear voice. Of course it can be done.¹⁶ However, as Sharkey rightly points out, passing federal regulation is not merely a grammatical exercise. It is also a highly political one, where sides jockey for position on the key question of whether state actions will be allowed in an area once the federal government has entered the field. This tension is real enough when both the federal and state government act through regulation. The federal statutes clearly preempt state “requirements” resulting from direct legislative or administrative action. The question of whether common law actions that can compel action are preempted is much closer, and has elicited a wide range of statutory responses.¹⁷ The stakes have become a thousand-fold more salient in light of the vast expansion of tort law since the adoption of the Second Restatement of Torts, which was published in 1966. All too often Congress combines a provision that first preempts state law but then expressly preserves common law rights of action.¹⁸ What’s a judge to do when Congress tries to square the circle?

Generally speaking, three schools of thought have arisen to deal with this question. The first of these rests on what is commonly termed the “presumption against preemption,” which means that all doubtful statutes should be construed in ways that do not block the imposition of additional sanctions at the state level. Justice Douglas’s famous passage in *Rice v.*

Loaf Enough?, 58 STAN. L. REV. 1793, 1801–04 (2006). The decision in *United States v. Lopez*, 514 U.S. 549 (1995), struck down a statute that prohibited the possession of firearms within 1,000 feet of a school. But in so doing it solidified the holding in *Wickard v. Filburn*, 317 U.S. 111 (1942), which is the current fount of federal power. See *Gonzales v. Raich*, 545 U.S. 1, 16–17 (2005) (“Our case law firmly establishes Congress’ power to regulate purely local activities that are part of an economic ‘class of activities’ that have substantial effect on interstate commerce. . . . As we stated in *Wickard*, ‘even if appellee’s activity be local and though it may not be regarded as commerce, it may still . . . be reached by Congress if it exerts a substantial economic effect on interstate commerce.’”) (quoting *Wickard*, 317 U.S. at 125).

¹⁶ Easy cases are in practice hard to find, in part because the only cases that make it to the Supreme Court have some genuine difficulty. One candidate for the easy class is *United States v. Locke*, 529 U.S. 89 (2000), preempting various state efforts to impose comprehensive regulation of interstate vessels while in state waters.

¹⁷ Compare *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), with *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431 (2005).

¹⁸ See Sharkey, *What Riegel Portends*, *supra* note 1, at 438 n.5 (citing National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1392(d) (1988) (current version at 49 U.S.C. § 30103(b) (2000)) (preemption clause); *id.* § 1397(k) (current version at 49 U.S.C. § 30103(e) (2000)) (savings clause); Consumer Product Safety Act, 15 U.S.C. § 2075(a) (2000) (preemption clause); *id.* § 2074(a) (savings clause); Federal Boat Safety Act of 1971, 46 U.S.C. § 4306 (2000) (preemption clause); *id.* § 4311(g) (savings clause)).

Santa Fe Elevator Corp. put it as follows:

Congress legislated here [on the matter of warehouse receipts] in a 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. Such a purpose may be evidenced in several ways. 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. Or the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. Likewise, the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose. Or the state policy may produce a result inconsistent with the objective of the federal statute. It is often a perplexing question whether Congress has precluded state action or by the choice of selective regulatory measures has left the police power of the States undisturbed except as the state and federal regulations collide.¹⁹

This passage has a Job-like quality, for what the Court giveth in the first sentence—the need to show a clear and manifest purpose—it taketh away in the three enumerated exceptions. Hence the tripartite debate. Ernest Young argues that the *Rice* presumption should be broadly read to preserve the historic role of the states in local regulation.²⁰ This view favors *no* implied preemption.

At the opposite extreme, according to the second school of thought, the arrival of federal regulation is held to transform the regulatory universe. This view, which I have defended with Michael Greve, insists that concurrent regulation mistakenly ratchets up government control so that the most intrusive regulator always wins. It therefore adopts the view of *field* preemption: let the regulation cover the topic, and the state intervention is banned.²¹ The third position, which Sharkey champions, falls in the middle. It avoids the strong presumption against concurrent regulation and insists that there be some demonstration of an actual *conflict* before the state rules are shown. Let us turn now to the various positions.

II. THE KESSLER-VLADECK POSITION

In their article entitled *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, Kessler and Vladeck begin their analysis of drug preemption cases by addressing institutional issues. They claim

¹⁹ 331 U.S. 218, 230–32 (1947) (citations omitted).

²⁰ Ernest Young, *Federal Preemption and State Autonomy*, in *FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS* 249 (Richard A. Epstein & Michael S. Greve eds., 2007).

²¹ See Richard A. Epstein & Michael S. Greve, *Introduction: Preemption in Context*, in *FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS*, *supra* note 20, at 1; Richard A. Epstein & Michael S. Greve, *Conclusion: Preemption Doctrine and Its Limits*, in *FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS*, *supra* note 20, at 309.

that the FDA performs admirably but is constrained by limited resources, which leads to mistakes of wrongfully letting dangerous drugs onto the market. Accordingly, they see the private state tort action as an important backstop to administrative failure by creating a second chance to correct the mistakes in the original FDA process.²² They further argue that this *ex post* review has significant advantages because it can rely on information about drug safety, side effects, and effectiveness that accumulates only after a drug is extensively used on the market. As a textual matter, Kessler and Vladeck note that the Food and Drug Administration Amendments Act of 2007 (FDAAA)²³ offers no safe harbor for pharmaceutical companies because it reaffirms their ability under the FDA's warning system to update their warnings based on newly acquired information.²⁴ Finally, they pooh-pooh the FDA's 2006 Preemption Preamble which announces its new-found conclusion that its warning labels preempt any state law judgment to the contrary.²⁵

Initially, much of their proposal builds on the presumption against preemption, which gains strength from the obvious contrast between the Medical Device Act, which created preemption in *Riegel*,²⁶ and the want of any preemption provision dealing with drugs, as in the *Levine* case. But even this point is not as clear as they claim. *Levine* presents a situation where the FDA gave explicit approval to the exact treatment, notwithstanding the precise side effect mentioned in the original warning. That warning, moreover, was not some slapdash or casual affair. In 1973, Wyeth's supplemental application to the FDA contained an explicit warning of the risk of arterial contamination, and that warning was strengthened in 1979 and 1997 on further petitions of Wyeth to the FDA.²⁷ The precise warnings were emphatic, as is evident from the text set out in the margin.²⁸ Sharkey seems clearly

²² Kessler & Vladeck, *supra* note 13, at 467, 477, 483–95.

²³ Pub. L. 110-85, 120 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.).

²⁴ See Kessler & Vladeck, *supra* note 13, at 468–69.

²⁵ *Id.* at 473–74. For a critical discussion of the FDA maneuver, see Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007).

²⁶ See David Vladeck, Summary of Remarks to Medical Device Preemption Conference Participants (July 22, 2008) (unpublished manuscript, on file with author) (discussing Professor Vladeck's rejection of *Riegel*).

²⁷ See James Copland & Paul Howard, The Case for FDA Preemption and Administrative Compensation 13–14 (2009) (unpublished manuscript, on file with author).

²⁸ The insert warning reads as follows:

Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Phenergan Injection, usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances.

Id. at 14. The package label also stressed twice in bold, uppercase letters: "INTRA-ARTERIAL INJECTION [CAN] RESULT IN GANGRENE OF THE AFFECTED EXTREMITY." *Id.*

correct when she notes that the FDA warnings covered the case.²⁹ Against this backdrop what would count as new information to render that explicit authorization obsolete? The mere occurrence of the identified side effect can't do it because it was warned of in advance. And in *Levine* the sketchy record reveals no evidence collected after the drug hit the market indicating a higher incidence of this failure (and perhaps others) that might call for a reevaluation of the risk/reward ratio for that procedure. But making that determination is hard because new information comes in dribs and drabs, ruling out some defining moment at which the new warning is mandated. Extensive litigation could easily produce a breakdown of uniformity, which the FDA has rightly decried. The FDAAA does not solve that issue.

In addition, the structural flaws in the Kessler-Vladeck approach are still more profound because of the simplistic way that they integrate the litigation process with the FDA approval process. Kessler and Vladeck consider only one kind of error in the drug approval process: its willingness to allow dangerous drugs, like Vioxx, on the market. But two kinds of errors are evident: letting drugs on the market that should be kept off and taking drugs off of the market that should be left on.³⁰ The FDA is buffeted with strong criticisms as many scholars and industry observers deplore its risk-averse attitude.³¹ I recently helped organize a conference on the FDA role in oncology cases with the American Enterprise Institute, where oncology experts reinforced this point by claiming that the FDA did not have the expertise to do state of the art review.³² Kessler and Vladeck are wrong to suppose that the undermanned and intellectually outgunned FDA will simply roll over by allowing new treatments onto the market. Quite often these

²⁹ On this point, the evidence seems powerful:

The bottom line is that the *Levine* Court upheld common-law actions for negligence and failure-to-warn in the face of not one, but two, specific determinations by the FDA regarding the precise regulated risk. The FDA-approved label warned of the risk of harm that transpired in the case . . . [and.] [a]fter initial approval, the manufacturer proposed a different warning to the FDA . . . and was told to “[r]etain verbiage in current label.”

Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 507 (2008).

³⁰ The point was made in at least one of the amicus curiae briefs submitted on behalf of Wyeth:

Because the harmful side-effects of the drug may be highly visible, a Type I error can and often does lead to impassioned criticism of the agency. On the other hand, a Type II error—the failure to permit marketing of a drug that would in fact provide benefits in excess of harms—is typically known only by the relatively few persons who are intimately involved in developing the drug and are largely hidden from patients and the larger medical community

Brief of John E. Calfee et al. as Amicus Curiae Supporting Petitioner at 7–8, *Wyeth v. Levine*, No. 06-1249 (U.S. June 3, 2008), 2008 WL 2322237, at *7–8. (cited in Copland & Howard, *supra* note 27, at 7 n.6.

³¹ See, e.g., Peter Loftus, *Drug Approvals Hit Hurdles*, WALL ST. J., Nov. 7, 2007, at B5A; Anna Wilde Mathews, *FDA Taps Chief for Drug Center Amid Scrutiny*, WALL ST. J., Mar. 11, 2008, at B10.

³² For more information on this conference, entitled *Oncology Drug Development: Rethinking FDA Oversight*, including event materials and audio and video recordings, see the AEI website, http://www.aei.org/events/eventID.1666,filter.all/event_detail.asp.

insecurities translate into a systematic reluctance to let many drugs on the market, lest the agency has to pay a political price if something goes wrong. That cautious form of institutional protectionism translates into ever longer clinical trials and administrative delays. All in all, the real risk is that too few drugs will reach the market, not too many.

After recognizing these two forms of error in regulation, the role of litigation in the FDA approval process is even more problematic. Where the FDA incorrectly blocks a drug from entering the market, litigation can do nothing to correct that error. Where the regulatory process lets drugs correctly on the market, litigation remains costly even if it vindicates the defendant. Worse still, litigation has disastrous consequences if safe and useful drugs are subject to extensive tort liability. Yet Kessler and Vladeck consider only the scenario where the permit is incorrectly granted, and litigation rightly imposes liability, presumably at the right financial levels. Why ignore those unwelcome possibilities, where judicial intervention through the tort system may only compound the errors of an overly harsh regulatory regime? In evaluating the role of the tort system, it is wrong to consider only those instances where it may do some good, albeit at a high cost, while ignoring the frequent instances where its use is either costly or harmful. The complete analysis must cover all possibilities.

At this point, we must ask whether the error rates in litigation will be low enough to make their system work. Probably not, for a number of reasons. First, litigation comes too little, too late. The drugs that usually generate the most litigation—such as Rezulin and Vioxx—usually are withdrawn before litigation commences. Indeed the plaintiffs' bar rightly free rides on FDA determinations, reducing the social gain from litigation.

Second, Kessler and Vladeck offer no defense of the soundness of the current tort system whose problems are legion. Litigation does not simply ask if FDA warnings are adequate. It must also decide knotty questions of causation: Did this drug, or the excess amounts of the drug, cause the plaintiff's malady? Would the needed information have changed the plaintiff's decision to use the drug? These questions are hard to disentangle for plaintiffs suffering from multiple ailments treated by multiple drug regimens. Often, no one knows for sure if a particular drug has been taken at all, taken in the right amounts, at the right time, or in the prescribed fashion. Likewise, liability determinations cannot isolate the effect of a given warning in any individual case. In contrast, the preemption rule forces the ex ante determination of the relevant issues, free from the distractions of any complex tort litigation.

The fact patterns of *Riegel* and *Levine* illustrate some of the complications in using the litigation process. In *Riegel*, the treating physician inflated the balloon to ten atmospheres of pressure when it was only rated at eight atmospheres. He also used the balloon in a patient who was not rated

as a suitable candidate.³³ Does his decision to ignore the label restrictions qualify as medical malpractice? Not if the decision was made by conscious choice instead of simple neglect. If other treatments have little chance of success, the doctor may rightly decide to take a long-shot by ignoring the warnings, and the jury may decline to impose malpractice liability.³⁴ So forget about preemption for the moment—does it make sense to hold the manufacturer liable for the physician's choice because the outcome may have been unforeseen, or even foreseen but consciously disregarded? We are not dealing here with teenagers who speed at 100 miles per hour on tires rated only for 80 miles per hour. We are dealing with devices that go through professional channels such that the upstream player should never be held accountable for the mistakes of the downstream players. If a state law finds liability, should Medtronic now rate its balloon for use only at six atmospheres—and run the risk that the people in the seven and eight atmospheres category will go without treatment? No way.

Similarly, in *Levine*, we know that the risk of arterial puncture is ever present. But who has better knowledge of the magnitude of the risk in a particular patient, the company that supplies Phenergan or the physician who can look at the condition of the patient's veins and arteries? Here again the drug warnings are instructive about what can go wrong:

When used intravenously, Phenergan Injection should be given in a concentration no greater than 25 mg per mL and at a rate not to exceed 25 mg per minute. When administering any irritant drug intravenously, it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.³⁵

Yet it turns out that this recommendation was not followed in this case. The dangerous procedure should clearly be performed by a physician or someone who is fully trained in these procedures. But in this particular case, the injection was performed by a physician's assistant who did the push at 25 mg per mL.³⁶ It is not clear exactly why the rate of injection is relevant, but it could well be that the greater rate was a downstream error that magnified the risk. Nor is there anything to the point that this warning contains the words "usually preferable," for they only refer to how the intravenous injections should take place if done. They do not displace the strong warnings against use of the IV push in the first place.

These variations in downstream matter because they show that the physician is in the best position to determine if a treatment that is undesirable in some patients is desirable in others, and of course to decide *who* will

³³ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1005 (2008).

³⁴ *See, e.g., Morlino v. Med. Ctr. of Ocean County*, 706 A.2d 721 (N.J. 1998) (holding that disregarding standard instructions on use of Ciprofloxacin is not conclusive evidence of medical malpractice).

³⁵ Copland & Howard, *supra* note 27, at 14.

³⁶ *Id.* at 14 n.17.

do the administration. It is in fact dangerous for the company to recommend that all physicians avoid the IV push if the other treatment options turn out to be more dangerous. The field preemption rule thus protects patients from the systematic errors of the tort system. On policy grounds, nothing commends the Kessler-Vladeck proposal.

III. SHARKEY'S AGENCY MODEL

Sharkey's agency proposal is superior to the Kessler-Vladeck position because of its greater willingness to accept conflict preemption. Therefore, her proposal would allow Wyeth to keep its case from the jury if the particular point in dispute was subjected to intensive agency review. In her words, "courts need a fine-grained account of the precise regulatory review conducted by the agency and evidence as to its compatibility with state law tort claims."³⁷ Moreover, that inquiry cannot be made on a blank record, but is intended "to facilitate input from federal agencies on these issues."³⁸ In doing so, "it is critical to discern whether the FDA has weighed in on the precise risk the state tort action likewise seeks to regulate."³⁹ In the end, her position leads to *Skidmore* deference, which asks whether the agency determination has the "power to persuade."⁴⁰ This deference in turn depends on "the thoroughness evident in its consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements."⁴¹

Sharkey's proposal thus allows the FDA to insert itself between a drug manufacturer and tort liability. And on this record it seems clearly to call for preemption, which is all to the good. But a general doctrine of preemption has to cover the full range of cases, not just the easy one. And in this regard the flexibility of Sharkey's agency model comes at too high a price. The successful application of the *Skidmore* standard depends in large measure on the number of occasions in which its far-reaching inquiry is needed. *Skidmore* involved a one-and-done dispute over whether all workers who were required to be on-call at night were entitled to overtime pay under the Fair Labor Standards Act.⁴² The case needed a single fact determination, without obvious repetition. The administrative agency only made one key decision about basic policy, which was done without any knowledge of, or concern with, the facts and circumstances of any particular case. *Skidmore* decided only that the Administrator's rulings had to be taken into evidence in the case, where it was entitled to some respect.⁴³

³⁷ Sharkey, *What Riegel Portends*, *supra* note 1, at 441.

³⁸ *Id.*

³⁹ *Id.* at 446.

⁴⁰ *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

⁴¹ *Id.* See also Sharkey, *What Riegel Portends*, *supra* note 1, at 447 n.48.

⁴² 29 U.S.C. § 207 (2000).

⁴³ *Skidmore*, 323 U.S. at 140.

Those burdens are trivial compared to wading through the normal complex FDA record. In addition, this onerous task would have to be done in thousands of separate cases. The sheer weight of litigation would open up the possibility of third-party depositions of present and past FDA employees, and extensive discovery of FDA doctrines. *Skidmore* is not scalable, and its huge protracted battles over preemption may only be a prelude for the underlying litigation. The simplest approach in these cases is to follow the kinds of information that was introduced in *Skidmore*, namely a broad statement of policy. In this context, this approach would exclude all the particular FDA judgments in reviewing the drug, but not the Preemption Preamble, which would be admissible to give some indication of the FDA's policy. Without this sort of restriction, the Sharkey inquiry in *Levine* could collapse into the approach of Kessler and Vladeck, barring preemption across the board.

The Sharkey proposal would also undermine long-term administrative stability. As she duly notes, my earlier piece on preemption describes the dangers of agency flip-flop, often in response to intense lobbying pressures from all sides.⁴⁴ For example, if the Preemption Preamble tipped the balance in favor of preemption under *Skidmore*, that precarious result could be gone with the present change of the guard in the White House and in the FDA. Given the billions of dollars at stake, that flip-flop will not be a simple random event. It will be a target of opportunity that will embolden lobbyists of all stripes. Those changes flout any notion of a rule of law as a set of stable social expectations.⁴⁵

Finally, Sharkey's proposal does not correct the deficient error-cost analysis in the Kessler-Vladeck plan. Nor does it take into account the substantive weaknesses of the current duty to warn law in most states, with the high risks of false positives on liability. The proposal's ex ante effects are also likely to deter new drug innovation by adding private law sanctions to the impressive administrative obstacles that now impede new drug development. Finally, its helter-skelter results undermine the uniformity that grounds the public acceptance of the law.

IV. FIELD PREEMPTION

By process of elimination, only field preemption remains standing. I shall not rehearse the case for this position again here, except to note that Wyeth did not appear to rely on it before the Supreme Court.⁴⁶ However, I

⁴⁴ Sharkey, *What Riegel Portends*, *supra* note 1, at 448 & n.54 (citing Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT L. art. 5, at 15 (2006), available at <http://www.bepress.com/jtl/vol1/iss1/art5/>).

⁴⁵ For my views on this point, see Richard A. Epstein, *Why the Modern Administrative State is Inconsistent with the Rule of Law*, 3 N.Y.U. J.L. & LIBERTY 491 (2008).

⁴⁶ See Transcript of Oral Argument at 11, *Wyeth v. Levine*, No. 06-1249 (U.S. Nov. 3, 2008), 2008 WL 4771230, at *11 (“[W]e are not seeking here a rule of field preemption.”) (Seth P. Waxman, counsel

do wish to add one point that I have since developed elsewhere. It is a mistake to think that the only ways to secure public health are through some combination of sanctions through the FDA permit system and the tort system. Right now an impressive role in monitoring product safety is played by intermediate organizations such as the National Comprehensive Cancer Network, which supervises the clinical use of off-label drugs, that is, those which are taken for one indication, although they actually received FDA approval for another.⁴⁷ This voluntary system is quick on the uptake and gets information on adverse events out to the profession faster than the dilatory FDA processes and the interminable tort litigation. So, it seems unwise to handle the issue of drug information by coercion when persuasion is still available. It is one way in which we can get more for less.

for petitioner).

⁴⁷ See Richard A. Epstein, *Against Permittitis: Why Voluntary Organizations Should Regulate the Use of Cancer Drugs* (Mar. 13, 2008) (American Enterprise Institute, Conference Paper), *available at* http://www.aei.org/docLib/20080314_EpsteinPaper.pdf. For the NCCN website, see <http://www.nccn.org/>.