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Symposium held at the New York University School of Law
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*HON. GUIDO CALABRESI**

It is great to be here, both because it is always nice to come to NYU, and also because it is nice to see so many friends, old and new, among the people who are visiting NYU. Today, we are talking about preemption. This issue deals not just with the question of torts and pharmaceuticals: It deals with some of the deepest questions we have before us in terms of regulation and incentives in a time of crisis.

It seems to me, speaking as an academic and not as a judge, that there has been a tendency for courts to view the topic of preemption very narrowly and to lose many of the nuances that are really involved. Judges view preemption questions in terms of the case coming before them, and they give binary, yes or no, answers. But most of the issues are more complicated. I am going to try to sort out some of these issues, which are often conflated in the cases.

The first question that has to be asked is: Does national centralized decision-making, as between safety and accidents—and as to who bears the cost of safety or the cost of accidents—work better than local, diverse, and diffuse decision-making? Does one want localities deciding these questions in a variety of different ways, both in terms of who bears the cost and what the cost-benefit is, or is the decision best made nationally and uniformly? This question has several different aspects to it. For example, what are the added costs of having a variety of different cost-benefit decisions made? What are the costs that come from having one place do one thing and another place do another?

The second question is: What are the benefits of allowing different local decisions? We all know, and repeat, the Brandeisian

† This is a modified transcript of remarks given by Hon. Guido Calabresi at the 2009 Symposium of the *New York University Annual Survey of American Law* (February 27, 2009). The Symposium was entitled *Tort Law in the Shadow of Agency Preemption*. Judge Calabresi provided the keynote address. The recording of the speech is on file with the *New York University Annual Survey of American Law*.

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notion that allowing different decisions fosters experimentation.¹ But we must also understand that in our system, local decision-making is very important so that we can have different values introduced into the system. We are profoundly red and blue. Abraham Lincoln was wrong when he said the nation could not live half-slave and half-free.² We did for a very long time live half-slave and half-free until *Dred Scott* said the country had to live all-slave.³ Then the Abolitionists, who were right but repulsive as far as most Northerners were concerned, became acceptable: If it was going to be all one way, then it was going to be our way.

How often in America do we have, and want to have, different values, different notions of what life is worth, of what things are worth? In this sense it is interesting and perhaps not surprising that we have not had a national tort law in the United States. I believe that the United States is much more divided in terms of values than is Europe—I am talking about the core, old Europe, because those countries share similar values. And that may be why Europe can stand not having a strong central government. Consider the death penalty. Countries that have the death penalty may not join the European Union. In the United States, opinions are widely divergent on that topic. And so it is with other things. Europe had better watch out when it decides to expand beyond the core that has certain values, because it will then need a strong central government. We survived, with different values, only because we had a very strong central government at the time of the Civil War. So that is what the second question asks: What are the benefits of introducing different values into a decision-making system?

The third question is: What does the difference between localized and centralized decision-making tell us about who bears the burden of these decisions? In torts cases, the choice is not only as to how many accident costs we want, how many safety costs we want, and which ones. That is certainly an important issue. But there is also the question of who bears the costs. If we do not allow new drugs, some people are going to suffer. If we do allow new drugs, other people will suffer. Will the person who uses a drug that has come in more recently, more quickly, bear the cost, or will it be the person who doesn't get the drug because there has been a greater

1. See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (“It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”).

2. Abraham Lincoln, House Divided Speech (June 16, 1858).

3. *Scott v. Sandford*, 60 U.S. 393, 405–06 (1856).

delay? They are different people, and that is separate from the question of which alternative is more efficient.

The fact that underneath all of these choices there are distributional issues was brought home to me dramatically many years ago when I went to the hospital to see my friend Alex Bickel, who seemed very well except that he had just been diagnosed with terminal brain cancer. I knew that his illness was a result of his smoking. I was, and am, against prohibition because it generally is inefficient, and prohibiting smoking would have all sorts of terrible consequences. But I also knew that if smoking had been prohibited, Alexander Bickel would have lived because he would not have broken the law. So maybe the option of prohibition is not efficient, but the distributional consequences of one rule as against another were brought home to me. Therefore, in this question of where we decide, centrally or locally, there is not just the efficiency question. Because wherever there is a cost-benefit there are some people who bear the costs and some people who receive the benefits, and we must ask ourselves: Who will those people be?

All of this is completely separate from the question of whether the cost-benefit and distributional decisions are best made through regulations or through incentives. The cases, because of the way they come up, make it appear as if central decision-making means regulation, and local decision-making means incentives. Yet, that is not necessarily so. One could perfectly well have a national tort system with national standards, which would apply to drugs all over the country. And one could have local regulation and then consider whether such local regulations are preempted by federal rules (either regulatory or torts-like). We simply assume in these cases that because, by-and-large, local rules consist of tort incentives and, by-and-large, the national system is a system of administrative regulatory decision-making, that the tradeoff between torts and administrative regulation is what is involved in the question of preemption. But *that* tradeoff is a very different question from whether to have local decision-making as opposed to national decision-making. It is a question of what kind of system we want, regardless of the level of government at which it is implemented.

In addition to acting as if centralized decision-making is regulatory and localized decision-making is not, we often look at the two systems in an idealized or demonized way. Justice Scalia, for instance, talks about the tort system in the most disparaging terms.⁴

4. See, e.g., *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (“A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned

He may be right, but the existing tort system is not the only possible system of incentives (as against regulation) that we could have. That is, one could have, either at the national or at the local level, a totally different system of incentives, like the old New Zealand system, which would avoid the perceived flaws in current tort law. Conversely, Justice Breyer, known to some of his friends as “the Commissioner,” sometimes describes agencies as if they were near-perfect.⁵ Of course they are not. Others describe regulation as being inevitably corrupt, overtaken by, and in the hands of, the regulatees.⁶ This too is an overstatement.

If we are serious, we should ask not just the questions of whether decisions should be made at the national or local level, and not just whether we should use regulation rather than incentives. Rather, we should also ask: Absent a perfect system, which system would work reasonably well? And, in doing so, we should consider variations from the existing regulation or tort models. Yet we talk about preemption in particular cases as if none of these alternatives are possible.

Now, of course, courts deal with specific cases that come before them. And, if the courts were only treating these issues in a traditional legal sense of saying, “this is what Congress said or this is what Congress intended,” then speaking as if the universe of options were closed would be understandable. But, when courts address the broadest policy questions and decide one way or another—because, for instance, they like or do not like existing tort law—the issues become more complicated. Thus, one often finds people saying, “torts means no experts; regulation means experts.” That is not necessarily so. It is possible to have a regulatory system comprised of rotating lay people, which would avoid the danger of having the decision-makers be co-opted by the regulatees, but which would also not have experts. Conversely, a system of incentives could be established through expert bodies. All of this gets

with its benefits; the patients who reaped those benefits are not represented in court.”).

5. See *Medtronic v. Lohr*, 518 U.S. 470, 506 (1996) (Breyer, J., concurring) (holding that courts should defer to the agency’s preemption determination because of “special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives”).

6. See, e.g., Richard A. Epstein, *Why the Modern Administrative State Is Inconsistent with the Rule of Law*, 3 N.Y.U. J. L. & LIBERTY 491, 492 (2008) (arguing that it is not possible to “shield administrative agencies in highly sensitive areas from various forms of factional and political influence that have little or nothing to do with technical expertise”).

lost in the simplicity of the legal case before courts that know little about regulation and virtually nothing about torts.

The current discussion also fails to ask some subsidiary questions that arise in the light of these first questions that I have put to you. Who, where, and by whom are *minimum* standards of behavior best set, as against total standards of behavior? What institutions are best suited to decide the minimum levels we want individuals (and corporations) to live up to? And is this “minimum” decision best made locally or nationally? These may be very different questions from the “who, where, and what level” questions for setting standards *above* that minimum. The classic tort position was very simple on this issue: Administrative regulation and legislation are very good at setting minimum standards, but minimum standards—for example, laws whose violation establishes negligence per se—are never safe havens. That was a rather simplistic notion, and I am not sure that it is a notion that can survive today. But the question of whether minimum standards are best set locally or nationally, and whether they are best set by experts or by lay people, is rarely talked about in the cases involving preemption.

There are consequences to this failure. If the government at its highest levels sets total standards, it determines who is worth living and who is worth dying because it determines what is worth doing to save lives and what is not. Symbolically, that is a dangerous position in which to put the State. I am reminded of Justice Potter Stewart’s question during the oral argument of the famous *Pentagon Papers* case.⁷ There he asked [to paraphrase],

Professor Bickel Let us assume that when the members of the Court go back and open up this sealed record we find something there that absolutely convinces us that its disclosure would result in the sentencing to death of a hundred young men whose only offense had been that they were nineteen years old and had low draft numbers. What should we do?”⁸

Professor Bickel started to answer as an academic, and then he remembered that he was a lawyer before the Court and so effectively said, “Justice Stewart, that isn’t this case. Don’t deal with it.”⁹ And of course Justice Stewart did not. Justice Black, who died shortly after writing an opinion in this case, told his clerks, who told to me: “Stewart asked the right question, but the answer was wrong.” The problem is not that a hundred lives would be lost. In

7. *N.Y. Times Co. v. United States*, 403 U.S. 713 (1971).

8. See Transcript of Oral Argument at 45–46, *N.Y. Times Co.*, 403 U.S. 713 (No. 1873).

9. See *id.*

the parlance of the time, we waste a hundred lives all the time for things far less important than freedom of speech. The terrible aspect is that the Supreme Court of the United States would be saying that a hundred lives are not worth saving. That is why we try to save people crazy enough to row across the Atlantic, or spend millions to save hostages who are taken. Even when lives in some sense are not "worth it," symbolically they are much too important to ignore.

Justice Black's answer to this problem was rather dire [to paraphrase]: We should have an absolute rule against all prior restraints so that if people die as a result of publication, they do so before any court can be involved. That is, ensure that the hostages die before anybody can go rescue them.

Justice Black's approach was draconian. But, whether he was right or wrong, there is a danger in having the State make very clear what lives are worth saving and what lives are not. One advantage—and I am not saying that it wins out—of having the State, whether national or local, set minimum standards is that the State is then in the position of saying: People must do at least this much, but more should be done. The State thereby avoids being in the position of saying it is okay to kill someone.

Of course, the other side is that if we use an incentive system we come mighty close to pricing lives. We find ways to avoid having the State say that Dick Epstein is worth more than Peter Schuck. But we do it by creating a system that tells us that Epstein and Schuck are both worth exactly \$87,327 (which sounds like rather much to me).

The other question that gets lost in this is whether these decisions are best made *ex post* or *ex ante*. Regulation tends to tell us what is acceptable ahead of time on the basis of what is known at that time. We all know that supposedly in torts, under the old Learned Hand test, liability for negligence is based on what a reasonable person should have known at the time the accident-causing event took place. But there is also strict liability, and, very often, torts decides on the basis of what we have learned because of the accident or after it and so creates incentives for people to think about what we do not yet know. Now again, is that good? Is it bad? Is it best done nationally? Is it best done locally? Is the decision best made by experts or not by experts if it is *ex post* or not? Is an *ex post* vantage point best for minimum standards or maximum standards? All these are the questions that are inherent in the problem of preemption.

Finally, there is the question of what kind of decision-makers we want to have make all these decisions. And this raises not only

the questions of: (a) what kind of decision-makers we want; if we want local or national, minimum or maximum, incentive or regulatory decisions; (b) when do we think lay people are good at making the decisions; and (c) when do we think experts are good at it. If the problem is as complex as I believe it to be, it also raises the question of who is best suited to make the decision *of what we do?*

If Congress speaks, we all know that we comply. But Congress rarely says anything, or if it says anything, it often does not know what it is saying. And that is so in both directions. Did Congress say something in *Medtronic*?¹⁰ Did it say something in *Wyeth*?¹¹ I do not believe that Congress said anything in *Wyeth*, though some people have suggested that it did. But in *Medtronic*, yes, Congress did say something; but did Congress mean it? And if Congress now turns around and says it meant the opposite in *Medtronic*, does that really mean anything at all? In the temple of truth, should we not at least ask: How can we make sure that the decision, as to who makes these decisions, is better made? If Congress is not good at it, believe me, the courts are lousy. State courts, elected as they are in most places, federal courts, selected as we are—God help us!

A federal court like the Supreme Court—which understandably spends most of its time talking about civil rights, national security, and how many people should be hanged—does not know a darned thing about this issue. As far as I am concerned, there is only one Justice of the Supreme Court who really understands torts and that is Ruth Bader Ginsburg. The other Justice who comes close is Clarence Thomas. But who else can make these decisions if not courts?¹² A royal commission of the United States? I do not know, but I think we ought to think about all this because otherwise these decisions will be made in the most simplistic way, and, inevitably, the nature of the decisions will shape the commentary in these discussions.

Now, some will say, as good Burkean conservatives, that if there is no way of making a decision well, we should stick with traditions and old presumptions. And for a long time we did just that. The old presumptions held that one does not assume preemption; that courts should not presume that federal standards do more than es-

10. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

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

12. Some, usually administrative law professors, suggest administrative agencies should decide who decides. But when they do so, they almost always speak of idealized agencies and not the real life, flawed ones.

tablish the minimum.¹³ That seems not to be working. But for a long time, the reason we stuck with presumptions like these was not because they were particularly good, but because we felt very uncomfortable with making any decisions in any other way.

* * * * *

The underlying questions remain: how to decide between regulation and incentives, how to decide between regulation and incentives locally and nationally, how to decide between regulation and incentives when we are unwilling to bear the distributional costs of incentives or of regulations. If we do not think seriously about these questions then the whole nature of the society in which we have all grown up, that we have taken for granted—a system, that is, that makes predominant use of incentives that are well-controlled, fine-tuned, often bad, and with dramatic distributional consequences—will cease to be in ways that might surprise us. That will be true not just in torts, but in the economy as a whole.

Thank you.

13. *See, e.g.,* *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (“[W]e 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.”).

REMARKS OF GILLIAN METZGER†

GILLIAN METZGER*

I thought that I would begin by putting my priors on the table. On that front, I am actually surprised but pleased to find out that I might be agreeing more with Rick [Hills] than I was expecting to on this panel. On the institutional design question I share some concerns with Susan [Frederick] and Dan [Schweitzer]. However, in the preemption context my inclination is that federal agencies can, and have the capacity to, do a better balancing of the federalism and national interests than either Congress or the courts. And I also think that there are instances in which agencies can legitimately preempt on obstacle grounds, although I find the recent expansion in obstacle preemption very concerning.

The point I want to start with, however, relates back to Congress. I think it is hard to challenge the legitimacy gains of greater congressional involvement in this area. In particular, Congress needs to be involved in order to address the social insurance aspect of preemption cases. This is because agencies do not have the ability to say, without congressional approval, that even if we make the right systemic regulatory decision, somebody is going to get hurt and maybe compensation should be available. A decision to provide compensation has to be made at the congressional level. I agree, though, with Rick [Hills] that Congress has shown too much predilection for addressing preemption without the kind of clarity and specificity that is needed. In addition, if we are talking about issues that are going to end up having an administrative edge, the reality is that Congress generally delegates very broadly to agencies. I find it difficult to imagine Congress as willing or able to change that practice and delegate more clearly when it comes to administrative preemption. The typical reasons given for why Congress delegates broadly—the political difficulties of reaching agreement on regulatory specifics; the lack of time and expertise needed to ad-

† This is a modified transcript of remarks given by Prof. Gillian Metzger at the 2009 Symposium of the *New York University Annual Survey of American Law* (February 28, 2009). The Symposium was entitled *Tort Law in the Shadow of Agency Preemption*. Professor Metzger spoke on the panel entitled “Issues of Federalism.” A recording of all speeches is on file with the *New York University Annual Survey of American Law*.

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dress specific issues; the need to have regulatory schemes that are flexible and can respond to new challenges as they emerge—all apply in the context of administrative preemption.

What I am even more convinced of is that a greater role for agencies in the preemption context is simply inevitable. The reasons are not only the economic and national political reasons that Rick [Hills] mentioned, but additionally, I do not think that courts are going to enforce rules requiring Congress to play a central role. It is just too much at odds with the norms of the national administrative state that we have developed over the last century—and are only developing further—to think that is going to happen. So I truly believe that we need to face the fact that agencies will inevitably play a bigger role here. I happen to think that that is not a bad outcome. Although agencies have many of the pathologies that have been identified already today, they also have some important strengths in terms of their ability to apply area-specific expertise and weigh state and national interests in particular regulatory contexts. I believe that too often the national-state debate is presented as being necessarily the kind of stark conflict that it was under the Bush Administration, without much sympathy to state interests at the national level. I am not so sure that national and state regulatory interests are always as opposed to one another as is sometimes conveyed. Another point to note about agencies, which is important for what I want to get to, is that agencies are more amenable to being checked by a variety of different actors than either Congress or the courts. That matters because I think the issue on which we should be focusing—the real institutional design question—is: Accepting that agencies are inevitably going to be playing a role here, how do we structure their involvement to make sure that they make the best decisions about preemption? In particular for federalism interests, how do we structure their involvement to ensure that state and local interests are adequately heard, responded to, and taken seriously? That was what Rick [Hills] was getting at in terms of the Vice President,¹ and I have somewhat similar suggestions to make.

First, let me talk about a couple of other approaches. As Rick [Hills] mentioned, one of the things I, [Catherine Sharkey], and a number of others have advocated for is the traditional administrative law response of enhanced judicial review. And I do think that subjecting preemption determinations to a more searching scrutiny could have some traction. If you look at some of the preemption

1. See Roderick M. Hills, Remarks at the *New York University Annual Survey of American Law* Symposium: Tort Law in the Shadow of Agency Preemption (Feb. 27, 2009) (transcript available at New York University Annual Survey of American Law).

regulations that came out under the Bush Administration, there are some fairly obvious APA [Administrative Procedure Act]² issues that can be raised. For example, there are issues involving inadequate notice. Such APA procedural reversal might only serve to slow down adoption of the agency's preemptive position. But with an agency that is even nominally responsive, the possibility exists that such reversals might have some substantive effect down the road. You can again put this down to my priors; I tend to believe that agencies are not so committed to a pre-chosen path that they are not interested in hearing other voices or open to responding to states' concerns. Agencies are under-resourced to be sure, and can have programmatic tunnel vision. Sometimes agencies can be overly politicized. But I believe it is a mistake to assume that agencies will be unresponsive. The critical issue is designing agencies and their relationships with their political and judicial overseers so as to encourage agencies to take other interests and perspectives seriously. As a result, I see some potential for the option of enhanced judicial scrutiny to improve preemption determinations.

Another option at the national level is enhanced congressional oversight. [Catherine Sharkey] has spoken a little bit about that in terms of Executive Order 13132³ and we heard some discussion today about FDA [Food and Drug Administration] oversight. There are some obvious avenues on this front that matter. The angle I would emphasize more, however—and Rick [Hills] made this point too⁴—involves intra-agency checks. I could not agree more with Rick [Hills] about trying to learn lessons from the example of cooperative federalism. If we accept the inevitability of federal agencies being involved in this area, a key question is how to structure the federal regulatory process to fully bring in state and local interests.

Another mechanism might be to try to require the establishment of advisory committees within each agency, embodying state and local interests, as a means to create ongoing contact between the different levels of regulators. Issues will of course exist about whom to put on such advisory committees to represent state and local interests. But what is needed is a formal intra-agency institutional structure to represent state and local interests [a] that has an existence beyond a particular issue, [b] that is not dependent on the agency triggering a request for comments in a particular case, and [c] that, over time and through ongoing interactions, can build confidence, relationships, and receptivity among federal, state, and

2. Administrative Procedure Act, 5 U.S.C. §§ 701–6 (2006).

3. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).

4. See Hills, *supra* note 1.

local regulators. While I think the Vice President can also serve a role in terms of appeals from agencies, we really should consider building into the agencies greater sensitivity to state and local interests. This should include even those agencies that do not take a cooperative form, that implement more dual regulatory regimes, or that represent centralized federal regulatory power without a state analog. Some kind of advisory committee structure is one option for building such a formal institutional representation of federalism concerns.

There is also the option of trying to do more with the executive order and OMB [Office of Management and Budget]. That only works, of course, if you have an OMB that is sympathetic. But as Susan [Frederick] was saying, some potential exists here for a more centralized emphasis on taking state and local interests seriously. When that has happened—when agencies start taking the 13132 process of federalism generally more seriously—agency institutional culture can be significantly affected.

The last point I want to make gets outside of the executive branch and focuses instead on what states and local governments can do, and do collectively, independently of federal agencies. One of the things I find very interesting, when you look at preemption clauses, is the extent to which they reserve what I would call “complementary state measures.” The language is often along the lines of, “state regulations that are identical and not in addition to federal regulation are preserved.” This may create an opening for states to do more policing of the federal administrative process than has so far occurred. And it certainly is an opening I would like to see state and local governments explore. For example, regulated entities that are filing reports with the FDA of certain complications could also be required to file with states and, perhaps, local bodies. These governments would then be in a better position to police whether or not the FDA is adequately responsive to such filings and to petition the FDA or use their contacts at the federal government to increase national regulatory responsiveness. This approach is obviously much easier when there is a cooperative regulatory scheme. But one of the things that states may need to do is develop analogous regulatory competency in areas where they may have ceded too much to the federal regime, so they can play such a policing role. Developing such competency might also lead to more regulatory experimentation. For example, state-level agencies may be able to develop mechanisms that enhance regulators’ access to information, so that tort suits need not be so important as information-gathering tools.

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REMARKS OF GILLIAN METZGER

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I am actually quite open to arguments that none of these ideas will work. The one point that I am certain of is that the issue that needs to be addressed is how agencies confront the federalism issue. I am skeptical that trying to bump up preemption determinations to Congress is going to work in the long run. And, as was said at the earlier panel, I am concerned that we are not going to end up with a very sensible regulatory regime if we try and leave preemption determinations in the first instance to the courts.

DUE PROCESS PREEMPTED: STEALTH PREEMPTION AS A CONSEQUENCE OF AGENCY CAPTURE

ELIZABETH J. CABRASER*

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INTRODUCTION

Proponents of widespread federal preemption are quick to portray our civil litigation system, established in the eighteenth century, as anachronistic when set against the backdrop of modern mass production and interstate and international marketing of goods and services by multinational corporations. These preemption proponents sympathize with manufacturers’ desire to predict, control, and predetermine judgments regarding product quality or defect, corporate conduct or misconduct, and truth or lies in marketing. They emphasize the value of the national uniformity that comes with determinations by federal agencies.¹ These values of

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1. This argument is frequently advanced in the context of a pro-business free-market stance. See, e.g., Daniel E. Troy & Rebecca K. Wood, *The Business of the Court: Federal Preemption at the Supreme Court, 2007–2008* CATO SUP. CT. REV. 257, 263–67 (2008). See generally Nancy L. Perkins et al., *Watters v. Wachovia: A Funda-*

uniformity and predictability are often frustrated by a system such as ours in which the substantive law in these areas is derived from state common and statutory law, and in which disputes are adjudicated by lay juries, instructed in state law by both federal and state judges. Yet in the view of consumers' advocates, this is all as it should be.²

The Supreme Court's March 4, 2009 decision in *Wyeth v. Levine*³ is the culmination and reflection of many conflicting considerations. Among them is a cautionary tale of what can happen to our revered concepts of access to justice and compensation for harms negligently or intentionally committed when the will of Congress and the expectations of the people are bypassed. In this tale, bypass was effected by an agency (whose expertise is medical and scientific) that, encouraged by the industry it regulates and empowered by a political administration, preemptively opines on profound matters of substantive law without bothering to observe the necessities of constitutional due process.

The operating system established by the Constitution and its amendments, known by the shorthand of "federalism," has been viewed by manufacturers and their trade groups as an anomaly to be cured by absolute deference to the expertise of the *federal* agencies charged by Congress with regulating the relevant products or services uniformly throughout the entire nation.⁴ However, legislative preemption is rare.⁵ It is likely to remain so, given congressional—and traditional—reverence for the common law system, the importance of federalism, and the extreme political difficulty of legislating a complete system of substantive law, adjudicatory proce-

mental Approach to Federal Banking Law Preemption, 27 REV. BANKING & FIN. L. 127 (2008) (discussing the balance of regulatory authority between the federal and state governments and the uniformity versus vulnerability of a system that completely defers to the presumptive expertise of a federal regulatory agency).

2. See, e.g., Associated Press, *Obama Undoes Bush-Era Policy That Undercut States*, S.F. CHRON., May 20, 2009 (reporting on positions of consumer and plaintiffs' advocates). See generally *High Court Dismisses FDA Preamble in Broad Rejection of Preemption*, 15 FDA WEEK 9 (2009).

3. *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (affirming the judgment of the Vermont Supreme Court awarding damages to plaintiff and respondent Diana Levine).

4. See, e.g., Lawrence S. Ebner, *Four Myths About Federal Preemption of State Tort Claims*, LEGAL BACKGROUNDER (Washington Legal Foundation, Washington D.C., June 5, 2009).

5. See, e.g., Sharon A. Kahn & Brian McCarthy, Note, *At-Will Employment in the Banking Industry Ripe for A Change*, 17 HOFSTRA LAB. & EMP. L.J. 195, 210 (1999) ("Explicit Congressional [sic] preemption of national banks is a rare occurrence.").

dure, and appropriate compensation. These features are already present in our litigation system, and Congress, with good reason, appears loath to duplicate or to supplant them.

A deep instinct preserves the check-and-balance system of state substantive law, as interpreted by state and federal courts, that provides compensatory and deterrent remedies which are determined with the participation of citizen fact-finders, and informed, but not foreclosed, by the opinions of regulatory agencies. This is a system that is neither perfectly consistent nor entirely predictable, but that trades perfect certainty for openness and flexibility. It avoids the extreme prejudice to consumers of an unbalanced, unilateral agency system in which those entrusted with regulating an industry bestow complete immunity from civil liability on those products they determine to be in initial compliance with agency standards. We have been reluctant, throughout our political and judicial history, to give the first, last, and only word on any issue that affects public health and safety, civil rights, or procedural due process exclusively to any one branch of government or its designees.⁶ Rare indeed should be the situation in which a single agency is allowed to nullify this system of checks and balances, arrogate to itself the powers traditionally distributed among the legislative, executive and judicial branches, and reign unchecked in the area of its presumed expertise.

I.

THE BIRTH (AND DEATH) OF A PREAMBLE

The Supreme Court's 2009 decision in *Wyeth v. Levine* addressed a regulation issued by the Food and Drug Administration (FDA) governing the content and format for prescription drug labels.⁷ As described in the Court's opinion, the preamble to that regulation "articulated a sweeping position on the [Food, Drug, and Cosmetic Act's (FDCA)] pre-emptive effect" that the Court characterized as a "conclusion" rather than a justification or even an "explanation."⁸ Justice Stevens's opinion striking the preamble

6. See Jennifer S. Hendricks, *Preemption of Common Law Claims and the Prospects for FIFRA: Justice Stevens Puts the Genie Back in the Bottle*, 15 DUKE ENVTL. L. & POL'Y F. 65, 97-98 (2004); see also Ernest A. Young, *Stalking the Yeti: Protective Jurisdiction, Foreign Affairs Removal, and Complete Preemption*, 95 CAL. L. REV. 1775, 1813-15 (2007).

7. *Wyeth*, 129 S. Ct. at 1187 (2009); see also Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pt. 201, 314, 601).

8. *Wyeth*, 129 S. Ct. at 1201.

pegged the George W. Bush Administration's end-run around legislative, regulatory, and litigation due process for what it was: an attempt at preemption by agency fiat that, by overreaching, ultimately short-circuited its own preemptive intent.⁹

The drug manufacturer, Wyeth, seeking to shield itself from legal and financial responsibility for injuries it caused by its anti-nausea drug Phenergan,¹⁰ argued that the FDA must be presumed to have established a specific labeling standard that leaves no room for different state law judgments. Its argument relied on the preemptive effect of an obscure preamble to a 2006 FDA regulation declaring that state law failure-to-warn claims threaten the FDA's statutorily prescribed role.¹¹ Although an agency regulation with the force of law can preempt conflicting state requirements,¹² respondent (the permanently injured Diana Levine¹³) and amici¹⁴ ar-

9. *See id.* at 1200–01.

10. As the Supreme Court decision describes the background of the case, after a clinician injected respondent Levine with Phenergan by the 'IV-push' method, whereby the drug is injected directly into a patient's vein, the drug entered Levine's artery instead, and she developed gangrene. Doctors amputated her forearm. Levine brought a tort action in Vermont state court, alleging, *inter alia*, that Wyeth had failed to provide an adequate warning about the significant risks of administering Phenergan by the IV-push method. The Vermont jury determined that Levine's injury would not have occurred if Phenergan's label included an adequate warning and awarded damages for her pain and suffering, substantial medical expenses, and loss of her livelihood as a professional musician. Declining to overturn the verdict, the trial court rejected Wyeth's argument that Levine's failure-to-warn claims were preempted by federal law because Phenergan's labeling had been approved by the FDA. The Vermont Supreme Court affirmed the lower court. *See id.*, 129 S. Ct. at 1190–94.

11. *See* Brief for Petitioner at 8, 11, 45, 50, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

12. *See Wyeth*, 129 S. Ct. at 1200 (citing *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)).

13. As the Vermont Supreme Court opinion described the events, in April 2000 Ms. Levine received two injections of Wyeth's drug Phenergan at a health clinic to treat nausea resulting from a migraine headache. The second dose was administered by direct intravenous injection into her arm, a procedure known as "IV push." This "resulted in an inadvertent injection of Phenergan into an artery. As a result, the artery was severely damaged, causing gangrene. After several weeks of deterioration, plaintiff's hand and forearm were amputated." Ms. Levine alleged that Wyeth failed to warn adequately of the dangers of IV push injection. *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006). As the Supreme Court opinion noted, Ms. Levine (a professional guitarist) alleged "substantial medical expenses and loss of her livelihood as a musician." *Wyeth*, 129 S. Ct. at 1191.

14. Amicus briefs were filed on behalf of petitioner Wyeth by the United States of America; Generic Pharmaceutical Association; Pharmaceutical Researchers and Manufacturers of American and Biotechnology Industry Organization; the

gued that the 2006 preamble involved no such regulation, but was merely an agency's assertion that state law is an obstacle to achieving its statutory objectives.

The *Wyeth* court held that where, as in the case of the challenged preamble, Congress has not authorized a federal agency to preempt state law directly, the weight the courts should accord the agency's explanation of state law's impact on the federal scheme depends on its "thoroughness, consistency, and persuasiveness."¹⁵ This standard was previously articulated in a series of federal (including Supreme Court) decisions.¹⁶

The plaintiffs argued that the FDA's 2006 preamble simply did not merit deference. In the view of the plaintiff and amici, the preamble, which effectively immunized all drugs receiving FDA marketing approval (even those subsequently recalled) from tort actions for compensatory and punitive damages brought by those harmed, could not, consistent with principles of due process, be allowed to perform its intended function. The plaintiff thus challenged the preamble as inherently suspect in light of the FDA's failure to offer interested parties notice or opportunity for comment on the preemption question.¹⁷ That failure was not only at odds

United States Chamber of Commerce; the Product Liability Advisory Council, Inc.; DRI-The Voice of the Defense Bar; the Generic Pharmaceutical Association; John E. Calfee et al., (economists and economic professors); American College of Emergency Physicians; and the Washington Legal Foundation. Amicus briefs for Respondent Levine included briefs for the Former FDA Commissioners Dr. Donald Kennedy and Dr. David Kessler; members of Congress; the New England Journal of Medicine; the California Medical Association; forty-seven states (including Vermont); the National Conference of State Legislatures; the American Association for Justice; the Center for State Enforcement of Antitrust and Consumer Protection Laws, Inc.; Constitutional and Administrative Law Scholars; the Constitutional Accountability Center; Consumer Union of the United States; the Citizens Commission on Human Rights; and the Senior League. See 2006 U.S. Briefs 1249 (Lexis).

15. *Wyeth*, 129 S. Ct. at 1201.

16. See Brief of Amicus Curiae Constitutional and Administrative Law Scholars in Support of Respondent at 34-46, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (citing *United States v. Mead Corp.*, 533 U.S. 218 (2001); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000)). As the Court noted in *Wyeth v. Levine*, "The weight we accord the agency's explanation of State law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness." *Wyeth*, 129 S. Ct. at 1201.

17. As respondent's amicus, NCSL stated in its brief:

Moreover, the question of whether a federal agency can, without a grant of authority to preempt from Congress, dictate preemption as a matter of agency policy has significant fiscal implications for State governments. Consumers' injuries do not simply vanish, nor are they magically healed, when the claims

with the available evidence regarding congressional purposes; it also reversed the longstanding position that state law is a complementary form of drug regulation without providing a reasoned explanation. In its opinion in *Wyeth*, the Supreme Court agreed, bluntly characterizing the preamble as “inherently suspect” and holding that it did “not merit deference.”¹⁸

The 2006 preamble was thus declared dead on arrival at the Supreme Court. Yet, in the intervening three years between its birth and demise the preamble wreaked havoc in American pharmaceutical litigation. Many, but not all, courts gave deference to the preamble and dismissed claims seeking compensatory and punitive damages for deaths and injuries attributed to dangerously defective drugs.¹⁹ The preemptive preamble defense was even attempted in cases in which changes were initially approved by the FDA but later recalled and withdrawn from the market.²⁰ Many thousands of plaintiffs found themselves out of court, without remedy for their injuries and losses, because the preamble not only declared their tort claims null and void but also provided no alternative administrative remedies to compensate tort victims.²¹

are preempted. Instead, the costs of their injuries are paid by insurers, borne by the individuals themselves, and, if the injured consumers cannot pay and are uninsured, State governments may pay (in whole, or with matching federal funds) for medical expenses and disability payments. These and other social costs, and the countervailing impact on States' economies of consumer litigation, have been the focus of much debate and legislation in the States. This vital decision-making process is a key part of our co-operative system of Federalism.

Brief of the National Conference of State Legislatures as Amicus Curiae Supporting Respondents at 2, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (hereinafter Brief of Amicus Curiae NCSL).

18. *Wyeth*, 129 S. Ct. at 1201.

19. See, e.g., *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 523–38 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008). But see *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 273–74 (E.D.N.Y. 2007); *In re Vioxx Prod. Liab. Litig.*, 501 F. Supp. 2d 776, 786–88 (E.D. La. 2007).

20. See, e.g., *In re Vioxx Prod. Liab. Litig.*, 501 F. Supp. 2d at 780–81 (denying defendants' motion for summary judgment on preemption grounds).

21. See, e.g., Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 HARV. L. REV. 1604, 1623–24 (2007) (describing how courts' consideration of consequences of preemption often aligns with the presumption against preemption); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933–34 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601). When state law tort claims are preempted, injured patients' damages suits are dismissed with prejudice, leaving them without any source of compensation for the medical expenses, lost wages, personal injuries, and emotional distress they and their families suffer when medical products fail. Prior to

Because of the vast amount of damage done by the preamble during its brief reign, the tale of its genesis bears repeating and needs remembering.

Any agency, once captured by the industry it is entrusted to regulate, may be hijacked or used as the mouthpiece for that industry, and may become the vehicle for the industry-friendly political objectives of any executive administration. The tale of the 2006 preamble teaches the satisfying lesson that usurped power will not necessarily remain unchecked if the judiciary ultimately does its job. But there is no reason to believe, despite the change of administration and shift in political alignment resulting from the 2008 election, that the preamble is a one-off: political strategies do not tend to the unique, and even a short period of success, like the three years of litigation advantage enjoyed by the pharmaceutical industry at the expense of state tort law, may be deemed sufficient justification and incentive to try it again.

II.

THE FDA'S HISTORICAL POSITION AND 2000 STATEMENT THAT PREEMPTION WAS NOT IMPLICATED BY AGENCY LABELING RULES

Courts have held that Congress specifically rejected a proposal to include a federal private right of action for damages because Congress recognized that such actions already existed under state common law when it enacted the Food, Drug, and Cosmetic Act (FDCA) in 1938.²² In 1962, when Congress passed amendments to the FDCA, it added a provision stating that:

the Supreme Court's *Wyeth* decision, many pharmaceutical personal injury cases were dismissed as preempted by FDA regulation. *See, e.g., Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009). The *Wyeth* decision has appreciably reduced the risk of preemption dismissals in many other pharmaceutical cases. *See, e.g., Demahy v. Actavis, Inc.*, No. 08-31204, 2010 WL 46513, at *1 (5th Cir. Jan. 8, 2010) ("While not directing our result, [*Wyeth*] shadows our conclusion that the federal regulatory regime governing generics is also without preemptive effect."). As Demahy observes, "the bar to a finding of preemption is set even higher" when "federal law provides no remedy for an injured consumer." *Id.* at *4. As to medical device cases, preemption is still the norm. *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009) (dismissing the tort claims of more than 1000 plaintiffs), *appeal docketed*, No. 09-2290 (8th Cir. June 5, 2009).

22. *See In re Paxil Litig.*, No. CV 01-07937, 2002 WL 31375497 at *1 (C.D. Cal. Oct 18, 2002) ("FDA and [defendant] invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of com-

[n]othing 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.²³

For nearly 40 years thereafter, the FDA consistently took the position that its labeling requirements represented *minimum standards* that did not preempt state law.²⁴

The FDA has historically and consistently recognized that product liability litigation asserting state law claims serves an important role in protecting the public.²⁵ In doing so, the FDA acknowledged that compliance with agency labeling requirements does not supplant state tort doctrines, such as the manufacturer's continuing duty to warn as new risks are discovered. The FDA has noted that "drug labeling does not always contain the most current information and opinion available to physicians about a drug because advances in medical knowledge inevitably precede formal submission of proposed new labeling by the manufacturer and approval by FDA."²⁶

For example, in 1998, when issuing regulations addressing pharmacists' provision of written patient information ("Medication Guides") for certain types of prescription drugs, the FDA stated that its regulations established only *minimum standards* that posed no actual or anticipated conflict with state law and that were not intended to preclude the imposition of additional labeling requirements.²⁷ Even though Medication Guides are subject to intense regulatory oversight by the FDA,²⁸ the agency reaffirmed its anti-preemption stance, and properly rejected comments from the

mon law state claims. This position contravenes common sense, and the Court declines the invitation.") (internal citation omitted); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 924 (1994).

23. 21 U.S.C. § 301.

24. 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, 474 (2008).

25. See, e.g., 44 Fed. Reg. 37,447 (citing *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974)).

26. *Id.* at 37,435.

27. Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (codified in 21 C.F.R. pts. 201, 208, 314, 601, 610); see also *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989); *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 431–32 (D. Vt. 2008).

28. See, e.g., *Kellogg*, 612 F. Supp. 2d at 431–32.

pharmaceutical industry calling for the preemption of state labeling requirements. In doing so, the agency stated that “FDA regulations establish the minimal standards necessary, but were not intended to preclude states from imposing additional labeling requirements. States may authorize additional labeling, but they cannot reduce, alter, or eliminate FDA-required labeling.”²⁹

Executive Order 13132, “Federalism,” issued on August 4, 1999, was designed to prevent runaway or captured agencies from preempting state law or circumventing federalism by fiat.³⁰ This executive order states that “[n]ational action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance.”³¹ The executive order also outlined several “Special Requirements for Preemption.”³² This section requires that federal agencies restrict any regulatory preemption of state law to the minimum level necessary;³³ that *prior to* publication federal agencies shall consult with appropriate state and local officials in an effort to avoid the possibility of conflict between state law and federal interests;³⁴ and that “when an agency proposes to act through adjudication or rule-making to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.”³⁵ The executive order specifies the due process required: “no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation . . . consulted with State and local officials early in the process of developing the proposed regulation.”³⁶

The FDA acknowledged these principles and procedures in 2000 when it published its proposed drug-labeling rule—the same rule before the courts in *Wyeth v. Levine*—declaring as follows:

FDA has analyzed this proposed rule in accordance with Executive Order 13132: Federalism. The Order requires Federal agencies to carefully examine actions to determine if they con-

29. 63 Fed. Reg. at 66,384 (codified in 21 C.F.R. pts 201, 208).

30. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).

31. *Id.* § 3(b).

32. *Id.* § 4.

33. *Id.* § 4(c).

34. *Id.* § 4(d).

35. *Id.* § 4(e).

36. *Id.* § 6(c)(1).

tain policies that have federalism implications or that preempt State law. . . .

FDA is publishing this proposed rule to revise its regulations governing the format and content of labeling for human prescription drug products. . . . [T]his proposed rule does not pre-empt State law.

Accordingly, FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.³⁷

Having expressly stated that the proposed new labeling rules did not implicate federalism or preempt state law, the FDA did not seek or receive comments on the federalism implications of preemption.

III. THE FDA IS CAPTURED AND ISSUES A HOSTAGE STATEMENT

In 2001 a new Chief Counsel of the FDA, Daniel Troy, was appointed. Mr. Troy had represented pharmaceutical and other industries in lawsuits against the FDA.³⁸ Once appointed, Mr. Troy publicly called for industry representatives to suggest cases in which the FDA could advocate for preemption.³⁹ The FDA subsequently began filing amicus briefs whose arguments mirrored the preemptive opinion later expressed in the 2006 preamble. No such position had ever been advocated in the over ninety-year history of the FDA.

Then a funny thing happened. On December 30, 2005, the Executive Branch Liaison for the National Conference of State Legislators (NCSL) received a call from FDA intergovernmental staff.⁴⁰ The FDA staffer informed her that the agency planned to finalize its long-dormant labeling rule in early January 2006 and would be

37. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201).

38. See generally Stacey Schultz, *Mr. Outside Moves Inside: Daniel Troy Fought the FDA for Years; Now He's Helping to Run It*, U.S. NEWS & WORLD REPORT, March 16, 2003, available at http://health.usnews.com/usnews/health/articles/030324/24_fda.htm (last visited Nov. 4, 2009).

39. James T. O'Reilly, *U.S. Food and Drug Regulation in Its First Century and Beyond*, 93 CORNELL L. REV. 939, 953–54 (2008).

40. Affidavit of Susan Parnas Frederick at 1 (attached to Brief for Nat'l Conference of State Legislatures as Amici Curiae Supporting Respondents), *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

including a statement preempting state laws. This was, to put it mildly, a surprise. NCSL's counsel immediately asked to be placed in touch with the FDA's general counsel's office and asked for a copy of this proposed "policy statement." She also asked that the consultation process under Executive Order 13132 occur and asked for the notice-and-comment period to be reopened.⁴¹

NCSL counsel then received a call from the office of the FDA's general counsel, and, as she states in her affidavit:

I was informed by Mr. Randy Luttig that NCSL could not review this proposed language in advance of its publication, that this telephone call constituted the consultation under Executive Order 13132, and that the comment period was closed and would not be reopened to permit NCSL to submit comments on the new language.

In a follow-up conversation with FDA staff, I was informed that the FDA considers the requirement of Executive Order 13132 satisfied, and was again told I would not be able to review a copy of the proposed "policy statement." I subsequently learned that FDA had received and accepted numerous late, non-public, comments from industry on the proposed regulation.⁴²

Thereafter, without further rulemaking or public notice, the FDA simply attached a "preamble" to its January 24, 2006 Final Rule on labeling that had not, prior to its publication, seen the light of day. The FDA attempted to explain away its failure to follow the requirements of Executive Order 13132 in this statement:

FDA sought input from all stakeholders on new requirements for the content and format of prescription drug labeling through publication of the proposed rule in the Federal Register. Although the proposed rule did not propose to preempt state law, it did solicit comment on product liability issues. FDA received no comments on the proposed rule from State and local governmental entities.⁴³

Those from whom the FDA supposedly did solicit comment were neither described nor identified.⁴⁴ With this as its only justifi-

41. *Id.* at 1–2.

42. *Id.* at 2.

43. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3969 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 214, 601) (emphasis in original).

44. *See generally id.* The FDA does indicate responsiveness to concerns of unidentified "manufacturers" regarding "product liability implications" and addressed these by stating "such product liability claims would be preempted." *Id.* at

cation, the FDA stated that it “believe[d] that it ha[d] complied with all of the applicable requirements under Executive Order 13132 and ha[d] determined that this final rule is consistent with the Executive Order.”⁴⁵

The FDA’s failure to describe those from whom it purported to have solicited comments would lead directly to the preamble’s demise at the hands of the Supreme Court, which considered the preamble as “inherently suspect” in light of the agency’s failure to offer interested parties notice or opportunity for comment on the preemption question.⁴⁶ The agency’s willingness to lie about its compliance with the comment requirement was a telling symptom of its extreme and ultimately self-destructive “capture” by the very group it was meant to police—drug manufacturers—and the corollary betrayal of the group it was created to protect—the drug-consuming public.⁴⁷

Shortly after the FDA published its preamble, ranking members of the House and Senate wrote to the FDA objecting to it.⁴⁸ They criticized the FDA for attempting to “reverse[] a long-standing FDA policy of permitting complementary State activities intended to protect consumers from unsafe drugs.”⁴⁹ Their letter noted the due process end-run: “[N]either affected state and local entities, nor the general public were given an opportunity to comment” because the FDA “provided no opportunity for dissenting

3933. No identification of entities from whom anti-preemption comments were sought or received was included, and support for the preemption position referred to arguments made in FDA amicus briefs. *Id.* at 3934–35.

45. *Id.* at 3,969.

46. *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009).

47. See Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003, 1009–10 (2008) (discussing judicial concerns about “agency capture” as applied to the FDA). Voices within the FDA itself have cast this as a failure of resources. The FDA’s own blue-ribbon panel agreed that the agency was not up to the task of ensuring public safety, stating that, “the scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the . . . regulatory system, and hence the safety of the public.” FDA SCIENCE BOARD, *FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY FOOD AND DRUG ADMINISTRATION SCIENCE BOARD 2* (2007).

48. See, e.g., Letter from Edward M. Kennedy and Christopher J. Dodd to Michael O. Leavitt (February 23, 2006); Letter from Henry A. Waxman, John D. Dingell, and Sherrod Brown to Michael O. Leavitt (February 23, 2006) (on file with the Annual Survey of American Law), available at <http://dodd.senate.gov/index.php?q=node/3381>.

49. Letter from Henry A. Waxman, John D. Dingell, and Sherrod Brown to Michael O. Leavitt, *supra* note 48.

views to be heard.”⁵⁰ The legislators also attacked the very foundation of the FDA’s analysis, which they claimed abrogated the roles and powers of the legislative and judicial branches, accusing the FDA of relying on “misleading characterizations of the governing statute and irrelevant cases, while ignoring contrary legislative history.”⁵¹

The NCSL, an organization representing the interest of the states’ legislatures in preserving the states’ role in America’s system of federalism, voiced similar objections, stating in a formal letter to the Secretary of Health and Human Services that the FDA’s radical shift in position, combined with its refusal to go through the legally required notice-and-comment process, constituted “an abuse of agency process and a complete disregard for our dual system of government. . . . It is unacceptable that [the] FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide.”⁵²

The FDA was intended to function as an independent regulatory agency deploying its medical and scientific expertise to protect the health and safety of the public. However, it has come under increasing fire from the medical profession itself (a constituency with undoubtedly relevant expertise), for its inability, through lack of funding and otherwise, to regulate the products of pharmaceutical laboratories and safeguard the public health effectively.⁵³ Whether or not such criticism is warranted, the FDA is without the legal authority or expertise to regulate, much less nullify, the legislative and judicial products of the states. Announcements of preemption made without expertise, authority, or due process should warrant no deference.

As noted by former Commissioner David Kessler, subsequent to the FDA’s issuance of the preamble, Congress passed and the President signed the FDA Amendments Act of 2007, which did not include a preemption provision.⁵⁴ The Act instead included a “rule of construction” that the FDA’s new authority over labeling did not

50. *Id.*

51. *Id.*

52. See Letter from Steven J. Rauschenberger, Assistant Senate Minority Leader, Illinois President, NCSL to Mike Leavitt (Jan. 13, 2006) (on file with the author).

53. As the *New England Journal’s* editors have now expressly stated, the FDA’s current preemptive position is also a threat to the broad-based expertise and patient-responsive role of the medical profession. See, e.g., Gregory D. Curfman, et al., *Why Doctors Should Worry About Preemption*, 359 *NEW ENG. J. MED.* 1, 1–3 (2008) (editorial by NEJM editors, criticizing FDA position in this case).

54. Kessler & Vladeck, *supra* note 24, at 467–70.

relieve manufacturers of their current responsibilities to provide up-to-date safety information and did *not* affect their ability and responsibility to do so without first securing the FDA's approval.⁵⁵ As Commissioner Kessler notes, the pharmaceutical industry unsuccessfully sought a preemption provision; when they failed to secure one, opponents of the bill criticized it as "a definite boon to trial lawyers."⁵⁶ Whether it was or was not a "definite boon" to the competing constituencies of consumers, their lawyers, or the pharmaceutical companies and theirs, or whether it assisted or facilitated the state legislatures and courts that have long considered and balanced the interests of these constituencies in the system of tort law, the FDA Amendments Act definitely did *not* authorize preemption.⁵⁷

The 2006 preamble on which Wyeth premised its preemption arguments in its campaign to overturn the jury verdict in favor of Diana Levine was thus not part of the FDA regulation, and it demonstrably did not go through the formal notice-and-comment process. Although the Supreme Court has sometimes given deference to an agency's interpretive rules—rules that do not have the force of law, but that set forth the agency's understanding of a law which Congress has authorized that agency to interpret via the regulatory process or enforce⁵⁸—in the case of the preamble, the FDA did not purport to issue an interpretive rule, as Congress had not authorized the FDA to preempt or replace state tort law. Instead, the FDA stated its belief on a legal question, in language resembling a lawyer's or a lobbyist's advocacy position.⁵⁹

IV. THE PREAMBLE UNDER FIRE

Respondent Diana Levine and those amici who supported an anti-preemptive interpretation of the preamble argued that, even if the Court were to view the preamble as an interpretive rule, no deference could be given to it without fundamentally undermining

55. FDA Amendments Act of 2007 § 901(a), Pub. L. No. 110-85, 121 Stat. 825, 925–26 (codified at 21 U.S.C. § 301); Kessler and Vladeck, *supra* note 24, at 468.

56. Kessler & Vladeck, *supra* note 24, at 468 n. 27.

57. *Id.*

58. *See, e.g.*, *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (holding that the Secretary of Labor's interpretation of the salary-basis test is controlling unless "plainly erroneous or inconsistent with the regulation").

59. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934, 3969 (Jan. 24, 2006) (to be codified at 21 C.F.R. pt. 201, 314, 601).

our system of federalism. The NCSL amicus brief (which was submitted by the author), for example, urged a denial of deference to the preamble out of concern that the member states' traditional authority over the products liability claims and recoveries by their citizens—i.e., their position “on the front line of the policy decisions about ‘Tort Reform’”—and the extensive work many states had completed in the field, including enactments that both approved and rejected preemption, had been negated by the preamble without due process or due regard for federalism.⁶⁰ The amici for respondents urged three reasons for denying deference to the preamble and its preemption manifesto:

1. The FDA failed to give state authorities any meaningful notice or opportunity to comment and participate in the proceedings as required by executive order 13132. The preamble's method of creation instead sought to preempt due process. The FDA's flagrant violation of a binding executive order designed to safeguard the system of federalism should not be enabled by the Court.

2. The FDA's procedural violation was exacerbated by the FDA's lack of congressional authority to determine the preemptive effect of drug labeling rules on state law causes of action. The FDA simply attempted to seize, in a manner never countenanced by preemption jurisprudence, the states' sovereign authority over their own tort law, in order to assist a special interest (the pharmaceutical industry). Respect for federalism requires the Court to reject the executive branch's effort to impose preemption absent clear congressional authorization and appropriate respect for procedural norms.

3. When an agency has radically and suddenly changed its longstanding views, as the FDA did in the preamble, is unable or unwilling to explain its profound change in view, and proceeds in a manner that demonstrates that external pressure or politics, rather than independent agency expertise, is the source of the new view, the agency's arguments for administrative preemption should be rejected. The NCSL brief implored that “preemption cannot be allowed to be implied based upon political decisions by the Executive Branch acting alone.”⁶¹

The NCSL and other amici argued that the FDA failed to comply with the unambiguous and mandatory directive of Executive Order 13132, and that no sensible or reasoned excuse was provided by the FDA for its failure to consult with appropriate state officials.

60. Brief of Amicus Curiae NCSL, *supra* note 17, at 1.

61. *Id.* at 15–16.

The FDA's arguably tautological explanation, that it need not consult with the state and local governments because it received no comments from them on preemption (after having told state and local government in 2000 that the proposed regulations did not preempt state law), would be comical if it were not so nakedly undemocratic.

As the NCSL brief described:

Section 4(d) of Executive Order 13132 *requires* all agencies to consult with appropriate State and Local officials whenever an agency foresees the possibility of a conflict between state law and a federally protected interest within the agency's area of regulatory responsibility. Section 4(e) . . . further specifies that, when an agency proposes to act through adjudication or rulemaking to preempt state law, it *shall provide* all affected state and local officials with notice and an opportunity to comment and participate in the proceedings.⁶²

The states thus argued that they had a reasonable basis to rely upon the executive order, and to expect that the executive branch would not engage in an end-run around due process to avoid what it knew to be unfavorable input and opposition. When the FDA issued its proposed drug labeling rule in 2000, it stated quite clearly in its notice of rulemaking that "this proposed rule does not preempt State law."⁶³ This unequivocal statement was consistent with the FDA's longstanding position on preemption.⁶⁴ The FDA's express message to the public, and to state and local officials, was that the proposed rule would not preempt or otherwise impact state law, effectively silencing interested parties during the notice-and-comment period by assuring them that federalism issues were not at stake. Without too much exaggeration, in light of the 2006 preamble's attempt (and temporary success) at absolute preemption, the FDA could itself be accused of "failure to warn."

The process by which the preamble was inserted without due notice, or due process, improperly placed expediency above respect for state governments. In its mission to implement the peculiar interest of a pressure group, the FDA disrupted the balance of powers and the system of checks and balances among the branches of our federal government, and between the federal and state governments that are the structural and functional bedrocks of our sys-

62. *Id.* at 16–17.

63. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201).

64. *See* *Wyeth v. Levine*, 129 S. Ct. 1187, 1202–03 (2009).

tem.⁶⁵ Unbalanced and unchecked, the preamble exalts the bureaucratic processes of the executive branch and subordinates the legislative and judicial branches of both the federal government, and the states themselves, without any constitutional basis or justification.

The preamble disregarded the clear intent of Congress to defer to the traditional role of the states in this area.⁶⁶ State tort laws have historically been the primary compensatory mechanism for negligence and product liability.⁶⁷ This system has been developed over two centuries and would have been destroyed had the Court deferred to the preamble.⁶⁸ No federal agency has ever fully occupied an area of the compensatory tort system without an explicit act of Congress. Such acts have been rare and usually provide for comprehensive adjudicatory procedures.⁶⁹ The preamble met neither requirement.⁷⁰ In the eyes of tort law's traditional enactors and guardians, it was nihilism, not preemption.

In the preamble, the FDA attempted, ultimately unsuccessfully, to preempt Congress, and to do so secretly, dispensing with the notice-and-comment requirements. This is a low-water mark in agency integrity and a rejection of due process that is likely unprecedented in the annals of federal regulation. It was, deservedly, short-lived, but wreaked havoc in the courts while it lasted.

While the executive branch is entitled to assert any position it wishes, it cannot do so through a legal process that fails to afford state governments the respect they are due under constitutional

65. See *Gregory v. Ashcroft*, 501 U.S. 452, 457–59 (1991) (describing federalism).

66. See David C. Vladeck, *FDA Preemption, Wyeth, Congress, and a Crystal Ball*, 32 *HAMLIN L. REV.* 707, 719 (2009); see also Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 *Fed. Reg.* 3922, 3934–35 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

67. See Philip H. Corboy & Todd A. Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption*, 15 *AM. J. TRIAL ADVOC.* 435, 451 (1992).

68. See Betsy J. Grey, *The New Federalism Jurisprudence and National Tort Reform*, 59 *WASH. & LEE L. REV.* 475, 519–20 (2002).

69. This did occur, uniquely, with respect to vaccines. See *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 251, 255–56 (3d Cir. 2009) (affirming the grant of summary judgment in favor of Wyeth, the manufacturer of the diphtheria-pertussis-tetanus (DPT) vaccine, and discussing the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-22(a)–(b), which expressly preempts design defect claims).

70. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 *Fed. Reg.* at 3933–36.

guarantees of federalism.⁷¹ There was no emergency or any other supposed exigency at issue in 2006 to justify the hidden process used to create the preamble.⁷² The procedural failure to give meaningful notice—the preamble’s stealth preemption—is fatal to its preemptive goal.⁷³ For the Supreme Court to have held otherwise would deprive state and local governments of important historical rights without giving them any voice in the proceedings, while rewarding what was essentially a bait-and-switch by the FDA. The FDA’s new 2005–2006 views, as expressed in the preamble, are therefore entitled to no deference.

Congress has never delegated to the FDA authority to determine the preemptive effect of drug labeling rules on state law causes of action. To the contrary, Congress specifically declined to provide a federal damages remedy in the FDCA because state law damages remedies were available, and Congress subsequently added a savings clause.⁷⁴ Congress can hardly be said to have authorized the FDA to supersede the damages remedies traditionally provided by the states, let alone to have made a “plain statement” of intent to preempt.

Congress expressly rejected a proposal to include a federal private right of action in the legislation creating the FDA itself, the FDCA, because “a common law right of action already exist[ed].”⁷⁵ There are no provisions within the FDCA delegating authority to the FDA to determine the preemptive effect of drug labeling rules on state law causes of action. There is only one logical conclusion: Congress did not confer upon the FDA the power to legislate for itself and unilaterally determine whether its drug labeling regulations preempt state law. Therefore, the FDA’s proposed preempt-

71. Exec. Order No. 13,132: Federalism, 64 Fed. Reg. 43,255, 43,257–58 (section 6) (Aug. 4, 1999) .

72. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3933–36 (only explanation for reversal of position on preemption is that “[s]ince the proposed rule was published, FDA has learned of several instances in which product liability lawsuits have directly threatened the agency’s ability to regulate”).

73. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009) (declining to give deference to preamble in light of “procedural failure” to give “notice or opportunity for comment” to states); cf. *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (“thoroughness evident” in agency’s consideration of the issue is a factor in assessing its “power to persuade”) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

74. See Brief of Amici Curiae Vermont et al. in Support of Respondent at 31, *Wyeth*, 129 S. Ct. 187 (No. 06-1249).

75. See Brief of Amici Curiae Members of Congress in Support of Respondent at 9, 31, *Wyeth*, 129 S. Ct. 187 (No. 06-1249).

tion analysis was an ultra vires political statement which exceeded the scope of the FDA's congressional authority and, in the view of state tort laws' protectors, was due no deference from the Court.

V.
THE PREAMBLE'S ABOUT-FACE ON PREEMPTION
UNDERMINED ITS ENTITLEMENT
TO DEFERENCE

Assuming that the FDA had the requisite congressional authority to determine the preemptive scope of its regulations, the plaintiff's position was that judicial deference would nevertheless be unwarranted, because the preamble reversed the FDA's longstanding position against preemption.⁷⁶ The Supreme Court had previously held that an agency's assertions of preemption that reversed prior longstanding agency policy are entitled to little or no weight by the courts.⁷⁷ The FDA's abrupt change in position regarding the preemptive scope of its drug labeling requirements reversed an anti-preemption policy which spanned decades, including an express statement by the FDA in 2000 that: "this proposal does not preempt state law."⁷⁸ During this time, numerous courts throughout the country relied on the FDA's interpretation of its regulations while continuing to develop and refine a substantial body of state common law. Notably, the final rule did not amend any of the regulations upon which these courts have relied in finding no preemption. The FDA's abrupt change in position unnecessarily disrupted

76. As also noted by several courts that were presented with the 2006 preamble as the basis for preemption, "FDA's current view of the preemptive effect of its labeling regulations is a 180-degree reversal of its prior position." *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M:05-1699 CRB, 2006 WL 2374742 at *8 (N.D. Cal. Aug. 16, 2006). Some courts therefore rejected the preamble and the FDA's claims of preemption. *See, e.g., In re Vioxx Prod. Liab. Lit.*, 501 F. Supp. 2d 776 (E.D. La. 2007) (noting change in prior position and refusing to give the preamble either *Auer* or *Chevron* deference).

77. *See, e.g., Bates v. Dow Agrosociences, LLC*, 544 U.S. 431, 449 (2005). *Bates* held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 (2006), a federal statute governing the safety of pesticides, did not preempt state common law tort claims. In *Bates*, the Court rejected arguments made by the government in amicus briefs and chastised the EPA for engaging in the same policy flip-flop at issue in *Wyeth*: "The notion that FIFRA contains a nonambiguous command to preempt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the [opposite interpretation]." *Id.*

78. Draft Guidance for Industry on the Content and Format for Labeling for Human Prescription Drugs and Biological Products, 65 Fed. Reg. 81082, 81103 (2000).

not only its own longstanding principles, but also those of stare decisis.

As the preamble's foes argued, ultimately, the FDA's preamble was simply an unwarranted and arbitrary change in position without any concomitant change in the law, as to which the Supreme Court should grant no deference.⁷⁹ And as it turned out, the Court did not.

VI. THE *WYETH V. LEVINE* DECISION DELIVERS THE COUP DE GRÂCE

The Supreme Court was unimpressed with Wyeth's argument that Diana Levine's tort claims were preempted because they interfered with Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives.⁸⁰ The opinion states: "[W]e find no merit in this argument, which relies on an untenable interpretation of congressional intent and an overbroad view of an agency's power to preempt state law."⁸¹ Wyeth contended that the FDCA established both "a floor and a ceiling" for drug regulation. That is, once the FDA has approved a drug's label, no state law verdict may deem it inadequate, directly or indirectly, "regardless of whether there is any evidence that the FDA has considered the stronger warning at issue."⁸² Of course, there is no federal system of compensatory law that would provide a substitute for the invalidated state law verdict, a point never emphasized (understandably) by Wyeth. This unstated consequence did not escape the notice of the Court, however:

The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary. Building on its 1906 Act, Congress enacted the FDCA to bolster consumer protection against harmful products. Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers.⁸³

79. *See, e.g.*, Brief of Amicus Curiae NCSL, *supra* note 17, at 29.

80. *See id.*

81. *Wyeth v. Levine*, 129 S. Ct. 1187, 1199 (2009).

82. *See id.*

83. *Id.* at 1199–1200 (internal citations omitted).

As the Court noted pointedly, Congress has never acted expressly to preempt prescription drug suits.⁸⁴ The Court did not accept Wyeth's position that the preamble sufficed to preempt, but instead reiterated its classic statement that "the weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness."⁸⁵ The Supreme Court delivered its own verdict: "Under this standard, the FDA's 2006 preamble does not merit deference."⁸⁶ Why? Because, when the FDA finalized the proposed rule it announced in December 2000 (at the time explaining that it would not "preempt State law"), it did so "without offering States or other interested parties notice or opportunity for comment" and "articulated a sweeping position" on "pre-emptive effect in the regulatory preamble. The agency's views on state law are inherently suspect in light of this procedural failure."⁸⁷

The Court's opinion contains further condemnation of the preamble, saying it is "at odds with what evidence we have of Congress' purposes, and it reverses the FDA's own long-standing position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence."⁸⁸ The Court observed the following:

[T]he FDA's 2006 position plainly does not reflect the agency's own view at all times relevant to this litigation. Not once prior to Levine's injury did the FDA suggest that state tort law stood as an obstacle to its statutory mission. To the contrary, it cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims.⁸⁹

As the Court observed, there has been good reason why "the FDA traditionally regarded state law as a complementary form of

84. *Id.* at 1200 ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express preemption provision for medical devices, Congress has not enacted such a provision for prescription drugs.") (internal citations omitted).

85. *Id.* at 1201 (citing *United States v. Mead Co.*, 533 U.S. 218 (2001); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

86. *Wyeth*, 129 S. Ct. at 1201.

87. *Id.*

88. *Id.*

89. *Id.* at 1201-02.

drug regulation.”⁹⁰ Here, the Court recognized the limited resources with which the FDA must do its work:

The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA’s premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.⁹¹

VII. CONCLUSION

As the Court observed, the FDA’s 2006 preamble represented “a dramatic change in position.”⁹² In the interim between the issuance of the 2006 preamble, and the 2009 issuance of the Supreme Court’s *Wyeth v. Levine* decision, however, the preamble’s drama had tragic consequences. While not universally honored by the lower courts, it drove motions for dismissal and summary judgment at the expense and to the lasting prejudice of many thousands of injured consumers and the families of thousands more who were killed by unsafe drugs. The revival of such claims presents obvious practical and legal problems. Substantial judicial resources were consumed in grappling with the preemptive intent of the preamble. Confusion and inconsistency were created in state tort law as interpreted by federal and state torts, and many claims were foreclosed on the technical ground of preemption without the opportunity to be adjudicated on their merits.

The Obama Administration acted decisively, shortly after the issuance of *Wyeth v. Levine*, to prevent a repeat of the preamble scandal. On May 20, 2009, President Obama issued a “Memorandum for the Heads of Executive Departments and Agencies/Subject: Preemption” which, inter alia, prohibits the inclusion “in regulatory preambles statements that the department or agency in-

90. *Id.* at 1202.

91. *Id.*

92. *Id.* at 1203.

tends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation.”⁹³ The Memorandum also reaffirms “the principles outlined in Executive Order 13132” and requires a retrospective review of “regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption.”⁹⁴ Any such provisions are to be eliminated: “Where the head of a department or agency determines that a regulatory statement of preemption or codified regulatory provision cannot be so justified, the head of that department or agency should initiate appropriate action, which may include amendment of the relevant regulation.”⁹⁵

The most uncompromising affirmation of the sanctity of federalism pervades Justice Thomas’ opinion concurring in *Wyeth*. Justice Thomas stakes out the high ground of federalism:

In order to ensure the protection of our fundamental liberties, the Constitution establishes a system of dual sovereignty between the States and the Federal Government. The Framers adopted this constitutionally mandated balance of power, to reduce the risk of tyranny and abuse from either front, because a federalist structure of joint sovereigns preserves to the people numerous advantages, such as a decentralized government that will be more sensitive to the diverse needs of a heterogenous society and increase[d] opportunity for citizen involvement in democratic process. Furthermore, as the Framers observed, the ‘compound republic of America’ provides a double security . . . to the rights of the people because the power surrendered by the people is first divided between two distinct governments, and then the portion allotted to each subdivision among distinct and separate departments.⁹⁶

Indeed Justice Thomas’ defense of federalism is a *tour de force* critique of the Supreme Court’s “entire body” of “purposes and

93. Memorandum From the White House Office of the Press Sec’y to the Heads of Executive Departments and Agencies (May 20, 2009) (on file with the Annual Survey of American Law), *available at* <http://www.whitehouse.gov/the-press-office/Presidential-Memorandum-Regarding-Preemption>.

94. *Id.*

95. *Id.*

96. *Wyeth v. Levine*, 129 S. Ct. 1187, 1205 (Thomas, J., concurring) (internal citations and quotation marks omitted).

objectives preemption jurisprudence [as] inherently flawed.”⁹⁷ Justice Thomas would eliminate the doctrine entirely:

Because such a sweeping approach to pre-emption leads to the illegitimate—and thus, unconstitutional—invalidation of state laws, I can no longer assent to a doctrine that pre-empts state laws merely because they stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives of federal law. . . .⁹⁸

It appears that President Obama and Justice Thomas stand together, albeit from opposite ends of the political and philosophical spectrum, as foes of preemption.

Yet the battle of preemption is not over. As Justice Stevens noted in *Wyeth*, Congress did expressly act to preempt lawsuits concerning medical devices, and legislation will be required to restore access to the courts to compensate and deter harms arising from defective medical devices.⁹⁹ Judicial sympathy for preemption has been driven in part by distain for, or distrust of, juries, or at least for a stated preference to rely upon experts rather than lay people for assessments of risk and responsibility. It is sometimes argued that juries do not consider both sides of the risk/benefit analysis, because they only see the dead and injured and not the many benefited by drugs. These arguments will continue to be made, and they have some, albeit limited, logical appeal.

However they do not square with the facts of litigation. Juries do indeed hear, incessantly, about the benefits of the drugs implicated in product liability trials: defendants’ experts testify as to the relative numbers of those benefited and harmed by the drug at issue to demonstrate that the former far outnumber, and outweigh, the latter.¹⁰⁰ Moreover, it is a medical reality that juries are made up of lay people who are also drug consumers, who have been benefited by many drugs, and who rely upon drugs and their manufacturers to maintain and restore their health.

It is only fitting, in our society founded upon a social contract of reciprocal rights, liberties, and responsibilities, that the purchasers and consumers of drugs have a say in the risk/benefit analysis,

97. *Id.* at 1211 (internal quotation marks omitted).

98. *Id.* at 1217 (internal quotation marks omitted).

99. *See id.* at 1200 (opinion of the court). The proposed Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009), would amend the FDCA to restore liability under state law.

100. *See*, for example, the drug manufacturers’ experts’ testimony as described in the ruling on *Daubert* motions in *In re Bextra & Celebrex Mktg., Sales Practices, & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166 (N.D. Cal. 2007).

determining, on the basis of the facts before them, presented by vigorous and expert adversaries, and assisted by expert witnesses, whether the risk/benefit balance has been observed by the defendant, or whether it must be restored through compensation to the victim. This can be a scary system (for plaintiffs as well as defendants), but it has been refined by innovations such as the parties' selection of bellwether trials to flesh out the issues, predict the merits, and set values for claims, without trying hundreds or thousands of claims ad infinitum.¹⁰¹ It is a testament to the fairness of the trial system and a rebuttal to the derogation of juries as hostile to manufacturers and coddling to consumers that plaintiffs do not invariably win such systematically selected bellwether trials; such trials present risks to both sides.¹⁰²

Federalism is and always has been an uncomfortable system. The check-and-balance system was designed neither for comfort nor for speed. Accordingly, it invariably frustrates litigants and courts. More greatly to be feared, and assiduously to be avoided, however, is the alternative presented, albeit temporarily, by the 2006 preamble: A system in which bureaucrats, insulated from direct access by citizens or effective oversight by Congress, are allowed to usurp all judicial and legislative roles in the course of immunizing from civil liability the manufacturers whose products they approve for marketing. Such "mission creep" can result in mission failure where the public health and safety is concerned, and, if it recurs, the damage to our jurisprudence of federalism, and to the common law itself, may be incalculable.

101. See generally Eldon E. Fallon et al., *Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323 (2008).

102. See, e.g., *id.* at 2335–36 (describing the bellwether trial process in the Vioxx federal and state litigation, under various states' laws: six bellwether trials were conducted in the Vioxx federal MDL, "only one of which resulted in a verdict for the plaintiffs," while "approximately thirteen additional cases were tried before juries in state courts in New Jersey, California, Texas, Alabama, Illinois, and Florida" with mixed results).

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HOW “IMPLIED EXPRESS PREEMPTION” HAPPENED, WHAT IT MEANS TO TRIAL LAWYERS, AND WHY IT MATTERS

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INTRODUCTION

This piece is written from the perspective of a long-time advocate for the use of tobacco products litigation as a public-health strategy. It describes the surprise arrival of preemption as an effective defense in tobacco (and other products) cases, the impact on the ability of plaintiffs’ lawyers to get plaintiffs their day in court, and the consequences for public health of the failure of tobacco litigation in the 1980s.

I. WHAT HAPPENED?

The current trend of finding that federal regulatory statutes preempt state law causes of action in the absence of any indication that Congress so intended—termed “implied express preemption”—started with the iconic tobacco case of *Cipollone v. Liggett Group*. *Cipollone* was heard in the Third Circuit in 1986¹ and six years later in the Supreme Court in a belated appeal.²

Until the Third Circuit’s decision—following a short and little-noticed opinion in another tobacco case the previous year by a Tennessee district court,³—the law on preemption with respect to torts concerning unsafe products was quite clear. Section 288C of the Restatement (Second) of Torts, adopted in 1965, the same year as the Federal Cigarette Labeling and Advertising Act (FCLAA),⁴ provided that “[c]ompliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where

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1. 789 F.2d 181, 187 (3d Cir. 1986).

2. 505 U.S. 504, 516 (1992).

3. *Roysdon v. R.J. Reynolds Tobacco Co.*, 623 F. Supp. 1189 (E.D. Tenn. 1985).

4. Pub. L. No. 89-92, 79 Stat. 282 (codified at 15 U.S.C. §§ 1331–41 (1965)).

a reasonable man would take additional precautions.”⁵ In other words, regulations set a floor, but not a ceiling, for the duty of care. In the 1984 case *Silkwood v. Kerr-McGee*, the Supreme Court refused to find that the Atomic Energy Act implicitly preempted a state law award of punitive damages despite Congress’s clear intention that the regulation of nuclear energy be centralized in a single federal agency.⁶ The settled law before the Third Circuit acted was well-stated and thoroughly discussed in the district court’s *Cipollone* opinion, which rejected the preemption defense.⁷

There were at least two good reasons for the pre-*Cipollone* preemption law. First, Congress generally passed statutes regulating product safety in response to concerns about the harm caused by the product.⁸ This was certainly true of the FCLAA, passed in 1965 in response to the Surgeon General’s landmark 1964 Report⁹ on the dangers of smoking.¹⁰ Reading such statutes to limit the safety-enhancing effects of product-liability suits, in the absence of explicit statutory language requiring such a reading, is simply perverse.

Second, as the Court has recognized at least since *Erie Railroad v. Tompkins*,¹¹ common law causes of action are matters of state law and policy whereby they carry out their retained power and responsibility to provide for the health and safety of their citizens. Congress intervenes in such matters in a surgical manner, making the changes and additions it thinks appropriate in the context of continuing state responsibility. As *Silkwood* made clear, this is especially true with respect to remedies for personal injuries where Congress has not provided a comprehensive individual remedy¹² or otherwise specifically indicated an intention to address these remedies.¹³ A presumption that ambiguous statutory language does not limit state law causes of action for harmed individuals thus respects the consti-

5. RESTATEMENT (SECOND) OF TORTS § 288C (1965).

6. 464 U.S. 238, 248–58 (1984).

7. 593 F. Supp. 1146, 1154 (D.N.J. 1984).

8. *E.g.*, Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified as amended at 21 U.S.C. § 321 (2000)).

9. OFFICE OF SURGEON GEN., SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE, PUBLIC HEALTH SERVICE PUBLICATION NO. 1103 (1964), available at http://profiles.nlm.nih.gov/NN/B/B/M/Q/_/nnbbmq.pdf (last visited Nov. 3, 2009).

10. See H.R. REP. NO. 89-449, at 3 (1965), reprinted in 1965 U.S.C.A.N. 2350, 2351 (discussing “appropriate remedial action . . . as recommended by the Surgeon General’s Advisory Committee”).

11. 304 U.S. 64 (1938).

12. For example, the FCLAA provided no individual remedies at all.

13. *Silkwood v. Kerr-McGee*, 464 U.S. 238, 256 (1984).

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tutional division of powers between the federal and state governments in the areas of health and safety.

When the Third Circuit heard *Cipollone*, it ignored existing preemption law and the reasons supporting it. Rather, in an opinion by Judge Robert Hunter, a former tobacco-industry lawyer,¹⁴ the court looked to the statute’s statement of purposes, which mentioned both “adequately” informing the public of the possible hazards of smoking by including a warning and also protecting commerce to the maximum extent possible.¹⁵ The court applied the principle that any state actions that conflict with the purposes of the statute are implicitly preempted.¹⁶ Accordingly, the court decided that any restriction on cigarette manufacturers’ communication to consumers, beyond the bare congressional warnings, impeded the free flow of cigarettes in commerce and hence was preempted.¹⁷ Additionally, the court held that the statute impliedly preempted claims of fraudulent communications.¹⁸ The opinion ignored the fact that statutory immunity for fraudulent conduct by private actors was unprecedented. The court’s holding also ignored the adverse impact of providing such immunity on the public’s health¹⁹ and would certainly have surprised the legislators who voted for the FCLAA, which was publicly understood as protecting the public’s health and not the industry’s profits.²⁰

The Supreme Court approached the issue differently. Seven Justices agreed that since there was an express preemption clause, there was no room for implied preemption.²¹ The FCLAA’s express preemption clause, the language of which had been amended in 1969 from the original 1965 Act, provided that “[n]o requirement or prohibition based on smoking and health shall be imposed under state law with respect to the advertising or promotion of any cigarettes”²² Justice Stevens, who authored the plurality opin-

14. *Cipollone v. Liggett Group*, 802 F.2d 658, 659 (3d Cir. 1986) (refusing to vacate the opinion and order on this basis).

15. *Cipollone v. Liggett Group*, 789 F.2d 181 (3d Cir. 1986).

16. *Id.* at 187.

17. *Id.*

18. *Id.*

19. See *infra* notes 48–50 and accompanying text.

20. “[T]he public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes.” 15 U.S.C. § 1331(1) (1965).

21. This argument has not stood the test of time. Three years later the Court sensibly backed off from the notion that express preemption inevitably ousts implied preemption. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

22. 15 U.S.C. § 1335(b) (1965). Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, § 2, Apr. 1, 1970, 84 Stat. 88 substituted the provision that “no

ion on behalf of himself, Chief Justice Rehnquist, and Justices White and O'Connor, thought the text was self-explanatory—although it is safe to say Congress probably had not predicted how the Court would interpret it. They held that the statute preempted post-1969 claims based on a failure to warn and the neutralization of federally mandated warnings to the extent that such claims are based on omissions or inclusions in advertising and promotional statements. However, the statute did not preempt claims based on express warranties, fraudulent misrepresentations, concealment of facts, conspiracy to commit fraud, and fraudulent concealment.²³

Justice Blackmun, also writing for Justices Kennedy and Souter, found the FCLAA non-preemptive. Blackmun's opinion considered Congress's actual intent in interpreting the text. The evidence showed that while Congress may well have understood that having warnings on the package would give the tobacco companies a good jury argument—that anyone suing them was adequately warned and had only themselves to blame—no one suggested in the hearings or debates that the warning requirement or the pre-emption language would have the legal effect of preventing failure-to-warn claims. As Blackmun concluded:

[N]ot only does the plain language of the 1969 Act fail clearly to require pre-emption of petitioner's state common-law damages claims, but there is no suggestion in the legislative history that Congress intended to expand the scope of the pre-emption provision in the drastic manner that the plurality attributes to it.²⁴

Justice Scalia, along with Justice Thomas, read the words to preempt all claims based on the industry's communicative behavior.²⁵ In effect, they would have granted the industry a license to lie by removing the most effective sanction: the possibility of having to pay for the health and lives lost in reliance on these lies.

requirement or prohibition based on smoking and health should be imposed under State law with respect to the advertising or promotion of any cigarettes which packages are labeled in conformity with the provisions of this chapter" for provision that "no statement relating to smoking and health should be required in the advertising of any cigarettes which packages are labeled in conformity with the provisions of this chapter."

23. *Cipollone v. Liggett Group*, 505 U.S. 504, 525–31 (1992).

24. *Id.* at 542 (Blackmun, J., concurring in the judgment in part, and dissenting in part).

25. *Id.* at 548, 550 (Scalia, J., concurring in part and dissenting in part) (finding petitioner's failure-to-warn claims preempted by the 1965 Act and all of petitioner's common law claims preempted by the 1969 Act).

Thus, Justice Stevens could point to six votes (his four plus Scalia and Thomas) for the series of claims he had found preempted and seven votes (his four plus Blackmun’s three) for not extending preemption beyond those claims. The opinion therefore became the de facto holding of *Cipollone*, but did not become clear precedent until 2008 when a majority of the Court adopted the plurality opinion in *Altria v. Good*.²⁶ The result was not all that the tobacco industry could have hoped for.²⁷ But *Cipollone* made tobacco litigation unnecessarily difficult for plaintiffs, greatly reducing the potential for reining in industry misbehavior, forcing increases in cigarette prices, and thus protecting public health.

II. WHY IT HAPPENED

Why did the courts overturn established preemption doctrine in the cigarette cases? I must shamefully admit some role in this. As the Chair of the Tobacco Products Liability Project, formed in 1984 to encourage litigation against tobacco companies as a public health strategy,²⁸ I promoted tobacco litigation, and publicly—and naively—predicted a flood of tobacco cases that would soon rival or surpass the number of asbestos cases.²⁹ Others made similar predictions.³⁰ At that time, federal judges viewed asbestos cases as a grave crisis, not for the sufferers, but for the courts which were una-

26. See *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 545, 549, 551 (2008).

27. For that see Justice Scalia’s dissent in *Cipollone*, 505 U.S. at 548, and Justice Thomas’ dissent in *Altria v. Good*, 129 S. Ct. at 552, which would have upheld the Third Circuit’s preemption of fraudulent communications claims and might have preempted tobacco litigation entirely.

28. See Tobacco Technical Assistance Consortium, Key Players in Tobacco Control, http://www.ttac.org/resources/key_players.html (last visited Oct. 22, 2009).

29. E.g., *The McNeil/Lehrer NewsHour* (PBS television broadcast Oct. 14, 1985) (transcript # 2621 at 12: Richard Daynard, Tobacco Products Liability Project: “It seems very likely that there would be several thousand cases filed within the next year or two. At that point I think it’s really all over for the tobacco companies.”).

30. E.g., David Margolick, *Antismoking Climate Inspires Suits Among the Dying*, N.Y. TIMES, Mar. 15, 1985, at B1 (“You can use whatever analogy you want—flies to honey, vampires to blood—but we’ve got a glut of lawyers out there just looking for someone to sue,” said John F. Banzhaf 3d, a professor at George Washington University Law School. Mr. Banzhaf, the executive director of Action on Smoking and Health, an antismoking group, said, “Suits against tobacco companies will soon make other toxic tort cases, like Agent Orange, asbestos or DES, look like preliminary bouts before the heavyweight match.”).

ble to clear their clogged dockets.³¹ I believed, as I had learned in law school and in turn taught my students, that courts would apply existing precedents and interpret statutes to promote the principles and policies embodied in them; it did not occur to me that courts could, and would, manipulate doctrine and language to prevent a tsunami of new cases, especially cases in which they might have thought the plaintiffs were more to blame than the defendants. The year after the Third Circuit's 1986 decision, the First,³² Fifth,³³ Sixth,³⁴ and Eleventh³⁵ Circuits all adopted the tobacco industry's preemption argument.

The two state supreme courts to consider the issue did not join the bandwagon, perhaps because the state courts, though they had handled many asbestos cases, had not been the focus of critical commentary for their failure to handle the cases expeditiously.³⁶ In *Forster v. R.J. Reynolds Tobacco Co.*,³⁷ the Minnesota Supreme Court found some, but not all, claims preempted, *a la* the Stevens plurality opinion in *Cipollone*. And in *Dewey v. R.J. Reynolds Tobacco Co.*,³⁸ the New Jersey Supreme Court ruled, for the reasons first stated by the trial court and later by Justice Blackmun in *Cipollone*, that the FCLAA simply did not preempt product liability suits.³⁹

31. See, e.g., Paul F. Rothstein, *What Courts Can Do in the Face of the Never-Ending Asbestos Crisis*, 71 Miss. L.J. 1, 10 (2001) (asserting that courts employed judicial maneuvers to clear asbestos claims from their dockets without regard to the effect it would have on existing and potential claimants); Michelle J. White, *Understanding the Asbestos Crisis* (2003), available at <http://www.law.yale.edu/documents/pdf/white.pdf> (last visited Jan. 7, 2010).

32. *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 629 (1st Cir. 1987), *rev'd* 633 F. Supp. 1171 (D. Mass. 1986).

33. *Pennington v. Vistrion Corp.*, 876 F.2d 414, 418 (5th Cir. 1989).

34. *Roysdon v. R.J. Reynolds Tobacco Co.*, 849 F.2d 230, 234–35 (6th Cir. 1988), *aff'd* 623 F. Supp. 1189 (E.D. Tenn. 1985).

35. *Stephen v. Am. Brands, Inc.*, 825 F.2d 312, 313 (11th Cir. 1987).

36. See, e.g., Stephen Labaton, *Judge's Panel, Seeing Court Crisis, Combines 26,000 Asbestos Cases*, N.Y. TIMES, Jul. 30, 1991, at A1 (describing the crisis that federal courts faced in asbestos litigation).

37. 437 N.W.2d 655, 660–62 (Minn. 1989).

38. 577 A.2d 1239, 1247 (N.J. 1990).

39. This was doubtless to the surprise of the tobacco companies, which had requested that the Third Circuit delay issuing its mandate in *Cipollone*, presumably in the hope of having an almost-clean sweep to oppose the inevitable certiorari petition from the plaintiffs.

III. WHAT PREEMPTION MEANS TO TRIAL LAWYERS

Most personal injury cases are filed by solo practitioners or small law firms in state courts.⁴⁰ This was certainly true of tobacco lawsuits in the 1980s. Out of 148 cases listed in the index to the Winter 1989/90 issue of the Tobacco Products Litigation Reporter, 107 (or seventy-two percent of tobacco cases) were filed in state court.⁴¹ Of the sixty-seven lawyers who filed these cases, eighteen were solo practitioners, while only five were associated with firms of twenty lawyers or more.⁴² The tobacco company defendants, on the other hand, always had both local counsel and at least one large national law firm representing them.⁴³ As a result of the string of federal appellate court decisions that preceded the Supreme Court's 1992 *Cipollone* decision, preemption was a plausible defense in every case, regardless of the cause of action. What this meant was that every state and federal case had a substantial, controversial, and rather abstruse federal issue, requiring small plaintiffs' firms to divert substantial time to rebutting these asserted preemption defenses even when they prevailed on the merits. Furthermore, defense counsel generally continued to raise legal issues, even where the judge initially ruled against them on these very issues, and take appeals whenever possible.⁴⁴ As an infamous internal memorandum from a lawyer for the R.J. Reynolds Tobacco company put it, "[t]o paraphrase General Patton, the way we win these cases is not by spending all of [R.J. Reynolds]'s money but by making that other son of a bitch spend all of his."⁴⁵

Even the partial plaintiffs' victory in the Supreme Court's *Cipollone* decision did not help plaintiffs very much. The process by which the lower courts tried to interpret the Court's essentially arbitrary edicts gave the tobacco industry more than the Supreme Court thought it had given them. The tobacco industry's greater legal firepower enabled it to produce confusion even where the Supreme Court tried to be clear, and to obtain preemption rulings on

40. See, e.g., Leslie C. Levin, *Preliminary Reflections on the Professional Development of Solo and Small Law Firm Practitioners*, 70 *FORDHAM L. REV.* 847, 850 (2001).

41. Tobacco Products Litigation Reporter's Reference Lists [hereinafter Reference Lists], 5.4 TPLR 9.1-9.13 (1990).

42. *Id.* 9.18-9.25.

43. See generally Reference Lists, 6.4 TPLR 9.20-9.22.

44. See generally William E. Townsley & Dale K. Hanks, *The Trial Court's Responsibility to Make Cigarette Disease Litigation Affordable and Fair*, 25 *CAL. W. L. REV.* 275 (1989).

45. *Haines v. Liggett Group, Inc.*, 814 F. Supp. 414, 421 (D.N.J. 1993).

some causes of action that the Supreme Court had probably thought were protected.⁴⁶ It is therefore no wonder that of the almost 150 tobacco litigation cases filed in the 1980s the great majority were dropped or dismissed, and none (including *Cipollone*) produced a penny for plaintiffs or their attorneys.⁴⁷

IV. WHY IT MATTERS

As to the impact on the public, preemption in the cigarette context has been devastating. The 1986 Third Circuit *Cipollone* decision ended the second wave of tobacco litigation, removing any incentive for tobacco companies to cease marketing to young non-smokers or to stop lying about the dangers of smoking. The opinion also eliminated the possibility that the price of cigarettes would rise to include an insurance premium for the harm the cigarettes would cause in the future. The price elasticity of demand for cigarettes among teenagers has been estimated at -1.4 ; thus, a ten percent increase in the price of cigarettes would have produced a fourteen percent drop in the number of teenagers smoking.⁴⁸ The tobacco industry gained one million new smokers—mostly teenagers—each year for the eight years between the Third Circuit decision and the revival of individual tobacco litigation in 1996,⁴⁹ and over 400,000 smokers died of tobacco-related diseases each year during this period.⁵⁰ Thus, had *Cipollone* come out the other way and successful tobacco litigation caused a modest ten percent increase in the price of cigarettes, 140,000 teenagers would not have begun smoking each year, resulting at some future point in 56,000 fewer Americans ($400,000 \times 14\%$) dying annually from tobacco-re-

46. For example, *Allgood v. R.J. Reynolds Tobacco Co.*, 80 F.3d 168, 171 (5th Cir. 1996), *cert. denied*, 519 U.S. 930; *Cantley v. Lorillard Tobacco Co.*, 681 So. 2d 1057, 1061 (Ala. 1996); and *Small v. Lorillard Tobacco Co.*, 679 N.Y.S.2d 593, 603 (N.Y. App. Div. 1998) all rendered the Supreme Court's non-preemption of fraudulent concealment claims useless for plaintiffs.

47. Clifford E. Douglas, Ronald M. Davis & John K. Beasley, *Epidemiology of the Third Wave of Tobacco Litigation in the United States, 1994–2005*, 15 TOBACCO CONTROL iv9 (2006), available at http://tobaccocontrol.bmj.com/content/15/suppl_4/iv9.full.pdf.

48. Andrew Ding, *Youth Are More Sensitive to Price Changes in Cigarettes than Adults*, 76 YALE J. OF BIOLOGY & MED. 115, 119–20 (2003).

49. This resulted from the plaintiff's success in *Carter v. Brown & Williamson Tobacco Co.*, No. 95-00934 (Fla. Cir. Ct. Aug. 9, 1996).

50. Centers for Disease Control and Prevention, Annual Deaths Attributable to Cigarette Smoking—United States, 2000–2004, http://www.cdc.gov/tobacco/data_statistics/tables/health/attrdeaths/ (last visited Nov. 3, 2009).

lated illnesses. Similar calculations may show substantial numbers of injuries, diseases, and deaths from other dangerous products that could have been avoided had preemption not stood in the way of legal accountability for the manufacturers of these products.

V. CONCLUSION

“Implied express preemption” of product liability cases—preemption based on a possible reading of statutory language, but a reading not required by the language and negated by considerations of federalism and actual legislative history—is unnecessary, of questionable constitutionality, disruptive of the orderly remedial processes of state courts, and at least sometimes inimical to the public health. It is unnecessary because Congress could have used unambiguous language to preempt remedial measures had it so desired. It contravenes the constitutional scheme by depriving states of their traditional power to provide private remedies without a clear congressional mandate, much less a strong argument that this preemption is necessary and proper to carry out a federal purpose. It disrupts state remedies for no good reason, leaving individuals who were injured within the meaning of state law with no remedies at all. And it imperils the public health by removing an otherwise effective deterrent to the sale and marketing of unreasonably dangerous products.

**WHAT TORT THEORY TELLS US
ABOUT FEDERAL PREEMPTION:
THE TRAGIC SAGA OF
*WYETH V. LEVINE***

RICHARD A. EPSTEIN*

I.
INTRODUCTION: THE STATE OF CURRENT
PREEMPTION LAW

Most of the papers in this conference volume grapple with whether the venerable federal preemption principle will block private tort rights of action based on state common law principles. Federal preemption derives from the Supremacy Clause, which stipulates that federal statutes, and the regulations adopted pursuant to them, trump any state law.¹ Two recent Supreme Court decisions, *Riegel v. Medtronic, Inc.*² and, especially, *Wyeth v. Levine*,³ now shape this debate. Taken together, these cases stand for two propositions. First, the doctrine of express preemption is alive and well in the Supreme Court; if Congress wants to block state tort actions against defendants that have complied with federal law, all it has to do is give the word. Second, while Congress has not spoken to the matter, recent decisions of the Supreme Court make it exceedingly difficult for defendants to persuade any court, federal or state, to preempt ordinary tort law actions under theories of either field or conflict preemption.⁴ Although the final verdict is not in, I am ruefully confident that implied preemption in drug duty-to-warn cases

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1. U.S. CONST. art. VI, cl. 2 (“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.”).

2. 552 U.S. 312 (2008).

3. 129 S. Ct. 1187 (2009).

4. See, e.g., *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 452–53 (2005); see also *infra* text accompanying notes 154–63.

has, at best, a cloudy future after *Wyeth*—a point that becomes clear with an analysis of *Colacicco v. Apotex Inc.*⁵

It is no accident that both *Riegel* and *Wyeth* arose out of the interaction between the Food and Drug Administration (FDA) and state tort law. *Riegel* held that the Medical Device Amendments of 1976⁶ preempted a state law products liability case brought against a manufacturer whose device had gone through the FDA's pre-market approval process.⁷ This command precluded the application of state law.⁸

In *Wyeth*, in contrast, the Supreme Court held that a plaintiff could bring a duty-to-warn case under state law relating to Phenergan, an antihistamine marketed continuously since 1955 for the treatment of nausea.⁹ Like all drugs made and marketed in the United States, Phenergan was accompanied by detailed warnings and instructions approved by the FDA.¹⁰ But unlike the Medical Devices Act in *Riegel*, the Food and Drug law contains no explicit preemption provision for drugs,¹¹ and indeed appears to contain a provision that limits preemption in cases where there is a "direct and positive conflict" between the federal statute and any state law.¹² That provision was read by Judge Sloviter in *Colacicco* as calling for only a conflict analysis of preemption.¹³ But the force of

5. 521 F.3d 253 (3rd Cir. 2008), *vacated*, 129 S. Ct. 1578, 1578–79 (2009) (remanding for further consideration in light of *Wyeth*, 129 S. Ct. 1187).

6. See Medical Device Amendments of 1976, 21 U.S.C. § 360k (2006) ("[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . 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."). For a perceptive account of the difficulties in construing the forms of state regulation that are allowed under this provision, see Mark Herrmann, David Booth Alden & Bradley W. Harrison, *The Meaning of the Parallel Requirements Exception Under Lohr and Riegel*, 65 N.Y.U. ANN. SURV. AM. L. 545 (2010).

7. See *Riegel*, 552 U.S. at 322–23.

8. *Id.* at 324–25.

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

10. *Id.* at 1195.

11. *Id.* at 1193–94, 1196.

12. See Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) ("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 . . . unless there is a direct and positive conflict between such amendments and such provision of State law.").

13. See *Colacicco v. Apotex Inc.*, 521 F.3d 253, 262 n.8 (3d Cir. 2008) ("Of course, the plain language of this provision states that the Amendments do not preempt state law in the absence of a conflict. Thus, to the extent that this provi-

that conclusion is muted when, only one page earlier, she quotes established Supreme Court case law that rejects any effort to regard three basic categories of preemption as “rigidly distinct.” “[F]ield pre-emption may be understood as a species of conflict preemption: A state law that falls within a pre-empted field conflicts with Congress’[s] intent (either express or plainly implied) to exclude state regulation.”¹⁴

If that is correct, the analysis of preemption under the food and drug laws collapses back into the elaborate body of Supreme Court rules applicable to implied preemption cases—which all date back to the watershed case of *Rice v. Santa Fe Elevator Corp.*,¹⁵ which established a presumption against preemption:

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.¹⁶

sion affects our analysis, it merely states that conflict preemption applies. In other words, this ‘express preemption’ provision simply leads us to a conflict preemption analysis, which may be applied independently of an express preemption analysis.”).

14. *Id.* at 261 n.6 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990)); see also *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000) (“We see no grounds, then, for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case.”).

15. 331 U.S. 218 (1947).

16. *Id.* at 230 (citations omitted). For different views on preemption, see, for example, Ernest Young, *Federal Preemption and State Autonomy*, in *FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS* 249, 250 (Richard A. Epstein & Michael S. Greve eds., 2007). See also Richard A. Epstein & Michael S. Greve, *Introduction: Preemption in Context*, in *FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS* 1 (Richard A. Epstein & Michael S. Greve eds., 2007); Richard A. Epstein & Michael S. Greve, *Conclusion: Preemption Doctrine and its Limits*, in *FEDERAL*

I have long believed that field preemption was the proper approach in light of the comprehensive control that the FDA exercises in issuing warnings about the dangerous side effects and counter-indications for the use of any drug.¹⁷ Efforts to impose more stringent warnings are best understood as efforts to interdict a set of uses that the FDA has either expressly or impliedly authorized in approving the particular warnings or instructions. The FDA, for all its flaws,¹⁸ does have one advantage over a system of tort liability: It makes its judgments on the overall effects of drug use, not on the particulars of individual cases where the question of proper warning is compromised in a number of ways.

The ex post tort system makes it difficult to disentangle decisions on the adequacy of a warning from those on causation. All warnings have to be issued before any particular use is made. To test the adequacy of a general warning in light of the peculiar circumstances in an individual case puts far too much emphasis on the responses of a particular physician or patient when what is needed is evidence of how the warnings play out in general. It runs a strong risk of inconsistent verdicts both within and across jurisdictions. The ex post tort approach allows plaintiffs' lawyers to attack and demoralize FDA scientists in a public forum. It ignores the fact that the FDA keeps too many drugs off the market. Finally, the social losses from untreated diseases, however real, are rarely laid at the FDA's doorstep. In sum, to the extent that a plaintiff's case relies solely on the inadequacy of the FDA-approved warning, it should be categorically preempted.

That preemption logic does not extend with equal force to those decisions about product promotion that take place *after* the FDA process has run its course. Suits brought against companies for activities beyond labeling are not covered by this institutional argument. Accordingly, cases in which it is alleged that drug companies engaged in fraudulent marketing practices and over-promotion after the release of drugs raise different questions than those in which a drug company is alleged to have fallen short in its obliga-

PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 309 (Richard A. Epstein & Michael S. Greve eds., 2007).

17. See Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 Nw. U. L. Rev. 463 (2009).

18. See Richard A. Epstein, *Against Permittitis: Why Voluntary Organizations Should Regulate the Use of Cancer Drugs*, 94 MINN. L. REV. 1, 35-40 (2009).

tions to report adverse incidents to the FDA after the drug is in the marketplace.¹⁹

The correct substantive position should therefore be to prevent all state law tort attacks. This position should be followed whether or not one agrees that the FDA is a poor gatekeeper. It should be followed by those who want to strengthen FDA oversight of warnings as well as by those, like myself, who would limit the FDA's power to keep drugs off the market once they have passed Phase 1 clinical trials—which are relatively inexpensive affairs designed to test basic toxicity.²⁰ Put differently, one can concede that the FDA plays a vital role in patient safety but still think that all duty-to-warn cases should be preempted when drug manufacturers comply with existing warnings.

This effort to separate judgments about preemption from judgments about the proper operation of the FDA is, however, not the current trend. It is a sign of the troubled status of implied preemption that Seth Waxman, who argued the case for Wyeth, specifically abandoned his reliance on the field preemption theory on appeal.²¹ Sadly, his preferred line of conflict preemption lost out as well.²² The Food and Drug Administration Amendments Act of 2007 (FDAAA)²³ changed the landscape significantly by allowing drug companies to update their warnings prior to FDA approval.²⁴ So Waxman's alternative position might well make sense for new drugs about which valuable information is often acquired from use, except that Phenergan has been used in the same way for decades, ruling out the need for updating. The FDAAA has altered drug policy for the worse, allowing plaintiffs to challenge drug warnings at any time. So long as a stricter warning can be imagined, it may well be for juries to decide whether it should be issued.

19. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.) (allowing the FDA to withdraw approval of any drug if its manufacturer fails to submit the required periodic reports that notify the FDA of adverse drug events and any other new information that might influence the choice of drug labeling). Drug manufacturers must revise their warnings as soon as they obtain reasonable evidence of a serious hazard with drug use. See *id.*

20. See Epstein, *supra* note 18, at 19–20.

21. *Wyeth v. Levine*, 129 S. Ct. 1187, 1192 (2009).

22. See *id.* at 1204.

23. Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.).

24. See *id.* at § 901(a)(4)(B), 121 Stat. at 924.

The approach of piling on tort remedies is counterproductive.²⁵ The implicit premise of this approach, urged most insistently by David Kessler and David Vladeck, is that tort law has to stand ready to pick up where the dilatory efforts of the FDA have left off.²⁶ But this is an oversimplification of the basic situation. The FDA is in a position to commit two equal and opposite sins. In some instances, it lets dangerous non-prescription drugs on the market too quickly.²⁷ More ominously, it often keeps drugs off the market for too long, preventing anyone from using them.²⁸ The threat of tort liability does not correct this second type of error. Rather, tort liability compounds the problem of the FDA's excessive caution. Unfortunately, Justice Stevens's majority opinion in *Wyeth* contains no mention of these offsetting considerations, raised explicitly in a brief filed on behalf of five distinguished economists, each well versed in the subject.²⁹

Catherine Sharkey and Robert Rabin present an intermediate position, which would give preemptive force to those regulations that the relevant enforcement agencies believe require it.³⁰ Unfortunately, Justice Stevens did not show much sympathy for that position either. Finally, by examining the relative institutional capacities of regulators and courts,³¹ Peter Schuck has sought to find the "sweet spot" between an implied preemption doctrine that occupies a field and one that allows all tort actions as a matter of course. His view of the subject—lying midway between Rabin's and Sharkey's on the one hand, and mine on the other—is that the

25. See, e.g., Epstein, *supra* note 17, at 470; Epstein, *supra* note 18, at 18 (noting that drug companies often delay making new, unapproved drugs available for fear of tort liability).

26. 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, 491–95 (2008). Justice Stevens explicitly relied on their article in *Wyeth*, 129 S. Ct. at 1203 n.12. For my futile response to their article, see Epstein, *supra* note 17, at 468–73.

27. See, e.g., Holly M. Spencer, *The RX-to-OTC Switch of Claritin, Allegra, and Zyrtec: An Unprecedented FDA Response to Petitioners and the Protection of Public Health*, 51 AM. U. L. REV. 999, 1000–01, 1030 (2002).

28. See, e.g., Ronald T. Libby, *Policy Analysis: Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers*, CATO INSTITUTE, June 16, 2005, available at <http://www.cato.org/pubs/pas/pa545.pdf>.

29. Brief of John E. Calfee et al. as Amici Curiae Supporting Petitioner, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

30. See Robert L. Rabin, *Territorial Claims in the Domain of Accidental Harm: Conflicting Conceptions of Tort Preemption*, 74 BROOK. L. REV. 987, 1000–02 (2009); Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 415, 437 (2008).

31. See Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73, 82 (2008).

passage of the FDAAA, which expanded the FDA's capacity to monitor drugs post-approval, should further tilt the scale to the pro-preemption side of the ledger.³² More regulation reduces the need for tort actions that cover the same field. Written before the Supreme Court handed down *Wyeth*, Schuck's view now also seems to have been rejected.

My reading of *Wyeth* is that it largely settles the preemption debate against preemption: Except in rare situations, my prediction is that the only protection drug companies can expect from tort litigation is through congressional action. Justice Stevens slapped down the 2006 effort by the Bush-era FDA to block tort actions³³ as a clear abuse of administrative discretion, including want of any notice-and-comment proceeding.³⁴ For the purpose of this paper, however, I wish to focus on a second strand of Justice Stevens's position, chiding the FDA for abandoning its "longstanding position against the preemptive force of FDA warnings without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence."³⁵ This line echoed the concern of Congress when it enacted the Food, Drug and Cosmetic Act (FDCA) seventy years ago, deliberately preserving state law damages claims.³⁶

In this paper I hope to offer some explanation as to why both these sentiments misapprehend the relationship between state tort law and federal preemption. The common wisdom that the FDA did not urge preemption until its ill-fated 2006 administrative preamble is beyond dispute.³⁷ But I will approach the preemption question from the opposite direction by asking whether the original attitude toward preemption should survive in light of the enormous

32. *See id.* at 83.

33. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3967 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

34. *See* *Wyeth v. Levine*, 129 S. Ct. 1187, 1200–01, 1203–04 (2009).

35. *Id.* at 1201.

36. Brief of Amici Curiae Members of Congress in Support of Respondent at 3, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (“[W]hen Congress enacted the FDCA 70 years ago, it deliberately preserved state-law damages claims. Since that time, Congress has consistently understood that federal law does not preempt state-law failure-to-warn claims with respect to drugs approved by the FDA. This understanding has been fortified by settled practice under the statute. For decades, innumerable state-law actions involving FDA-approved pharmaceuticals have been prosecuted to final judgment or settlement.”).

37. *See* Victor Schwartz et al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising*, 32 HARV. J.L. & PUB. POL'Y 334, 385 (2009).

changes that occurred during this formative period of tort law prior to its vast expansion after the passage of the Second Restatement of Torts. Put simply, context matters. Preemption makes perfect sense against the backdrop of tort law as it was formulated in 1939, right after the 1938 FDCA added requirements dealing with safety,³⁸ through the 1962 Kefauver-Harris Amendments that conferred on the FDA the power to examine the effectiveness of questionable drugs.³⁹ This article reinterprets the peaceful coexistence between tort law and the FDA as a function of the narrow and sensible content of the earlier tort law, which has been undermined by substantive state law developments over the last forty years.

Even the most ardent defender of field preemption would find *nothing* in the tort law before 1965 that could ever collide with the commands of the FDA. To show this, the next section traces the evolution of both duty-to-warn and design-defect products liability cases. The huge expansion of state products liability law immediately followed the adoption of the Second Restatement of Torts in 1965, with its famous, but modest, strict liability provision in Section 402A.⁴⁰ This expansion has put strains on the law that are powerfully exhibited by the facts in *Wyeth* and other modern cases, including *Colacicco*. Section I of this paper shows the absence of conflicts between tort law and FDA policy prior to 1965. Section II explains why modern tort law placed the two on a collision course in cases like *Wyeth*. Section III explains how the distortions in Vermont tort law (which governed in *Wyeth*) pose real threats to the operation of the federal system and require a rejection of the position of the *Wyeth* majority decision of Justice Stevens. Section IV explores the post-*Wyeth* landscape through the lens of *Colacicco*.

II.

PRE-1965 PRODUCTS LIABILITY LAW⁴¹

Products liability law began in restrictive fashion with the 1842 English decision in *Winterbottom v. Wright*,⁴² which arose out of an

38. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938).

39. See Drug Amendments of 1962, Pub. L. No. 87-781, § 102(d)-(e), 76 Stat. 780, 781-82 (1962) (codified as amended in scattered sections of 21 U.S.C.).

40. RESTATEMENT (SECOND) OF TORTS § 402A (1965) (introducing strict liability regime).

41. I have given a longer treatment of these issues in RICHARD A. EPSTEIN, MODERN PRODUCTS LIABILITY LAW 9-35 (1980) [hereinafter Epstein, MODERN PRODUCTS LIABILITY LAW]. I have also addressed many of these issues in 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. 1 (2006).

42. 152 Eng. Rep. 402 (1842).

action brought by an injured driver of a defective coach against the coach repairman. There was no direct contractual relationship between the plaintiff and the defendant, and the lack of privity blocked the action without regard to any causal relationship between the defect introduced by defendant's repairs and the injury to the plaintiff.

In reality, the outcome was not quite as strange as the common denunciations—Prosser described the decision as “a fishbone in the throat of the law”⁴³—might suggest. However, Prosser's arguments are manifestly incorrect. First, he contends that “nothing is more foreseeable than that [goods] will be resold to a consumer, or, if they are dangerously defective that he will be injured by them.”⁴⁴ But the resale of goods with possible defects is equally foreseeable to a plaintiff, so the question is what allocation of risk minimizes total accident costs when each party can foresee errors by the other. Foresight there may be, but its relationship to liability is left unexplained. His second argument is little more than a rephrase of the first: “[H]e has so dealt with the goods that they are likely to come into the hands of another, and to do harm if they are defective.”⁴⁵ This suppresses reference to the mechanism of causation and the knowledge of intermediate parties and product users, both of which could well matter. A complete analysis should ask whether the plaintiff might have an action against his employer for his failure to supply a safe place of work, and what should happen if the defendant had been released from potential liability under his contract with the Postmaster General. *Winterbottom* could be read as an effort to give priority of place to downstream control or to freedom of contract principles. But both points were generally ignored in the subsequent evolution of the doctrine.

Be that as it may, it was quite clear that the privity defense had fully evaporated by the time of the 1938 FDCA. The key landmarks are well known, but the Act's overreliance on foresight has always escaped the criticism it deserves. This critique rests on two related themes. The first theme is that intentional harms by concealment or deliberately mislabeling can be a source of liability. The second is that parties have a differential capacity to avoid risk. In all cases, the conduct of both the plaintiff and third parties matters.

43. W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 96 (5th ed. 1984).

44. *Id.*

45. *Id.*

Both of these themes are evident in *Thomas v. Winchester*,⁴⁶ which carved out the first exception to the privity limitation for unreasonably dangerous products. In modern terminology, *Thomas* was a mislabeling case where a druggist sold the poison belladonna in a bottle that was labeled as extract of dandelion, a harmless substance. The issue of negligence seems trivial, for no careful person would confuse the two substances. But any supposed causal complications were eliminated because the plaintiff had taken the belladonna from its original container in reliance on the label. Liability followed because no one thought that she would have taken the drug if she had known the true state of affairs.

This pattern of bad defendant/good plaintiff carried over into the twentieth century. In *Kuelling v. Roderick Lean Manufacturing Co.*,⁴⁷ the plaintiff was injured when he hitched to his team of horses a defective roller he had acquired from a dealer who purchased it from the defendant. The defendant knew the wood was defective and concealed the defect with putty. Neither the plaintiff nor the dealer was aware of the defect. This is *worse* than *Thomas v. Winchester*, even if the poison was inherently dangerous and the roller imminently dangerous because badly made. The modern analogy to *Kuelling* would be deliberately putting poison in a container that supposedly contained medicine.

*MacPherson v. Buick Motor Co.*⁴⁸ is commonly read to mark the demise of the privity defense. It held that plaintiffs could sue automobile manufacturers in negligence if the wheels were made of defective wood that caused damage in ordinary use.⁴⁹ The description offered by Judge Cardozo simply stated that “while the plaintiff was in the car, [the wheel] suddenly collapsed” because it was made of defective wood.⁵⁰ From this description, there may be a coherent principle that allows for, but limits, the scope of products liability. The product was defective in its original position, the defect was latent, and the plaintiff and all third parties had used it in normal and proper condition. To be sure, this case is more difficult than *Kuelling* where the active concealment of the defect turned the case into one of asymmetrical information. It is easy to impose liability on the party with knowledge of the risk; but, in *MacPherson*, the shift to negligence rests on a (defensible) judgment that the defendant is in a better position to avoid the risk through

46. 6 N.Y. 397 (1852).

47. 75 N.E. 1098 (N.Y. 1905).

48. 111 N.E. 1050 (N.Y. 1916).

49. *See id.* at 1053.

50. *Id.* at 1051.

various techniques of quality control (including systems of inspection).

Yet there are two gaps in Cardozo's opinion, one of fact and the other of law. On the former, a careful study by Professor Henderson exploded the myth that this wheel suddenly broke without explanation. Rather, this Buick car, which had been used to haul concrete, had its wooden wheel break when the plaintiff, while driving thirty miles per hour, sought to turn after sinking into four inches of gravel.⁵¹ That level of downstream misuse was so acute that this plaintiff would have had a hard time winning before a jury even under today's law.

The second gap is conceptual. Cardozo's opinion has an odd juxtaposition of narrow and broad justifications. He explains that: "We are dealing now with the liability of the manufacturer of the finished product, who puts it on the market to be used without inspection by his customers. If he is negligent where danger is to be foreseen, a liability will follow."⁵² The first sentence is quite narrow and follows the pattern of harms caused by latent defects in products subject to ordinary use. The asymmetry between the parties that justifies liability is the greater capacity to avoid harm through inspection, which the customer need not do precisely because the manufacturer has done it. The second sentence turns on foresight, and the potential scope of liability that could be much broader when that notion is, as happened, wrenched out of its narrow context. But foresight is a useless tool in all these cases: If the defendant can foresee danger from defects, so too can the plaintiff. If the defendant can foresee product misuse by the plaintiff, the plaintiff can see subpar product manufacturing by the defendant. The issue is not what can be foreseen. The issue is what steps each party should be expected to take so that when they act together losses are minimized. On that score, the individual plaintiff could have superior access to information because he has knowledge of both the product and the context in which it is being used—a fact which looms large in many cases.

This issue of downstream knowledge looms large in the next major case, *Escola v. Coca Cola Bottling Co.*⁵³ In his famous concurrence, Justice Traynor indicated that he would have applied strict

51. James Henderson, Jr., *MacPherson v. Buick Motor Company: Simplifying the Facts While Reshaping the Law*, in *TORTS STORIES* 45–46 (Robert L. Rabin & Stephen D. Sugarman eds., 2003).

52. *MacPherson*, 111 N.E. at 1053.

53. *Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436 (Cal. 1944).

liability when an exploding Coca Cola bottle injured the plaintiff.⁵⁴ Once again, the majority's statement of the facts makes it appear that the explosion "just happened," but the prospects for downstream misuse were manifold: The record revealed that the distributor had placed the bottles behind the counter for thirty-six hours before the plaintiff picked them up, only to have one explode in her hand. Her coworker testified that she had not banged the bottle.⁵⁵ We do not know, of course, whether the testimony was true or rehearsed. But even if that testimony were 100 percent accurate, the downstream risks are not eliminated. In other explosion cases, the bottle could be mishandled during distribution, which could create liability, although likely in negligence. Or an explosion could result from a sharp tap on the edge of a sound bottle that has been left to sit in the sun. If the distributor had failed to exercise reasonable care, liability could follow under *res ipsa loquitur* if it could be shown that the bottle was safe when it reached the distributor and promptly exploded when unloaded. That theory of liability (even if the distributor was the same party as the manufacturer) would have rendered irrelevant Traynor's disquisition on why strict liability is appropriate for manufacturers.⁵⁶ Likewise, if there was product misuse by the end user—and there were alleged fraud rings for these bottle cases at the time—Justice Traynor would have rightly denied recovery because the product did not cause damage in its "normal and proper" use.⁵⁷

What is most important about the case is not the broad statement of "public interest" rationales, but the narrow content of the strict liability rule: "The manufacturer's liability should, of course, be defined in terms of the safety of the product in its normal and proper use, and should not extend to injuries that cannot be traced to the product as it reached the market."⁵⁸ *Escola* thus makes explicit two limitations on tort liability that were also present in Cardozo's *MacPherson* decision. First, the product must be in its original condition, which, by implication, means that no third party altered the product. Second, the product must have been used in its normal and proper way; the original manufacturer whose prod-

54. *See id.* at 440 (Traynor, J., concurring).

55. *Id.* at 437–38 (Gibson, C.J.).

56. *See id.* at 440–44 (Traynor, J., concurring).

57. I cannot trace down the oral references to this effect that I heard years ago in California, but the prospects can never be dismissed. For the detailed exposure of the fraud rings that undermined the California workers' compensation law, see Gary T. Schwartz, *Waste, Fraud and Abuse in Workers' Compensation: The Recent California Experience*, 52 MD. L. REV. 983, 987–92 (1993).

58. *Escola*, 150 P.2d at 444 (Traynor, J., concurring).

uct was safe in its original condition drops out of the case once a misuse has taken place.

Interestingly, while Justice Traynor offers reasons why strict liability provides a simpler and more powerful rationale than negligence, he does not utter a syllable to explain either of the two limitations he adds. It is, however, possible to supply the missing rationale, but only by dispensing with the foresight reasoning. A sensible social welfare function in torts cases starts with the awareness that there is sequential control over a dangerous instrumentality, where each person handles it out of the sight of others. The parties can, through intermediaries, adjust their price to reflect the risk. The task, therefore, is to find an efficient but general way to describe what each party is entitled to expect of the other. The usual language of “reasonable expectations” is often attacked as circular, and thus unequal to the task in this area as in others.⁵⁹ As the argument goes, the only way one can use reasonable expectations to determine what the law is, is to first know the law.

In fact, that facile argument is incorrect. The right way to approach the problem is to ask, in this sequential game, which steps taken by both parties will minimize social loss—here defined as the sum of accident costs and their prevention, including the costs of litigation. Reasonable expectations set out a pattern whereby if both sides comply, no accidents will happen. Traffic rules do the same thing, for no intersection collisions will occur if all parties follow the rules of the road. The hard issues arise when one side deviates and some other party (the plaintiff or a third person) has to decide without notice what to do in response. In a highway accident, the party who has the last clear chance, i.e., knows of the peril, must take prudent steps to react to the new burst of relevant information.⁶⁰ The harder question is whether he can recover for the costs of those precautions in the absence of injury.⁶¹ In the

59. One example is the use of reasonable expectations in Fourth Amendment law. See, e.g., *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1035 (1992) (Kennedy, J., concurring); *Katz v. United States*, 389 U.S. 347, 358–59 (1967). I have tackled this issue in Richard A. Epstein, *Privacy, Publication, and the First Amendment: The Dangers of First Amendment Exceptionalism*, 52 STAN. L. REV. 1003 (2000), and Richard A. Epstein, *Lucas v. South Carolina Coastal Council: A Tangled Web of Expectations*, 45 STAN. L. REV. 1369 (1993).

60. See, e.g., RESTATEMENT (SECOND) OF TORTS §§ 479–80 (1965); Donald Wittman, *Optimal Pricing of Sequential Inputs: Last Clear Chance, Mitigation of Damages, and Related Doctrines in the Law*, 10 J. LEGAL STUD. 65, 78–82 (1981).

61. See Susan Rose-Ackerman, *Dikes, Dams, and Vicious Hogs: Entitlement and Efficiency in Tort Law*, 18 J. LEGAL STUD. 25, 26 (1989) (advocating for a rule that allows for the recovery of costs taken to avoid actionable harm).

road case, it means that one driver has to get out of the way if the other crosses over into his lane. In the products liability context, it means that a consumer who knows that there are worms in a candy bar cannot eat it and then sue for damages⁶²—a decision that coincidentally came down in 1962, the year of the Kefauver Harris amendments.

The impact of the early innovations in products liability law was to treat the two parties as though they were in direct contact with each other. Some measure of the cautious attitude regarding these developments is gleaned from *Pease v. Sinclair Refining Co.*,⁶³ decided in 1939. The plaintiff was a science teacher injured in an explosion that occurred when he placed a substantial amount of sodium in water, causing the loss of an eye and serious burns. The plaintiff knew well the dangers of mixing sodium with water, but he put the concoction together because the water was from a bottle marked kerosene. The defendant oil company had marked it as such in order to allow its shipment through the mails. The plaintiff relied on the label and did not smell the bottle. After an extensive trial, the jury found the defendant guilty of negligence and the plaintiff free of contributory negligence.⁶⁴ As a sign of the times, it took an appellate decision by Chief Judge Clark to establish that it was proper to leave the questions of both negligence and contributory negligence to the jury.

What is striking is how easy the case should have been for the plaintiff. The defendant misled the plaintiff, who had a right to rely on the label. That deliberate misrepresentation did not lose its sting because the defendant clearly had no intention to harm the plaintiff. It was quite enough that it disarmed the plaintiff's well-honed instincts for safety. Today, liability is too certain for a parallel case to get within miles of a jury, except perhaps for punitive damages for reckless disregard of safety.⁶⁵ It takes little imagination to ask what would have happened if the fluid which had been mislabeled to facilitate shipping was supposed to be used as a drug for medical treatment.

62. See *Kassouf v. Lee Bros.*, 26 Cal. Rptr. 276, 278–79 (Dist. Ct. App. 1962) (using assumption of risk to achieve that result).

63. 104 F.2d 183 (2d Cir. 1939).

64. See *id.* at 184–85.

65. For a modern view on punitive damages, see *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416–28 (2003) (reviewing constitutional requirements for punitive damages).

The issue in *Pease* regarded a danger that was latent on one side and patent on the other. *Campo v. Scofield*⁶⁶ encompassed the exact opposite pattern of risk, one that was open and obvious to the product user. The facts were simple enough: The plaintiff caught his hand in the revolving rollers of an “onion topper,” where they were badly mangled. Judge Fuld stressed that the obviousness of the defect put the user in a position to decide how best to use it: “[I]f the machine is without any latent defect, and if its functioning creates no danger or peril that is not known to the user, then the manufacturer has satisfied the law’s demand.”⁶⁷ Note that this defense blocks not only the duty-to-warn claim—why impose a duty to tell someone what he already knows—but also the design defect cause of action. The logic of the position is that full information allows downstream parties to decide whether, and if so how, to use the product in question. The threat of personal injury to the user, and the prospect of workers’ compensation payments for the employer, will lead to a selection of equipment suitable for its intended purposes. The clear logic behind this decision is that the downstream users are in a position to customize any equipment in ways that meet their respective demands. And once they do, the equipment is no longer in its original condition, so that liability for the manufacturer ceases on the ground that the “[t]hing used was not the thing sold.”⁶⁸ Supply full information and the logic flips over from *Pease* to *Campo*. Information allows the party that possesses it to organize the efforts that reconcile the conflicting demands of output and safety. And the temptation to redesign equipment to fight the last war is ruled out on categorical grounds because the defendant gets summary judgment on both warning and design theories of liability.

This attitude toward risk was reflected in the “open and obvious” defense in design defect cases. In *Evans v. General Motors*,⁶⁹ the decedent was killed when his GM car was broadsided. The court refused to allow a negligence case based on a crashworthiness theory by pointedly refusing to extend liability “despite the manufacturer’s ability to foresee the possibility” of collision.⁷⁰ Once again, the transfer of full information properly precluded the plaintiff from moving back along the chain of distribution. Joint causation

66. 95 N.E.2d 802 (N.Y. 1950).

67. *Id.* at 804.

68. *See* *Young v. Aeroil Prods. Co.*, 248 F.2d 185, 190 (9th Cir. 1957).

69. 359 F.2d 822 (7th Cir. 1966).

70. *Id.* at 825.

theories of liability for successive liability, so critical in *Wyeth*, were not used in these full information settings.⁷¹

These cases give an accurate description of the state of the law at the time of the Second Restatement of Torts in 1965.⁷² So long as liability was confined to latent hazards, the preemption issues of later times are just not implicated. But the once-solid distinction between patent and latent defects was crumbling. A famous passage in the Fowler Harper and Fleming James treatise argued strongly against the open and obvious rule, claiming that obviousness should count as only one factor in a general negligence equation.⁷³ They did not think of their work as particularly revolutionary, but by taking a huge category of cases from the land of defendant summary judgments into hotly contested jury trials, it surely was.

This widespread academic ferment led some manufacturers to do what they had never contemplated before. Sensing they would be held responsible for losses that were better controlled at the downstream level, they started to insert contractual provisions where tort law had started to turn wobbly, including of course the limited liability provisions at issue in *Henningsen v. Bloomfield Motors*.⁷⁴ But this tactic failed under both contract and tort law. Disclaimers of warranties were effectively banned under the Uniform Commercial Code,⁷⁵ and their role was sharply limited in much-celebrated cases that dealt with implied warranties⁷⁶ or strict liabil-

71. There could clearly be some argument as to whether these cases merit the description "full information." The use of the term "open and obvious" was intended to make liability turn on what was publicly known so as to avoid the risk of perjured defenses of the sort that denied the existence of that knowledge. In fact, the single most important feature about automobile safety, weight, is well known. To require perfect awareness of all that follows from an open and obvious condition clearly makes it impossible to accept any argument of that sort.

72. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

73. See 2 FOWLER V. HARPER & FLEMING JAMES, JR., THE LAW OF TORTS § 28.5 (1956) ("[T]he bottom does not logically drop out of a negligence case against the maker when it is shown that the purchaser knew of the dangerous condition.").

74. *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 74 (N.J. 1960) (finding disclaimers unconscionable in implied warranty case brought by nonpurchasers of the product).

75. See, e.g., U.C.C. § 2-318 (1995) (stating that a "seller may not exclude or limit the operation of this Section"); U.C.C. § 2-719(3) (holding that a limitation on "consequential damages for injury to the person in the case of consumer goods is prima facie unconscionable," without indicating any way in which that presumption could be rebutted).

76. See *Henningsen*, 161 A.2d at 74.

ity in tort.⁷⁷ At this point, contractual correction of judicial errors was no longer possible. The judges who failed to appreciate the importance of downstream conduct effectively froze the law in the wrong place for the wrong reasons.

The Second Restatement is better viewed as a consolidation of earlier trends than the adumbration of the impending transformation of the law.⁷⁸ In its original formulation, the movement to strict liability did not dislodge any of the constraints on downstream conduct that Judge Traynor thought were an integral part of his strict liability rule.⁷⁹ The definition of “product defect” makes it clear that the strict liability rule “applies only where the product is, at the time it leaves the seller’s hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him.”⁸⁰ On the flip side, the doctrines of contributory negligence and assumption of risk hold that:

Contributory negligence of the plaintiff is not a defense when such negligence consists merely in the failure to discover the defect in the product, or to guard against the possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense⁸¹

At this point, the one question that matters is whether any form of liability that was contemplated either in negligence or strict liability could pose the slightest threat to the way pharmaceutical companies made or marketed their products under these early rules. The answer has to be an emphatic “no.” It therefore made perfect sense for many statutes to have a clause that saved common law causes of action—and why not, when such actions clearly reach only issues that fly beneath the radar of these statutory schemes?

Cases of mislabeling and defective preparation are open and shut as to liability today and nothing about the ill-fated 2006 FDA preamble was meant to alter what has become a hard and fast rule. Deviate from the standards of purity or make a mistake in labeling and your goose is cooked. Meet standards on purity and labeling

77. *See, e.g.*, *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963) (approving the “refusal [of the law] to permit the manufacturer to define the scope of its own responsibility for defective products” by contract).

78. For a review of the narrowness of its rules, see Epstein, *MODERN PRODUCTS LIABILITY LAW*, *supra* note 41, at 57–67.

79. *See supra* text accompanying note 58.

80. RESTATEMENT (SECOND) OF TORTS § 402A cmt. g (1965).

81. *Id.* cmt. n.

and you are home free. The responsibility now moves downstream to subsequent actors. Rightly understood, the simple explanation for the state of play between the regulatory system of 1939 and the tort system of that date is that they do not come into conflict. To say that there was peaceful coexistence between the two is correct, but only in a highly restricted sense. The critical but modest aspirations of the early tort law assured that never a conflict, never an overlap, never an occupation of a field could arise. It therefore made perfectly good sense to insert in federal statutes provisions creating express preemption on the one hand and common law savings clauses on the other. For example, the National Traffic and Motor Vehicle Safety Act of 1966⁸² contained both an express preemption clause⁸³ and a savings clause providing that “[c]ompliance with” a federal safety standard “does not exempt any person from any liability under common law.”⁸⁴

Just two years later, tort liability experienced a vast expansion in the series of crashworthiness cases initiated by *Larsen v. General Motors Corp.*⁸⁵ In the pre-*Larsen* environment, it is incorrect to say that the question of preemption did arise and that it was resolved in favor of allowing the private right of action. In the post-*Larsen* environment, however, the conflict became acute. This was shown in the case of *Geier v. American Honda Motor Company*,⁸⁶ where Justice Breyer, over a Justice Stevens dissent, allowed for federal preemption after exhaustively reviewing the complex negotiations that led to a postponement of the introduction of air bags into passenger vehicles.⁸⁷ In effect, his views of preemption did not block any common law product liability actions of the sort maintained before 1965, of which *Geier* was surely not one. Justice Breyer treated *Geier* as a case of conflict preemption, but it could have been decided as easily as a case where tort liability frustrated a coherent federal scheme or where the active intervention of the Department of

82. Pub. L. No. 89-563, 80 Stat. 718 (1966) (repealed 1994).

83. § 103(d), 80 Stat. at 718, 719 (“Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment, any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.”).

84. § 108(c), 80 Stat. at 718, 723.

85. 391 F.2d 495 (8th Cir. 1968).

86. 529 U.S. 861 (2000).

87. *See id.* at 874–81.

Transportation occupied the field.⁸⁸ In any event, *Geier* represents the type of case that could not have survived summary judgment before the advent of the crashworthiness cases. In closing, I know of no litigated case in the pre-1965 period in which the court should have found preemption under any of the three established doctrines.

III. PRODUCTS LIABILITY LAW IN ITS MODERN VOICE

The shift in the basic thrust of products liability came in the immediate aftermath of the Second Restatement. Most critically, the massive expansion of tort liability in products liability cases had little to do with the strict liability innovations of Section 402A. Strict liability provisions proved relevant in the cases where they were hardly needed, namely those dealing with manufacturing defects built into the product before it leaves the manufacturer's hands.⁸⁹ The manufacturer's complete control over the fabrication process, including the capacity to impose quality control standards and inspections, makes it wise to dispense with the use of a negligence inquiry, which even in the pre-1965 period was hurried along by a generous dollop of *res ipsa loquitur*.⁹⁰

Yet the design and warning cases present entirely different issues precisely because the passing down of full information no longer created a shield against liability. The decision to expand liability did not, of course, undercut the traditional product liability cases for latent defects that caused harm in ordinary use. Those cases became so easy (and with good quality control, so rare) that they quickly disappeared, as it became truly hopeless to contest liability. But the pre-1965 pressure to push responsibility down the chain of distribution toward the user came to a halt with the abrogation of the open and obvious rule.

The change was first felt in the design defect area when the courts quickly moved away from the position that concentrated

88. *See id.* at 873–74 (discussing the ways in which various models of preemption might apply).

89. *See, e.g., Moore v. Jewel Tea Co.*, 253 N.E.2d 636, 647 (Ill. App. Ct. 1969) (requiring plaintiff to prove that her injury resulted from a condition of the product which was unreasonably dangerous and which existed at the time the product left the manufacturer's control).

90. *See Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436, 440 (Cal. 1944) (Gibson, C.J.) (affirming the judgment below in reliance on the *res ipsa loquitur* formulation, which applied once it was clear that the downstream users did not alter the product).

solely on latent defects by adopting the Harper and James view⁹¹ that even if a condition was open and obvious to the user, some duty could exist on the part of the manufacturer to guard against it. *Micallef v. Miehle Co.*⁹² unceremoniously overruled *Campo* by treating all accidents arising from the use of machine tools as raising hard questions of joint causation. The downstream parties may have incurred some responsibility, but the initial supplier of the product remained a “substantial factor” in the mix even if foolish things were done downstream.⁹³

Similarly, theories of joint causation in the crashworthiness area displaced the downward pressure of the open and obvious rule. Thus, in the watershed case of *Larsen*,⁹⁴ the decisive question now was what design features the defendant had to install to deal with the anticipated misbehavior of the plaintiff,⁹⁵ which could include driving drunk at over one hundred miles per hour.⁹⁶ Once again, any foreseeable injury was sufficient to trigger the manufacturer’s duty, while the knowledge of the condition of the vehicle by the driver necessarily became a secondary issue. And once again the expansion of liability came under the negligence rubric, given that the manufacturer was “under a duty to use reasonable care in the design of its vehicle to avoid subjecting the user to an unreasonable risk of injury in the event of a collision.”⁹⁷ Sharp boundary conditions and joint causation displaced the relatively sharp separation of responsibilities under the open and obvious rule.

The new developments did not necessarily displace the older tests that tied liability to the reasonable expectations of product users. Indeed, the critical decision in *Barker v. Lull Engineering Company*,⁹⁸ expressly preserved a reasonable expectations strand of product liability when it articulated this two-pronged test for product liability:

[W]e have concluded from this review that a product is defective in design either (1) if the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if, in light

91. See HARPER & JAMES, *supra* note 73.

92. 348 N.E.2d 571, 573 (N.Y. 1976) (“The time has come to depart from the patent danger rule enunciated in *Campo v. Scofield* . . .”).

93. See *id.* at 575.

94. *Larsen v. General Motors Corp.*, 391 F.2d 495 (8th Cir. 1968).

95. See *id.* at 501.

96. See *LeBouef v. Goodyear Tire & Rubber Co.*, 623 F.2d 985, 989 (5th Cir. 1980).

97. *Larsen*, 391 F.2d at 502.

98. 573 P.2d 443 (Cal. 1978).

of the relevant factors discussed below, the benefits of the challenged design do not outweigh the risk of danger inherent in such design. In addition, we explain how the burden of proof with respect to the latter “risk-benefit” standard should be allocated.⁹⁹

The first prong of this test keeps alive, in somewhat expanded form, the noncontroversial approach to product liability cases dealing with latent defects. But the second prong opens up vast new vistas of liability (which the *Barker* court might not have fully appreciated) that notably undermine the old approach to sequential conduct in full information settings.

Specifically, *Barker* involved a high-lift loader designed for work on level ground. The product manuals stated explicitly that it should not be used on uneven terrain, where more complex equipment was required. The plaintiff, a substitute driver with limited experience in using such equipment, was hurt when he fell from the loader. The regular driver was smart enough to call in sick. The plaintiff’s case rested on the claim that the loader should have been designed in ways that would prevent this injury, such as including outriggers to provide greater lateral stability.¹⁰⁰ The original jury refused to find for the plaintiff, and the case was remanded on the ground that the instructions did not take into account the manufacturer’s need to guard against foreseeable misuse, even when the risks in question were obvious to all concerned.¹⁰¹

Barker’s entire framework resulted in a vast misalignment of legal responsibility because the real breakdown in the system occurred at the worksite level where liability, perhaps under workers’ compensation, should apportion the loss. The employer had full information as to the limits of the machine, and the plaintiff may have had it as well. If he did not, we know who was in the better position to communicate the needed information to the worker. But to require this loader—and by implication, every loader—to be designed for uneven terrains, would make it impossible to adopt efficient segmentation of worksite equipment. The decision imposes a heavy tax on anyone who makes a cheaper loader that is proper in most situations simply because they can be misused in settings where they are unsafe. The price will increase, use will dry up, and older equipment will remain in service longer than it should.

99. *Id.* at 446.

100. *See id.* at 447–48.

101. *See id.* at 449.

To reach this misguided result, Judge Tobriner had to deny the exclusive application of the reasonable expectations test, under which the efficient solution requires each party to do its part. To do so, he appealed to an influential article by John Wade that insisted a consumer expectations test could never set the exclusive standard for liability: "In many situations . . . the consumer would not know what to expect, because he would have no idea of how safe the product could be made."¹⁰² But Wade asked the wrong question. The issue for the consumer or product user is not what else is on the market, but rather what steps to take in deciding when and how to use the equipment at hand. By that standard, there was no information gap in *Barker*, where it was painfully apparent that the loader was not designed for use on rugged terrain. Of course, additional design features found in other loaders could have been added, but only in ways that would render the loader less useful.

At this point, the twin sins of the expanded scope of products liability law become clear. First, because reasonable expectations do not do the entire job, the jury is allowed, with the benefit of hindsight, to conduct its own cost-benefit analysis of the product design. The temptation to overrate the risk that did occur, as opposed to those that might have occurred in other settings, is manifest, and it increases the prospect of inconsistent jury decisions in response to alternative hazards. Second, that judgment on product design is not made on the expectation that the product user will make normal and proper use as under the *Escola* formulation. Instead the rule is that the design must also cover cases where the product is used in an "intended and reasonably foreseeable manner,"¹⁰³ which includes all sorts of misuses against which it is possible to guard, but only at a cost. The effect of this rule is to impose a tax on the prudent to protect the foolish. No longer is it permissible to narrow the scope of use to make the equipment more efficient for its intended function. Downstream managers and professionals are now being treated as though they will misbehave, which only increases their incentives to do so.¹⁰⁴ The dangers of departing from a full information model, under which the sole duty is to let downstream users know what is expected of them, conditional on the product manufacturer delivering what he has prom-

102. *Id.* at 454 (citing John Wade, *On the Nature of Strict Tort Liability for Products*, 44 *Miss. L.J.* 825, 829 (1973)).

103. See, e.g., *Barker*, 573 P.2d at 443.

104. See Richard A. Epstein, *Products Liability as an Insurance Market*, 14 *J. LEGAL STUD.* 645, 653-54 (1985).

ised to do, are manifest. The dominant theme is to substitute inefficient upstream precautions for efficient downstream ones, and the seeds are planted for *Wyeth v. Levine*.

The revolution behind these post-1965 design defect cases is matched by a parallel revolution in the duty-to-warn cases that is directly relevant to pharmaceutical cases. A fair reading of the pre-1965 cases is that, as in *Pease v. Sinclair*, once the product was properly identified, additional obligations to warn were modest.¹⁰⁵ Poisons had to be labeled as such, but the labeling of most medicines rarely, if ever, generated any form of potential liability. The simplest explanation is two-fold. For widely disseminated generic products, finding information is relatively easy. And in any event, with respect to prescription drugs, the patient can rely on the professional knowledge of the physician to steer clear of trouble on pain of possible malpractice liability. Clearly this picture has some element of tension in it because many dangers from the use of medicine are not discoverable by ordinary inspection. Therefore, there would be no objection to statutes requiring certain products to be labeled before sale, which was also the case in the pre-1965 period.¹⁰⁶ Explicit warnings, provided in advance, could be required for the sale of drugs to close any remaining information gap. There was some modest expansion of warning liability in the Second Restatement, bridging the gap between old and new: "Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required."¹⁰⁷ But even that cautious sentiment does not translate into the huge expansion of duty-to-warn liability against manufacturers, which, under modern law, uses a fine-toothed comb to go through every nook and cranny of ever-long warnings.

In a fashion that was largely unanticipated, the law soon spilled over beyond the narrow confines of the Second Restatement. Early landmarks in this transformation were the 1968 case of *Davis v. Wyeth Laboratories*,¹⁰⁸ followed by *Reyes v. Wyeth Laboratories*,¹⁰⁹ which took the position that there was a duty to disclose a less than one-in-a-million chance that a polio vaccine could cause polio.¹¹⁰ One

105. See *supra* text accompanying notes 63–65.

106. See, e.g., *Osborne v. McMasters*, 41 N.W. 543, 543 (Minn. 1889) (requiring a label that said "poison").

107. RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965).

108. 399 F.2d 121 (9th Cir. 1968).

109. 498 F.2d 1264 (5th Cir. 1974).

110. See *Davis*, 399 F.2d at 124 (quoting a report from the Surgeon General: "The level of this risk can only be approximated but clearly is within range of less than I [sic] case per million doses. Since the cases have been concentrated among

possibility in both these cases was to insist that the duty to warn rested with the party who administered the drugs in the first instance—a pharmacist in *Davis*¹¹¹ and a registered nurse in *Reyes*¹¹²—neither of whom passed specific information onto their respective plaintiffs.

In a sense, it was easy to find liability since the vaccines were administered without any warning to the patient. The issue of the warning's adequacy did not have to be assessed. But the stress on upstream control of the warning process comes at a real cost. The risks in question are generic, so other sources of information are available about them. And it is risky business to insist on the disclosure of a downside risk without being sure that the far greater risk of getting polio from a wild strain is disclosed as well. As a simple matter of fact, the odds were overwhelming that the wild strain, and not the vaccine, caused the injury in light of the epidemic of polio at that time.¹¹³ The net effect of judicial intervention here is to raise the price of vaccines and reduce the likelihood of their dissemination.¹¹⁴ And even when full attention is paid to the issue of information transfer, the task of informing a widely disparate set of persons is quite formidable because there is always the opportunity for slippage in translation. Special conditions of individual plaintiffs could be overlooked; language and literacy barriers could easily exist. Finally, a conscientious doctor or nurse could use a bit of encouragement that would effectively negate the warning in full. These are all issues that are better handled downstream than by a manufacturing company that can ill-afford to monitor a process that it cannot effectively control.

The key issue in many cases, however, arises when the desired warning from the manufacturer is transferred to the recipient of the drug or vaccine. Just what should that warning say? In line with higher levels of judicial oversight, the hairsplitting begins over whether they should be regarded as adequate for the occasion.

adults the risk to this group is greater; whereas, the risk to children is exceedingly slight or practically nonexistent.”). The duty to warn was also explicitly recognized. *Id.* at 126.

111. *See id.* at 123.

112. *See Reyes*, 498 F.2d at 1270.

113. *See id.* at 1290.

114. For an estimate of the cost with respect to whooping cough vaccine, see Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 288 (1985) (noting that the whooping cough vaccine causes twenty-five cases of serious, long-term brain damage each year, while it saves 413 lives). There is with these numbers no need for ex post compensation for injuries. The huge reduction in total losses should supply compensation enough.

Overly chill-inducing warnings that “paralytic disease following the ingestion of live polio virus has been reported in individuals” can be found inadequate because they do not say that this outcome is to be expected.¹¹⁵ There is a catch-22 here. It is wrong to make those statements when the evidence does not support them. But let the jury decide that the evidence cuts the other way, and it will then deem these false statements as true, imposing liability on the strength of its own misperceptions. In consequence, the vaccine cases can usher in a destructive pattern of strategic behavior that cannot be deployed against drug manufacturers when the downstream player is the only person who bears the risk of liability: A plaintiff can settle with the doctor or other responsible intermediary and use his or her testimony to land the larger fish, the drug manufacturer. This is precisely what happened in *Wyeth v. Levine*.¹¹⁶

This trend extends beyond vaccines to other medical contexts. Perhaps the most famous (or notorious) case of this sort is *MacDonald v. Ortho Pharmaceutical Corporation*,¹¹⁷ which held that juries could find a drug company liable under a duty-to-warn theory for alleged injuries caused by birth control pills.¹¹⁸ In *MacDonald*, unlike in *Davis* and *Reyes*, no one doubted that the drug caused the twenty-six year-old woman’s stroke. The issue was whether the warning could be adequate if it did not contain the word “stroke,” even if it did warn that “[t]he most serious known side effect is abnormal blood clotting which can be fatal.”¹¹⁹ The question of the warning’s adequacy was left to the jury as was the causation question, or, more specifically, the question of how likely it would be that someone who knew that a drug could be fatal would nevertheless decide to take the drug (to avoid some alternative peril) because she did not know that the fatal injuries could be caused by a stroke. The marginal impact of the missing information has to be judged against the background information already known. In this case, it is not credible to think that this additional piece of information could alter behavior. Yet even given the tiny omission in this warning, causation in drug duty-to-warn cases will always be a jury

115. *Givens v. Lederle*, 556 F.2d 1341, 1343 (5th Cir. 1977); *see also id.* at 1345.

116. 129 S. Ct. 1187, 1191 (2009). The dangers of the odd dynamics of settlement negotiations have been well known and are clearly set out in Justice Stevens’s opinion in *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 212–13 (1994) (noting how under the credit rule the more responsible defendant can escape by paying less).

117. 475 N.E.2d 65 (Mass. 1985).

118. *See id.* at 71.

119. *Id.* at 66.

question. The error costs of false positives are thus very high indeed.

MacDonald also made clear that the drug company could not escape liability because the plaintiff was in the care of a physician who had all the relevant knowledge about her condition and the drug in question.¹²⁰ The downstream-only option was explicitly rejected in favor of a joint causation model that allowed the plaintiff to simultaneously sue the drug company under a duty-to-warn theory as well as the physician under a negligence theory by including the physician's failure to meet the requirements of an informed consent rule.¹²¹ Not surprisingly, by this time, the issue of federal preemption did surface, because the FDA had approved the warning in question. That additional warning meant that any gap in information had been addressed in the first instance by the FDA warning. But far from letting that warning stabilize the overall situation, "the FDA commissioner specifically noted that the boundaries of civil tort liability for failure to warn are controlled by applicable State law."¹²²

IV. WYETH V. LEVINE, AT LAST

We are now in a position to put all the pieces together to see how the great transformation in tort law creates a genuine tension with the objectives of the food and drug laws. In duty-to-warn cases, such as *Wyeth*, liability depends on the rejection of the full information model; the unwillingness to accept technological specialization at different stages of the production process; the adoption of extensive theories of joint causation; the disregard of downstream abuse; the ineffectiveness of disclaimers and contractual limitations; and the use of collusive settlements between plaintiffs and downstream actors. None of these elements was in play before the tort revolution of the late 1960s. In the modern environment, federal preemption becomes the last line of defense against the combined weight of all of these factors. The key point is that none of the favorable state law doctrines could be invoked unless the plaintiff could first claim that the FDA warning was inadequate. Yet just that possibility was blocked by the FDA preamble, which "interprets the act to establish both a 'floor' and a 'ceiling'" in all duty-to-warn

120. *See id.* at 69.

121. *See id.* at 138–39, 139 n.13.

122. *Id.* at 70 (citing 43 Fed. Reg. 4214 (1978)).

cases.¹²³ Once the FDA began treating its warning as setting both maximums and minimums, it blocked liability at the outset; none of the other changes in state product liability law mattered. Yet once that barrier is overcome, the combined force of all the new state law doctrines comes into play.

To understand how the state law doctrinal transformations work in unison, start with Levine's complaint, alleging that the defendant's warning was inadequate. In the words of Justice Stevens:

Although Phenergan's labeling warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, Levine alleged that it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug's therapeutic benefits.¹²⁴

The choice of methods in this case depends on this cost-benefit analysis.

The FDA concluded that a two-tiered strategy was correct. The first-line treatment was the IV-drip method, which should be used in most cases. But where the pain was acute and the system did not work, resort to the second-line treatment might be appropriate on the ground that the additional benefits might justify the riskier method, at least if all appropriate precautions were taken. It should be evident that each step in the use of the IV-push method relies on optimal downstream actions, both in the evaluation of the risk and the execution of the riskier IV-push procedure. The FDA, whose warnings were tied to the sale and distribution of the drug, could not make the individualized judgment. Downstream cooperation was essential, and allowing for recovery in the face of the occasional, if inevitable, downstream misuse by medical professionals wrecked the coordination. There is no way for good doctors to get sound information on product use if the warnings are designed to prevent abuse by incompetent ones. Warning the doctor to take extreme care makes perfectly good sense as a matter of overall system design, and this is precisely what the Wyeth warning did when it specified the quantity limitations on drug levels, the preferred mode of application, the warning signs of danger, and the extreme

123. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2006).

124. *Wyeth v. Levine*, 129 S. Ct. 1187, 1192 (2009).

level of care required.¹²⁵ I cannot think of anything that it should have done differently.

But Levine sought to make an end-run around this system. In a world of free jury discretion, the question of *whether* to use a procedure is always in play along with *how* to use the procedure. So Levine's key tactic was to attack the risk-segmentation strategy by insisting that Wyeth should have warned against any use of the IV-push method. In her view, the bottom line was that Wyeth was negligent because it had not "earnestly attempted" to strengthen the warning against any use of the IV-push method, and because the evidence had shown that the risk of gangrene "can be almost entirely eliminated through the use of the IV-drip."¹²⁶ Levine took the same line in her interview, alluding to how the company might have put profits before welfare in choosing not to issue that warning:

Pharmalot: What's your view of Wyeth and its actions?

Levine: They should've taken responsibility for changing the label It's not a bad drug. It's a good drug, for what it is. But I'd much rather throw up than lose my arm. I think they should've come out and said that, under no circumstances

125. *Id.* at 1192 n.1. The warning for "Inadvertent Intra-arterial Injection" stated:

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. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs. . . . Aspiration of dark blood does not preclude intra-arterial needle placement, because blood is discolored upon contact with Phenergan Injection. Use of syringes with rigid plungers or of small bore needles might obscure typical arterial backflow if this is relied upon alone. 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. In the event that a patient complains of pain during intended intravenous injection of Phenergan Injection, the injection should be stopped immediately to provide for evaluation of possible arterial placement or perivascular extravasation.

Id.

126. *Id.* at 1192.

should the drug be administered under push IV. They didn't protect me and ensure my safety They have strong economic incentives and, sometimes, those things take precedent They say the FDA is their first line of defense, but if a drug company recognizes there's something that could hurt the public, they have an obligation to do something.¹²⁷

Her belated demand for a stiffer warning or categorical exclusion, however, ignores the benefit side of the cost-benefit equation. In particular, it assesses the ex ante use of the IV-push method on the strength of the ex post outcome in the one case that went awry.

The upstream side of the equation looks impenetrable for Wyeth. The last thing any jury should be allowed to do is to decide, after the fact, that instructions on the use of the IV-push method under any circumstances count as negligence per se. What is a drug company supposed to do if one jury finds that Wyeth warnings were accurate and thus denies liability, when a second jury regards the failure not to insist on banning the IV-push method as negligent? In the case where IV-push might have worked when the IV drip failed, is it negligent not to have instructed on its use? Is it possible to write and revise labels to give respect to two, or more, inconsistent judgments?

It is also unclear what the FDA should have done in response to the warning. Its chosen course of action was to insist that the Black Box warning¹²⁸ be used to highlight the risks of the IV-push system.¹²⁹ But there are real costs associated with the use of Black Box warnings. They can over-deter patients from accepting treatments whose benefits outweigh their costs. They also can deter physicians from using the Black Box treatment for fear of malpractice

127. Ed Silverman, *Preemption and Amputation: Diana Fights Wyeth*, *Pharmalot.com* (Feb. 20, 2008), <http://www.pharmalot.com/2008/02/preemption-and-amputation-diana-fights-wyeth/>.

128. According to the *Federal Register*:

Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. . . . The box must contain, in uppercase letters, a heading inside the box that includes the word "WARNING" and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the "Contraindications" or "Warnings and Precautions" section

21 C.F.R. § 201.57(c)(1) (2001).

129. See Press Release, U.S. Food and Drug Administration, FDA Requires Boxed Warning for Promethazine Hydrochloride Injection (Sept. 16, 2009), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182498.htm>.

liability with the same effects. To require a Black Box warning in response to the outcome of a single jury verdict in Vermont shows how dubious jury verdicts can reorient national policy for the worse.

The powerful influence of common law decisions creates gratuitous expense and uncertainty that feed their way back into the cycle of drug development, testing, and marketing. Properly understood, the entire duty-to-warn apparatus has become a tax on drugs, which, in some instances, may drive both old and new products off the market and, in most instances, will increase drug cost and reduce the levels of beneficial patient use. Yet any liability disclaimer for bad uses is dead in the water in the post-1965 period.¹³⁰ There is no set of warnings that could remove the risk of liability after *Wyeth* and convey the message that IV-push has a net patient benefit in some cases.

The outcome looks only worse when we look at downstream behavior. Justice Alito's dissent notes that the plaintiff's suit was originally against the physician, Dr. John Matthew, his assistant Jessica Fisch, and the local hospital.¹³¹ Justice Alito also reports that the two individual defendants settled with the plaintiff and testified against Wyeth on her behalf,¹³² but he does not comment on the obvious risk of a collusive settlement.¹³³ Justice Alito also noted that two medical defendants offered profuse apologies for their negligence, perhaps in order to increase their credibility before the jury.¹³⁴ Most instructively, he states that:

[H]er medical practitioners testified that they used IV-push in order to help her "in a swift and timely way" when she showed up at the hospital for the second time in one day complaining of "intractable" migraines, "terrible pain," inability to "bear light or sound," sleeplessness, hours-long spasms of "retching" and "vomiting," and when "every possible" alternative treatment had "failed."¹³⁵

130. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 18 (1997) ("Disclaimers and limitations of remedies by product sellers or other distributors, or waivers by product purchasers, and other similar contractual exculpations, oral or written, do not bar or reduce otherwise valid products liability claims against sellers or other distributors of new products for harm to persons.").

131. *Wyeth*, 129 S. Ct. at 1218 n.3 (Alito, J., dissenting).

132. *Id.*

133. *Cf. Booth v. Mary Carter Paint Co.*, 202 So. 2d 8, 8 (Fla. Dist. Ct. App. 1967). For critical commentary, see Lisa Bernstein & Daniel Klerman, *An Economic Analysis of Mary Carter Settlement Agreements*, 83 GEO. L.J. 2215 (1995).

134. *Wyeth*, 129 S. Ct. at 1218 (Alito, J., dissenting).

135. *Id.* at 1226 (Alito, J., dissenting).

That version of the facts jibes perfectly with Levine's. In an interview about her case, she gave the following account:

Pharmalot: But in 2000, you went to the hospital and Phenergan was administered. What happened?

Levine: I have a history of these migraines and, normally, I can manage them, but on occasion, they could be excruciating and debilitating, and I'd get hauled off to the emergency room. Normally, I'd get Demerol for the pain and then Phenergan, because the Demerol would make me nauseous. And it would be intramuscular administration, which was normally a shot in the butt. This time, they gave me a push IV and that's what caused the problem. When I woke up, I was still in pain.¹³⁶

Which way does her testimony cut? The evidence shows that Levine's case was serious, one for which neither the FDA nor Wyeth should rule the IV-push method out of bounds. It proves that the physician and his assistant knew which cases needed only the first-line approach and which cases called for the second-line approach, which, if properly executed, might have provided much needed palliation. This account of the facts makes it clear that Dr. Matthew and Ms. Fisch were not negligent in ordering the IV-push given their prior failure with the less aggressive technique. Justice Stevens, however, studiously declined to mention what their negligent actions and omissions were. He notes twice that the warnings specified that Phenergan "should be given in a concentration no greater than 25 mg/ml and at a rate not to exceed 25 mg/minute."¹³⁷ But he did not say that it was the admitted failure to follow those precise instructions that prompted their profuse apologies.

And Levine did no better when she recounted the case. She mentioned that she got the IV-push but did not utter a word about the misconduct of Matthew and Fisch. That information was, of course, included in Wyeth's brief, which reads as follows:

Although Phenergan's labeling specified a dosage range for nausea of 12.5 to 25 mg, Fisch gave respondent a 50 mg dose—double the labeled amount. Moreover, Fisch administered the entire 50 mg double dose without pausing, despite respondent's complaints of pain—pain she later described as "one of the most intense pains that [she] had ever felt" to that point—

136. Silverman, *supra* note 127.

137. 129 S. Ct. at 1192 n.1.

even though the labeling instructed that IV injection should stop immediately if the patient complains of pain.¹³⁸

It is also worth noting that an injection into an artery produces a wholly different response than an injection into a vein. Arterial pressure is roughly 100 mm (of mercury)¹³⁹ while that of venal pressure is usually, approximately a tenth that amount.¹⁴⁰ An arterial injection typically produces spurting of blood, which sometimes is strong enough to dislodge a needle. Neither of these happens with an intravenous injection. Here, the responsibility to monitor the downstream risk of arterial injection lay exclusively with Ms. Fisch. If there is a claim for negligent supervision, it lies against Dr. Mathews. Wyeth should be nowhere in the mix. At bottom, the only risks that came to pass in obvious fashion at the downstream level were the ones that the Wyeth warnings and instructions had specifically taken into account. To put it mildly, the deviation from the stated warnings “increased the risk or hazard” of the injury suffered far beyond what would have happened if the correct procedures had been followed. And the use of a theory of joint causation in these circumstances can only be described as a grotesque extension of sound tort theory, which is not made any more palatable by its constant use.

It is unassailable as a matter of law that successive actions of negligence render both defendants responsible.¹⁴¹ That is true where one defendant digs a hole that the other does not see before he falls in. But it should not hold where the first person has filled a hole into which the second decides to jump head first. Unfortunately, once the full information model is rejected, the theory of joint causation gobbles up all sorts of defendants who should be categorically insulated from liability.

These massive doctrinal errors are now compounded by settlements that build off the underlying tort doctrine. Settlements generate little complexity in two-party situations. But strategic settlements between two parties are capable of creating real negative externalities against any third person not party to the agreement. Whether the third person will be hurt depends critically on

138. Brief of Petitioner Wyeth at 20, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (citations omitted).

139. See RODNEY RHOADES & RICHARD PFLANZER, *HUMAN PHYSIOLOGY* 590–91 (4th ed. 2003).

140. See *id.* at 606–07 (“The pressure in the venules and small veins is only about 10 mm Hg.”).

141. See, e.g., *Atherton v. Devine*, 602 P.2d 634, 636 (Okla. 1979) (original wrongdoer not excused by negligence of treating physician).

how the initial settlement between the plaintiff and the first defendant(s) affects the potential liability of the remaining nonsettling defendant. Everyone agrees that once a given defendant has settled with the plaintiff he is protected from a cross-claim by a nonsettling defendant. Without that protection, no settlements will take place. But the question remains: What effect does the first settlement have on the subsequent litigation of the claims against the nonsettling defendants?

One rule, called the “proportionate share” or “carve-out” rule, holds that the plaintiff who settles with one defendant loses the entire portion of the loss attributable to that claimant. Under this rule, if the physician and assistant’s apportionment of liability is ninety percent, then ninety percent of the claim is gone whether they settle for a lot or a little. The plaintiff knows she can only recover ten percent of the total loss against the remaining defendant. This rule is used in admiralty in order to avoid strategic settlements, as ably explained in Justice Stevens’s earlier opinion in *McDermott, Inc. v. AmCLYDE*.¹⁴²

But Vermont does not follow the carve-out rule.¹⁴³ Instead, it follows the *pro tanto* rule, which gives the second defendant a credit against final judgment equal to the amount paid out by the settling defendant. Under this rule, the risks of strategic bargaining are manifest, for it is widely understood that the bulk of responsibility for compensation could be placed on the wrong defendant, which is why Justice Stevens wisely opted for the proportionate share rule in admiralty cases.¹⁴⁴

To make the difference explicit, suppose that we decide (charitably for Matthew and Fisch) that these defendants were ninety percent responsible for the \$7,400,000 settlement. If they settled for, say, \$500,000 under the Vermont rule, Wyeth is left with \$6,900,000 in damages. But if the proportionate share disappears, the opportunity for game-playing by early settlement vanishes, and the plaintiff can get only \$740,000 from Wyeth regardless of the order in which the suits against the separate defendants resolved. The credit rule thus leaves Wyeth at the mercy of the downstream players. When the dust settles, Wyeth gets slapped with the bulk of the damages, every bit of which should be paid by downstream actors.

142. 511 U.S. 202, 215–16 (1994).

143. See *Wyeth*, 129 S. Ct. at 1193 (noting Vermont’s use of the credit rule).

144. For an explanation, see *McDermott*, 511 U.S. at 217; *Am. Motorcycle Ass’n v. Super. Ct.*, 578 P.2d 899, 919–20 (Cal. 1978) (Clark, J. dissenting).

V.
BEYOND WYETH

There is little doubt that *Wyeth* poses major obstacles for preemption defenses in duty-to-warn cases brought against drug manufacturers. On its facts, *Wyeth* is an uncommon case because of the infrequency with which downstream physicians and physician assistants will be as grossly negligent as Dr. Mathews and Ms. Fisch. But the same rules on field and conflict preemption also apply to the many cases in which drugs are alleged to cause harm wholly without regard to the palpable negligence of those who administer them. The litmus test is as follows: A detailed warning will preempt only if the FDA precisely addresses potential risks in a manner that Sharkey and Rabin support.¹⁴⁵

This issue is raised by cases involving suicides committed by depressed persons, previously medicated by selective serotonin reuptake inhibitors, or SSRIs. For example, in *Colacicco v. Apotex Inc.*,¹⁴⁶ the decedent Lois Colacicco, age fifty-five, had been put on Paxil, a generic SSRI, and committed suicide less than one month later. At the time of her death, the Paxil labeling included a specific warning about the possibility of suicide attempts.¹⁴⁷ In a companion case, a patient was prescribed Zoloft for anxiety and depression, and committed suicide a week later. The label for Zoloft also explicitly warned of suicide.¹⁴⁸

In *Colacicco*, Judge Sloviter offered an extensive demonstration of FDA oversight that relied on its Psychopharmacological Drugs Advisory Committee. The Committee rejected the need for additional warnings on SSRIs, and in 1991, 1992, and 1997, the agency had rejected citizen petitions to either take Prozac (an SSRI) off the market or require additional warnings.¹⁴⁹ Judge Sloviter was cor-

145. See Rabin, *supra* note 30; Sharkey, *supra* note 30.

146. 521 F.3d 253 (3d Cir. 2008).

147. See *id.* at 256 (noting that the "Precautions" section of the label included the following language: "*Suicide*: The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for PAXIL should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose . . .").

148. See *id.* at 257 (noting that the precautionary language for Zoloft included the following: "*Suicide*—The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Zoloft (sertraline) should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.").

149. See *Colacicco*, 521 F.3d at 269.

rect to conclude that “[t]he FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.”¹⁵⁰ This makes sense. Virtually everyone who takes an SSRI is drawn from a suicide-prone portion of the population. No doubt some people on these drugs will commit suicide, but there is always an argument as to whether that desperate act was a function of the prior condition alone, the drug alone, or some combination of the above. Any effort to sort out that form of causation in an individual case is bound to fail.

It is, however, no surprise that the vast majority of deaths that occur after one goes on SSRIs results in lawsuits. This will continue to happen unless the preemption defense is rock solid. It is impossible to decide in a single case whether a person who commits suicide after a week or a month, as in these cases, did so because the drug had not yet had time to work, was not going to work at all, or pushed someone over the edge. That causation question is fair game in all cases, and is, under current law, the type of issue on which summary judgment against the plaintiff will not be granted, no matter the statistics on the rate of suicides for those who do and do not take an SSRI.¹⁵¹

What matters is not the etiology of the individual case but rather the overall distribution of suicides. We know from the recent aggregate data that the decision to place the Black Box warning on Prozac reduced its use for the reasons stated above¹⁵² and may have also caused some increase in suicides in young populations.¹⁵³ The usual—and correct—caution about the interpretation of data means that the correlations could well turn out to be

150. *Id.*

151. *See supra* text accompanying notes 120–21 (noting that causation is a question for the jury).

152. *See supra* text accompanying notes 128128–29.

153. See Robert D. Gibbons et al., *The Relationship Between Antidepressant Prescription Rates and Rate of Early Adolescent Suicide*, 163 AM. J. PSYCHIATRY 1898 (Nov. 2006), which reports as follows:

RESULTS: After adjustment for sex, race, income, access to mental health care, and county-to-county variability in suicide rates, higher SSRI prescription rates were associated with lower suicide rates in children and adolescents.

CONCLUSIONS: The aggregate nature of these observational data precludes a direct causal interpretation of the results. More SSRI prescriptions are associated with lower suicide rates in children and may reflect antidepressant efficacy, treatment compliance, better quality mental health care, and low toxicity in the event of a suicide attempt by overdose.

Id. at 1898.

positive at which point we can fully expect psychiatrists to take the necessary corrective action in the interests of their patients.

What becomes clear is that no legal regime is truly sustainable if matters as complex as this are trusted to juries to make of the evidence what they please. It is critical in this context to remember that each and every jury trial in these suicide cases has to conclude both that the drug caused, alone or in combination, the suicide and that the existence of a stronger warning would have made a difference, given that the warning in question is strong already. If a jury is seventy percent confident on each issue, the likelihood that the plaintiff has made out all elements of his or her case is still below fifty percent. Most cases of this sort will not come close to meeting the standard of a preponderance of the evidence for the entire case. The upshot is that the huge expense of defending these cases will lead to a shrinkage in the use of SSRIs, which, if appropriate, should be taken for medical reasons, not for a fear of liability gone amok.

The entire jury process represents yet another instance of how it is possible to spend a fortune in litigation only to achieve an inferior outcome to that which could be reached by using a field preemption theory to block all these suits in their inception. But that result, as Judge Sloviter notes, cannot be “seriously” pursued today.¹⁵⁴ Given that juridical reality, she conducts no independent analysis as to the soundness of her rules. Nor, it appears, will the Supreme Court, which summarily returned the case to the Third Circuit.¹⁵⁵ Originally, the two district courts split on the preemption question, and it is of course possible that the same result will arise on remand.¹⁵⁶ But as to the warnings, there is little that distinguishes Prozac from Phenergan except the mechanism of causation, which is far more complicated for the former drug than for the latter. So on balance, even I would be forced, against my better judgment, to refuse to find preemption in *Colacicco* after *Wyeth*; the doctrine is all but dead in these cases.

VI.

CONCLUSION: PREEMPTION AT LAST

Linking up all these disparate pieces reveals two essential propositions. The first goes to the historical arc of the tort law and its

154. *Colacicco*, 521 F.3d at 262.

155. *See Colacicco v. Apotex Inc.*, 129 S. Ct. 1578, 1578–79 (2009) (remanding for further consideration in light of *Wyeth*).

156. *See Colacicco*, 521 F.3d at 256–57.

relationship to federal preemption. It is simply incorrect to think that the relatively limited and sensible doctrines of the pre-1965 period gave rise to any occasion requiring the preemption issues seen today. Tension arose only after two prominent developments in product liability laws. First, courts' refusal to honor contractual limitations on liability opened up the possibility of tort liability, generating excessive deterrence—if parties had contracted as to the ideal risk allocation, ignoring such agreements constituted a deviation from optimal deterrence. Second was the decision, as a matter of state law, to treat FDA warnings as adequate with respect to drug risks. At this point, where tort liability is generally available but a federal agency has sent a different message by approving warnings, all the pressure falls on the doctrine of implied preemption. Unfortunately, Justice Stevens's profound misunderstanding of the historical evolution of tort law prompted him to adopt the mischievous substantive position articulated by Kessler and Vladeck, which wrongly assumes that the only failures of the FDA are to let too many new drugs onto the market with warnings too weak for the occasion, with no failures in the opposite direction.¹⁵⁷ If there was ever a reason to apply the doctrine of "changed circumstances" in understanding the relationship between litigation and the administrative state, this was it. Why federal preemption should ignore that profound sea change for the worse is never explained.

For whatever it is worth, *Riegel* presents the same pattern of downstream disregard of explicit warnings and instructions that *Wyeth* did. The defendant physician used the defendant's angioplasty device at pressures higher than those for which it was rated.¹⁵⁸ It could well have been that the treating physicians made a correct downstream judgment that exceptional circumstances called for exceptional treatment in disregard of the explicit warnings and instructions. Such a deviation from standard practice is, of course, not negligence per se, given just this possibility.¹⁵⁹ Right now, legislation is before Congress to remove the explicit bar to preemption in medical device cases,¹⁶⁰ so that *Riegel* could go the same way as *Wyeth*, even though the reverse result is sorely needed. But the use

157. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1203 n.12 (2009) (citing Kessler & Vladeck, *supra* note 26).

158. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008).

159. See RESTATEMENT (SECOND) OF TORTS § 288A (1965); RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 12 (Proposed Final Draft No. 1, 2005).

160. See Medical Device Safety Act of 2009, S. 540, H.R. 1346, 111th Cong. § 2 (2009) (amending Section 521 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360K, by adding the following language: "Nothing in this section shall be

of tort law in modern circumstances makes it harder to be sure that safe and effective drugs can be delivered to the public at large.

The judicial failure to understand the historical arc of the law of torts leads to a second set of unsound judgments on matters of institutional competence—the second proposition. There is nothing that erratic and expensive juries can do to make accurate scientific judgments that will allow people to plan their conduct in advance. Stability of expectations is indispensable in marketing dangerous compounds, and, for all its manifest failings, the FDA is better at this task than juries. So even if one utterly rejects market solutions to drug liability, there is still no reason to embrace the looming no-preemption regime in drug cases.

Congress's stated purpose in establishing the FDA, as taken from the 1962 amendments to the FDCA, was to "assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority"¹⁶¹ How, institutionally, does this square with a system that allows juries to override systematic decisions by a risk-averse agency without having to say a word on their behalf? If the state of Vermont wanted to impose a \$1,000 fine on Wyeth for using its Phenergan label, its action would surely be preempted. But a \$6 million tort judgment that offers none of the procedural protections of the administrative state is said to pose no threat to the integrity of the federal system.

In sum, the imposition of past liability and the threat of future liability pose a serious threat to the continued viability of what Diana Levine called a "good" drug. Yet Justice Stevens appears to be oblivious to the institutional chaos that his decisions introduce. Thus in *Bates v. Dow Agrosciences, LLC*,¹⁶² he held against preemption, stating:

A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue . . . it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action.¹⁶³

construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.").

161. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in various sections of 21 U.S.C.).

162. 544 U.S. 431 (2005).

163. *Id.* at 445.

His naively optimistic account assumes that all that can be expected in response to a major liability shock is a label change. But as the Bendectin saga of the 1980s shows, sometimes warning changes will not do the work, and drugs are pulled from the market.¹⁶⁴ That is not likely to happen with Phenergan because staggering incompetence inside the hospital is not likely to be a common occurrence. The makers of Bendectin did not have that protection because the birth defects were said—incorrectly—to arise from the prescribed usages of the product.¹⁶⁵ Yet the massive disruption that even a single trial causes to a blameless product makes the pro-preemption conclusion entirely appropriate. Unless and until someone writes a warning that can provide conscientious drug makers with a safe harbor, the entire system will have less to do with warning patients than with second-guessing drug warnings in courts.

Justice Stevens's decision to belittle conflict preemption in *Wyeth*, after the passage of the FDAAA, is indefensible.¹⁶⁶ There was no new information that indicated that the older understandings were defective. To the contrary, *Wyeth* reveals facts that show how unwise it is to adopt a per se rule against IV-push. This entire episode reaffirms the wisdom of the pre-1965 products liability tort law, which, if adopted, would allow the confused doctrine of federal preemption to fade into the woodwork. But this is a second-best world, in which state law has to be taken as a given, warts and all. Any federal preemption must be evaluated against the tort law as it is, not as it was once or should be. By that standard, *Wyeth* was decided wrongly—egregiously so.

164. For an account of the demise of Bendectin, see *Lynch v. Merrell-National Labs., Inc.*, 830 F.2d 1190, 1194 (1st Cir. 1987) (noting a decline in usage from one million new therapy starts in 1979 to zero in 1984).

165. See *id.* (noting no change in the incidence of birth defects following the removal of Bendectin from the market).

166. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1195–96 (2009).

IS LOCAL CONSUMER PROTECTION LAW A BETTER REDISTRIBUTIVE MECHANISM THAN THE TAX SYSTEM?

BRIAN GALLE*

INTRODUCTION

As Judge Calabresi has argued, preemption decisions are, at their core, a choice about which tier of government should have policy-making authority.¹ In prior work, Mark Seidenfeld and I argued that the choice of whether or not to preempt state law decisions should be based explicitly on “fiscal federalism” considerations.² The economic discipline of fiscal federalism attempts to measure the welfare effects of situating a given policy either locally, nationally, or somewhere in between.³

In order to decide whether to preempt state-level tort law or other consumer safety regulation, policy makers must first determine the goals of the tort system and its alternatives. According to one highly influential welfarist⁴ account, while tort law may serve

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1. See Hon. Guido Calabresi, Remarks at the *New York University Annual Survey of American Law* Symposium: Tort Law in the Shadow of Agency Preemption, 65 ANN. SURV. AM. L. 435, at 435 (2010).

2. Brian Galle & Mark Seidenfeld, *Administrative Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933, 1997, 2003–04 (2008).

3. Wallace E. Oates, *An Essay on Fiscal Federalism*, 37 J. ECON. LIT. 1120, 1121 (1999). Thus, our argument is that when courts attempt to decide whether a federal enactment preempts other government actors, one of the central considerations should be whether restricting power to the federal government would in that instance increase national welfare. Galle & Seidenfeld, *supra* note 2, at 1997. We also argue that applying this standard to agency efforts to preempt would likely lead to increased agency consideration of the fiscal federalism question, as well. *Id.* at 2003–04. Although courts have long been thought to struggle with these kinds of fact-intensive questions, we suggest that administrative involvement can go a long way towards remedying that problem. *Id.* at 2004–05.

4. A welfarist is someone who believes that society should maximize overall social utility, but that part of the relevant calculus should include consideration of the public's preferences for the fair distribution of wealth or utility across the population. See Louis Kaplow & Steven Shavell, *Fairness Versus Welfare*, 114 HARV. L. REV. 961, 977–93 (2001).

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legitimate policy goals, such as promoting optimal deterrence, insuring accident victims, or even achieving corrective justice, it should not be a tool for redistributing wealth.⁵ Commentators holding this view argue redistribution should occur *solely* through the tax system because using tort law or any other set of legal rules and regulations is inefficient.⁶ However, there has never been any sustained consideration of whether redistribution through the tort system could be carried out more efficiently at the local level.

My central argument is that redistributive tort rules can be more efficient at the local level than the national level, and may be more efficient than local or national redistributive taxation. As a result, theory does not clearly predict whether society should prefer local tort law over national or local taxation. Federal preemption of local tort law therefore might well prevent society from using its most efficient tool for redistributing wealth. Thus my argument implies a need for further empirical work to determine whether federal preemption of local tort rules would reduce national welfare.

Tort law may be the superior alternative because, although it is less efficient than tax at the national level, it may be the lesser of evils at the local level. That is, while we would not choose local tort regulation in a world with no economic distortions, tort law may be the best available choice—the “second best”—in a world where the market has other flaws. While redistributive tort laws have costs that taxes do not, government cannot effectively satisfy a heterogeneous society’s preferences for redistribution with a single national set of tax rules. Local tort rules can better capture a wide variety of preferences. It is unclear whether this gain is large enough to overcome the additional losses accompanying the use of a tort system.

Of course, government can impose taxes locally as well. The trouble is, at least under existing legal arrangements, local redistributive taxes create distortions and deadweight losses that local tort laws do not. For example, firms cannot easily sell products in a market without being exposed to its tort law, while current constitutional restrictions on state taxing power make it easier for a firm to gain the economic benefits of a market without being subject to its taxes. As a result, sellers can easily avoid redistributive taxation, but

5. Louis Kaplow & Steven Shavell, *Why the Legal System Is Less Efficient than the Income Tax in Redistributing Income*, 23 J. LEGAL STUD. 667, 669 (1994) [hereinafter Kaplow & Shavell, *Less Efficient*].

6. See, e.g., *id.*; David A. Weisbach, *Should Legal Rules Be Used to Redistribute Income?*, 70 U. CHI. L. REV. 439, 446–53 (2003); see also ROBERT COOTER & THOMAS ULEN, *LAW AND ECONOMICS* 8–10, 111–13 (4th ed. 2003); Lior Jacob Strahilevitz, *Wealth Without Markets?*, 116 YALE L.J. 1472, 1509–11 (2007).

cannot escape redistributive tort law without surrendering the market entirely. In jurisdictions where escaping redistribution is easy, redistribution is difficult, and the accompanying economic costs are correspondingly high.

This Article proceeds in four Parts. Part I details the welfarist argument against redistributive legal rules. Part II argues that both national and local taxes are inefficient redistributive tools. Part III explains that local consumer protection rules share some of these inefficiencies while avoiding others, so it is ambiguous which method is most efficient. Part IV considers the objection that tort systems give rise to externalities, which may cause over-production of redistribution.

I.

THE REDISTRIBUTION STORY SO FAR

Louis Kaplow and Steven Shavell have put forth a number of influential arguments against redistributive legal rules.⁷ Kaplow and Shavell are most interested in utility, but they concede that social preferences for how resources are distributed in society should be considered in calculations of which rule best maximizes social welfare.⁸ They argue, however, that achieving this distribution should be the exclusive domain of the tax system because “using legal rules to redistribute income distorts work incentives fully as much as the income tax system . . . and also creates inefficiencies in the activities regulated by the legal rules.”⁹

Consider the way in which taxation could affect work incentives. Suppose, for example, that in deciding how many hours to work Bruce will figure that for every hour he does not work, he can stay home, garden, and watch Oprah. Each hour of leisure time Bruce enjoys costs him the money he could have earned working.¹⁰ The net opportunity cost to Bruce of each hour of leisure is the salary he would have earned, less the costs of earning that salary, such as commuting expenses and taxes. As taxes increase, leisure becomes more attractive for Bruce, because the net opportunity cost of leisure has shrunk.¹¹

7. See Kaplow & Shavell, *Less Efficient*, *supra* note 5, at 669; Strahilevitz, *supra* note 6, at 1509–11; Weisbach, *supra* note 6, at 446–53.

8. Kaplow & Shavell, *supra* note 4, at 987–92.

9. Kaplow & Shavell, *Less Efficient*, *supra* note 5, at 668.

10. RICHARD A. MUSGRAVE & PEGGY B. MUSGRAVE, *PUBLIC FINANCE IN THEORY AND PRACTICE* 299–301 (5th ed. 1989).

11. For example, if Bruce could earn \$10 perhour, a 10% tax would mean that the opportunity cost of leisure is \$9. If taxes increase to 20%, the cost of an

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In essence, Kaplow and Shavell's first claim is that redistributive legal rules will affect Bruce's incentives in the same way as a tax.¹² Suppose Bruce must make his decision to work or stay home before he knows the liability costs he will incur as a result of working. Thus, he bases his decision on the ex ante expected cost of working. If a legal rule on average redistributes money from Bruce to others in the same amount as a 20% tax, then the ex ante expected cost to Bruce must be the same as under the tax. Some people similarly situated to Bruce may face 40% costs; others will face zero. But since the expected costs will be 20%, Bruce will assume that is the cost of going to work.

Unlike a tax, however, the redistributive legal rule also changes other kinds of behavior, producing the so-called "double distortion" problem. Kaplow and Shavell use the example of a tort rule aimed at reducing accidents.¹³ An optimal non-redistributive rule would maximize the tradeoff between accident prevention and the cost of prevention.¹⁴ However, once the rule is altered to also redistribute wealth, the behavior of actors changes, increasing or decreasing the number of accidents to a non-optimal level.¹⁵ Taxation would not have this additional distortive effect, assuming the rate did not vary depending on whether the taxpayer was involved in an accident.¹⁶ Thus, according to Kaplow and Shavell, taxes should always redistribute more efficiently.¹⁷

Using legal rules for redistribution may have other problems as well. Redistributive legal rules often reach only those parties affected by the legal rule, thereby making redistribution arbitrary and perhaps deterring wealthier parties from engaging in the regulated activity.¹⁸ Also, rules that operate on the assumption that one party—every plaintiff or every defendant—is usually richer or poorer than the other run some risk of distributing in the wrong

hour of leisure drops to \$8. A complete account of Bruce's incentives would also include the possibility that changes in his wealth would change his demand for leisure, but for the sake of parsimony I set aside that situation here. MUSGRAVE & MUSGRAVE, *supra* note 10, at 299 (distinguishing "income" from "substitution" effect of taxation).

12. Kaplow & Shavell, *Less Efficient*, *supra* note 5, at 670–71.

13. *Id.* at 669–72.

14. *Id.* at 669.

15. *Id.*

16. *Id.* at 671–74.

17. *Id.* at 677.

18. Richard A. Epstein, *The Social Consequences of Common Law Rules*, 95 HARV. L. REV. 1717, 1719–20 (1982); Kaplow & Shavell, *supra* note 4, at 994.

direction, while rules that are crafted to take account of each particular individual can be very costly.¹⁹

Critics have responded with a number of reasons to be skeptical of reliance solely on redistributive taxation. Some detractors, arguing from a welfarist perspective, claim that it is unlikely, or at least not always the case, that workers take into account legal rules to the same extent they do tax considerations.²⁰ Similarly, they argue that redistribution through taxation is politically more difficult than through legal rules.²¹ Another welfare critique, suggested by Chris Sanchirico and others, is based on a technical claim concerning the way behavioral distortions affect social welfare.²² Because the economic cost of a change in behavior—a “deadweight loss”—rises exponentially with the size of the distortion causing it,²³ it should be more efficient to redistribute through many small rule changes, rather than one large tax. Finally, non-welfarist arguments present another potential defense of redistributive legal rules. Daphna Lewinsohn-Zamir, for example, argues that the results Kaplow and Shavell reach assume that society should maximize a particular form of utility.²⁴

For my purposes here, I accept for the sake of argument that Kaplow and Shavell’s points are all well-taken. As I will explain, I think that even on their own terms their claims have serious potential holes.

19. Kaplow & Shavell, *Less Efficient*, *supra* note 5, at 675; Weisbach, *supra* note 6, at 449.

20. Christine Jolls, *Behavioral Economics Analysis of Redistributive Legal Rules*, 51 VAND. L. REV. 1653, 1657 (1998); Richard S. Markovits, *Why Kaplow and Shavell’s “Double-Distortion Argument” Articles Are Wrong*, 13 GEO. MASON L. REV. 511, 550–55 (2005); Edward J. McCaffery & Jonathan Baron, *The Political Psychology of Redistribution*, 52 UCLA L. REV. 1745, 1748–90 (2005). For a helpful survey of other welfarist exceptions to the Kaplow & Shavell position, see Nicholas L. Georgakopoulos, *Solutions to the Intractability of Distributional Concerns*, 33 RUTGERS L.J. 279, 304–17 (2002) (noting arguments for role of legal rules in deterring socially undesirable behavior that is connected to wealth of actor; in targeting behavior that reveals underlying characteristics of the actor; and in redistributing non-monetary wealth).

21. Brett McDonnell, *The Economists’ New Arguments*, 88 MINN. L. REV. 86, 111 (2003).

22. Chris William Sanchirico, *Deconstructing the New Efficiency Rationale*, 86 CORNELL L. REV. 1003, 1006–11 (2001). *But see* Louis Kaplow & Steven Shavell, *Should Legal Rules Favor the Poor? Clarifying the Role of Legal Rules and the Income Tax in Redistributing Income*, 29 J. LEG. STUD. 821 (2000) (discussing Sanchirico’s arguments).

23. Sanchirico, *supra* note 22, at 1006–11.

24. Daphna Lewinsohn-Zamir, *In Defense of Redistribution Through Private Law*, 91 MINN. L. REV. 326 (2006).

II. INADEQUACY OF LOCAL TAXATION AS A REDISTRIBUTIVE IMPLEMENT

Whatever the persuasiveness of the two sides in the redistribution debate, it should be noted that both have assumed a model with only one government. I argue in this Part that redistributive taxation in a federalist system with many competing governments is fundamentally different than in the one-government model. To some degree, this difference is because local taxes distort choices about where to live or do business. Location-specific rents can mitigate some of these distortions.²⁵ But current tax law makes those rents small, at least as to multistate firms. In contrast, Part III establishes that states may be able to extract large location-specific rents through tort and contract law. Thus at the local level, redistributive tort law may prove more efficient than redistributive taxation.

As Kaplow and Shavell acknowledge, one of their key assumptions is that there exists a tax system capable of providing the socially-preferred degree of redistribution.²⁶ They do not detail what would remain of their argument if that assumption were false. In all likelihood they would contend that, in the absence of full redistribution through taxation, their argument would not collapse completely. Instead, the policy planner would be faced with determining the second-best option.²⁷ Given two imperfect options, the planner must ask which would result in the smaller loss of social welfare: frustrating society's preference for optimal redistribution, or distorting the economy to achieve optimal redistribution through non-tax means?

It is a familiar point among federalism scholars that a single government probably cannot fully satisfy its citizens' preferences for redistribution or other public goods.²⁸ If the government sets one uniform national policy for redistribution, then some voters will be left who would prefer more redistribution and some who would

25. A locational rent is simply an opportunity for a taxing jurisdiction to capture some of the value it provides to private parties through tax. See Saul Levmore, *Interstate Exploitation and Judicial Intervention*, 69 VA. L. REV. 563, 571-72, 601 (1983).

26. See Kaplow & Shavell, *Less Efficient*, *supra* note 5, at 675; see also Weisbach, *supra* note 6, at 452.

27. On the theory of the second-best, see R.G. Lipsey & Kelvin Lancaster, *The General Theory of Second Best*, 24 REV. ECON. STUD. 11 (1956). For a summary, see Richard Markovits, *Second-Best Theory and Law & Economics: An Introduction*, 73 CHL-KENT L. REV. 3, 3-10 (1998).

28. MUSGRAVE & MUSGRAVE, *supra* note 10, at 451.

prefer less.²⁹ In contrast, if redistribution policy can be set in smaller governmental units, such as at the city or county level, then each unit can offer a different level of redistribution, and citizens can choose to live in the jurisdiction that matches their preferences, barring a number of other obstacles.³⁰ While the central government might conduct this arrangement itself, there would be informational challenges for the central coordinator as well as the problem that the coordinator may not be perfectly politically responsive to the information it receives from each locality.³¹

This analysis implies that in order to show that redistribution only through taxation is more efficient than the alternatives, Kaplow and Shavell must defend their theory not only in a single monolithic government, but also in a more complex federalist system. Redistribution only at the national level would not fully satisfy social preferences for distributive justice.³² Thus, they have two options. They can argue that local redistributive taxes are no more distortive than local non-tax redistribution. Or they might pursue the second-best argument, claiming that the welfare losses from local non-tax redistribution would exceed any gains from more fully satisfying the public's tastes. This latter line of argument will be awfully hard to get a handle on, so for now let me focus on the first.

It is well established in the fiscal federalism literature that redistributive taxation in a multi-jurisdictional world is more distortive than in a model with only one sovereign.³³ If a government extracts from residents or businesses more money than they are willing to spend on public goods (including redistribution), they may move to a rival jurisdiction with lower taxes.³⁴ This relocation

29. *Id.* at 455.

30. Gregory v. Ashcroft, 501 U.S. 452, 457–58 (1991); Michael W. McConnell, *Federalism: Evaluating the Founders' Design*, 54 U. CHI. L. REV. 1484, 1498–99 (1987) (reviewing RAOUL BERGER, *FEDERALISM: THE FOUNDERS' DESIGN* (1987)).

31. Mariano Tommasi & Frederico Weinschelbaum, *Centralization vs. Decentralization: A Principal-Agent Analysis*, 9 J. PUB. ECON. THEORY 369, 378–80 (2007); Ernest A. Young, *The Rehnquist Court's Two Federalisms*, 83 TEX. L. REV. 1, 53–63 (2004).

32. I assume here that individuals have a taste for redistribution that is tied in part to their own personal participation in the act of giving, or to the benefit of those who are geographically near or personally known to them, so that the incentives of any one jurisdiction to free ride on the redistributive efforts of others should be small.

33. Charles C. Brown & Wallace E. Oates, *Assistance to the Poor in a Federal System*, 32 J. PUB. ECON. 307, 328 (1987); Helen F. Ladd & Fred C. Doolittle, *Which Level of Government Should Assist the Poor?*, 35 NAT'L TAX J. 323, 328–32 (1982).

34. Mark V. Pauly, *Income Redistribution as a Local Public Good*, 2 J. PUB. ECON. 35, 35 (1973).

results in deadweight loss: the firm has given up its most-preferred location for the second most preferred, lowering its profit, while this reduction in profit has not resulted in any additional tax revenues for the government.³⁵ This is simply a contraction in the economy, with no corresponding benefit for anyone.

Another familiar reason local redistribution is inefficient is because it can create a race to the bottom in the amount of redistribution.³⁶ When tax-paying firms or residents exit in response to redistribution, every remaining taxpayer must pay more for the same level of services. Moreover, redistribution may attract migrants who would like to benefit from the more generous services, also increasing costs for those who remain. Thus, localities may not be able to offer the level of redistribution they would prefer for fear of driving costs up while tax revenues plummet.³⁷

These two lines of thought suggest that in a federalist system it is more efficient to impose taxes on things that cannot move.³⁸ The more mobile the tax base, the more difficult the redistribution.³⁹ Additionally, the more firms respond to redistributive taxation in their decisions on where to locate themselves, the greater the deadweight loss.

This is not to say that the only efficient taxes are those imposed on land or things bolted to the ground. Firms and people may also

35. *Id.*

36. John Shannon, *Federalism's "Invisible Regulator"—Interjurisdictional Competition*, in *COMPETITION AMONG THE STATE AND LOCAL GOVERNMENTS: EFFICIENCY AND EQUITY IN AMERICAN FEDERALISM* 117, 118–19 (Daphne A. Kenyon & John Kincaid eds., 1991). *But see* Richard L. Revesz, *Rehabilitating Interstate Competition: Rethinking the "Race-to-the-Bottom" Rationale for Federal Environmental Regulation*, 67 *N.Y.U. L. REV.* 1210, 1210, 1239–41 (1992) (challenging the accepted wisdom on the race to the bottom).

37. MUSGRAVE & MUSGRAVE, *supra* note 10, at 455; Michael I. Luger, *Federal Tax Reform and the Interjurisdictional Mobility Impulse*, 23 *J. URB. ECON.* 235, 236 (1988). Some commentators claim that this interjurisdictional competition is actually a race to the top, not the bottom. GEOFFREY BRENNAN & JAMES M. BUCHANAN, *THE POWER TO TAX: ANALYTICAL FOUNDATIONS OF A FISCAL CONSTITUTION* 203–05 (1980); John Douglas Wilson, *Theories of Tax Competition*, 52 *NAT'L TAX J.* 269, 296–98 (1999) (reviewing claims by others); Jeffery S. Zax, *Is There a Leviathan in Your Neighborhood*, 79 *AM. ECON. REV.* 560, 560–67 (1989) (reviewing studies showing competition between governments can reduce the size of the local public sector). These commentators argue that because of the disproportionate lobbying power of interest groups, the limited time horizon of local officials, and similar factors, redistribution will usually be greater than socially optimal. Competition reduces redistribution back to (or below?) efficient levels. I take no position on that debate here.

38. MUSGRAVE & MUSGRAVE, *supra* note 10, at 470–71.

39. *Id.* at 455, 470–71.

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be relatively immobile because there is inherent value in being in their first-best location.⁴⁰ If so, the jurisdiction can likely extract a tax equal to the costs of exit, including the decline in value from the first-best to the second-best location.⁴¹ In these cases, the locality can impose a tax without causing deadweight loss from relocation and can mitigate the extent to which the preferences of its citizenry are frustrated.⁴²

A potential worry with location-specific rents is that they may themselves cause inefficiencies by distorting the jurisdiction's political processes.⁴³ If these rents are borne by outsiders, the proceeds from them may look like free money to the voters in the jurisdiction. Since the voters do not consider the burdens of the tax when they set tax levels, they may demand too much redistribution relative to the socially optimal point.⁴⁴ Tax-setting officials may be less politically responsive to the needs of non-voting outsiders.⁴⁵ While outsiders can lobby or make campaign contributions, there could be free rider and coordination problems among outside firms, and one doing business in many jurisdictions may have trouble acting effectively in all of them.⁴⁶

40. See David Schleicher, *The City as a Law and Economic Subject*, 2010 ILL. L. REV. (forthcoming).

41. See Levmore, *supra* note 25, at 571–72, 601–02; cf. Marcel Kahan & Ehud Kamar, *Price Discrimination in the Market for Corporate Law*, 86 CORNELL L. REV. 1205, 1217–32 (2001) (arguing that Delaware's corporate tax system is designed to extract from firms the added value of Delaware's legal system).

42. See Charles E. McClure, Jr., *Legislative, Judicial, Soft Law, and Cooperative Approaches to Harmonizing Corporate Income Taxes in the US and the EU*, 14 COLUM. J. EUR. L. 377, 389 (2008); cf. MUSGRAVE & MUSGRAVE, *supra* note 10, at 455 (noting that redistribution may still be effective at the local level where "mobility is checked by nonfiscal factors such as job location"); *id.* at 470 (arguing that sales taxes may be employed with lesser distortion when the taxing jurisdiction is large enough "to exclude avoidance by shopping abroad").

43. See Daniel Shavero, *An Economic and Political Look at Federalism in Taxation*, 90 MICH. L. REV. 895, 927–28 (1992).

44. *Id.* Some scholars are dubious that this form of "tax exporting" can work in practice. See Charles E. McLure, Jr., *Tax Exporting and the Commerce Clause, in FISCAL FEDERALISM AND THE TAXATION OF NATURAL RESOURCES* 169, 170 (Charles E. McLure, Jr. & Peter Mieszkowski eds., 1983). However, it may be that the perception that exporting works is itself sufficient to distort political outcomes, a point I will return to in Part V.

45. For a more detailed discussion, see Brian Galle, *Designing Interstate Institutions*, 40 U.C. DAVIS L. REV. 1381, 1398–1400 (2007).

46. See *id.* at 1400. Locational rents may have yet other costs, as well. For example, as Roberta Romano explains, the fact that firms are aware of locational rents may mean that, before a firm will commit to a start business in a state, the state will have to credibly commit not to siphon off all of the firm's profits. Roberta Romano, *Law as a Product: Some Pieces of the Incorporation Puzzle*, 1 J. L.

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Perhaps as a result of these kinds of concerns, the law of state and local taxation has evolved to minimize location-specific rents, especially for firms doing business in more than one jurisdiction. In other words, companies gain the financial rewards of doing business more easily without bearing much tax for doing so. Constitutional limits on states' power to tax, together with collective action problems among them, combine to provide a variety of tax-minimizing strategies.

The jurisprudence of the dormant Commerce Clause is responsible for one of the larger of these tax loopholes.⁴⁷ Sales taxes are an obvious way for jurisdictions to capture some of the value created by their efforts to establish a thriving economic community.⁴⁸ However, merchants can avoid sales taxes by selling from outside the jurisdiction. For example: northern New Jersey malls annually attract hordes of New York shoppers because of New Jersey's lower sales taxes.⁴⁹ To counter this problem, states have created the "use tax," which is essentially a sales tax imposed on goods bought outside the jurisdiction and then brought back to it.⁵⁰ In reality, though, the use tax is almost unenforceable unless merchants collect it directly.⁵¹ States, however, have been barred by the Supreme Court from compelling merchants to collect sales or use taxes on the states' behalf unless the merchant has some substantial "physical presence" in the jurisdiction other than the use of a common carrier.⁵² Thus, mail-order and internet sales,

ECON. & ORG. 225, 235–36 (1985). Since talk is cheap, this "bond" will have to be costly to the state. On the other hand, these bonding mechanisms oblige the state to internalize some of the cost of the tax, diminishing the danger of tax exporting.

47. For extended discussion, see Galle, *supra* note 45, at 1390–92.

48. See Walter Hellerstein, *Jurisdiction to Tax Income and Consumption in the New Economy: A Theoretical and Comparative Perspective*, 38 GA. L. REV. 1, 15 (2003).

49. For a review of the literature on the effects of political borders on sales taxes and recent evidence at the international level, see Marcus Asplund et al., *Demand and Distance: Evidence on Cross-Border Shopping*, 91 J. PUB. ECON. 141 (2006). The classic articles in this area in the U.S. context are Ronald C. Fisher, *Local Sales Taxes: Tax Rate Differentials, Sales Loss, and Revenue Estimation*, 8 PUB. FIN. Q. 171, 173 (1980) (summarizing earlier studies of New York area) and John L. Mikesell, *Central Cities and Sales Tax Differential: The Border City Problem*, 23 NAT'L TAX J. 206 (1970).

50. See Hellerstein, *supra* note 48, at 19–21.

51. John A. Swain, *Cybertaxation and the Commerce Clause: Entity Isolation or Affiliate Nexus?*, 75 S. CAL. L. REV. 419, 428–29 (2002).

52. *Quill Corp. v. North Dakota*, 504 U.S. 298, 313–18 (1992); see Charles E. McClure, Jr., *Sales and Use Taxes on Electronic Commerce: Economic, Administrative, and Political Issues*, 34 URB. LAW. 487, 493 (2002) (stating that the ability of out-of-state sellers to escape sales tax is "more-or-less inevitable given the complexity of the system and the constitutional prohibition against barriers to interstate trade").

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and northern New Jersey malls, all allow merchants to benefit from a thriving market without charging any sales tax.⁵³ Consequentially, merchant behavior is highly sensitive to taxation: when a tax is present, the merchants can alter their business behavior without having to give up the opportunity to sell to customers in the taxing jurisdiction.⁵⁴

State-level corporate taxes have similar problems. Firms can shift taxable income from high-tax jurisdictions to low-tax jurisdictions easily.⁵⁵ For instance, a firm can license its intellectual property from a related entity in a low-tax jurisdiction, taking a deduction for the cost of licensing in the high-tax state.⁵⁶ The Due Process Clause limits states' power to tax transactions without any "nexus" to the state, preventing a high-tax state from exacting any revenue from the licensor.⁵⁷ However, state supreme courts are split over that issue, and other possible work-arounds exist.⁵⁸ Another common tax-reduction technique is to arbitrage the different state methods for "apportioning" corporate income.⁵⁹ Again, this

53. See Charles E. McClure, Jr., *Taxation of Electronic Commerce: Economic Objectives, Technological Constraints, and Tax Laws*, 52 TAX L. REV. 269, 377 (1997); cf. Mitchell A. Kane, *Risk and Redistribution in Open and Closed Economies*, 92 VA. L. REV. 867, 904–05 (2006) (explaining that one theory for imposing tax in jurisdiction where sales occur is that it permits that jurisdiction to capture some of the "rents," or value, it provided to seller).

54. See McClure, *supra* note 53, at 377.

55. See Mark J. Cowan & Clint Kakstys, *A Green Mountain Miracle and the Garden State Grab: Lessons from Vermont and New Jersey on State Corporate Tax Reform*, 60 TAX LAW. 351, 353–73 (2007); Julie Roin, *Can the Income Tax Be Saved? The Promise and Pitfalls of Adopting Worldwide Formulary Apportionment*, 61 TAX L. REV. 169, 212–13 (2008).

56. See *Geoffrey, Inc. v. S.C. Tax Comm'n*, 437 S.E.2d 13, 16 (1993). That is, suppose Firm A owns a toy store in South Hightax, which has a 10% corporate tax. Firm A has \$100 million in net profits for this year. To avoid paying \$10 million in tax, Firm A could enter into a licensing agreement with a sister corporation, A-Del, owned by a common parent, A'. A-Del is incorporated in Delaware and pays a flat \$500 annual incorporation fee to Delaware regardless of revenues. A' assigns the legal right to use the Firm A logo (say, a lovable giraffe) to A-Del. Firm A then must contract with A-Del for the rights to use the logo. Because costs are ordinarily deductible from taxable income, Firm A reduces its net profits by the entire amount of the license fee. It will be very difficult to identify a fair market value for the license, so that Firm A can likely claim virtually any number and stand a reasonable chance of prevailing against state challenge. Thus, Firm A pays A-Del \$100 million, reducing its tax to zero, while A-Del continues to pay only \$500 in tax. Shareholders of A' are indifferent to the location of the \$100 million, except to the extent that they want to minimize their tax.

57. *Quill Corp. v. North Dakota*, 504 U.S. 298, 305–09, 313–18 (1992).

58. Roin, *supra* note 55, at 213–15.

59. *Id.* at 212–13.

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tactic rests on a federal constitutional rule: states may not impose a tax on 100% of a multi-jurisdictional entity's income, but instead must "fairly apportion" the piece of the firm's value attributable to the contributions of the taxing state.⁶⁰ These formulae are highly complex and can easily be gamed so the firm is taxed on much less than 100% of its full value, or so most of the firm's income is apportioned to low-tax jurisdictions.⁶¹ States could probably solve both the sales-tax and corporate-tax problems by effective interstate coordination, but such efforts have routinely failed.⁶²

One could argue that these problems can be overcome by a system of federal subsidies. Indeed, several such subsidies are already in place. For example, federal taxpayers may take a deduction for many of the taxes they pay to their state and local governments.⁶³ Many commentators, however, claim that the deduction and similar subsidies are unsatisfying solutions to the local redistribution problem.⁶⁴ One difficulty they point to is that the availability of the deduction creates a common-pool problem, where each jurisdiction's taxes create a fiscal externality for the rest of the nation, inducing each to outspend what its preferences would have been absent the subsidy—in effect, an over-correction.⁶⁵ Further, federal support for local taxes may also weaken the incentives of unhappy citizens to leave an underperforming jurisdiction, which is an important accountability mechanism for local

60. Joseph Bankman, *State Tax Shelters and State Taxation of Capital*, 26 VA. TAX REV. 769, 779 (2007); see Michael J. Graetz, *Taxing International Income: Inadequate Principles, Outdated Concepts, and Unsatisfactory Policies*, 54 TAX L. REV. 261, 319 (2001).

61. Roin, *supra* note 55, at 212–13. *But cf.* Kane, *supra* note 53, at 924–26 (noting the possibility that apportionment could solve other problems with taxation of multi-jurisdictional enterprises). R

62. See Galle, *supra* note 45, at 1394–1400, 1413–20. R

63. 26 U.S.C. § 164 (2006); Brian Galle, *Federal Grants, State Decisions*, 88 B.U. L. REV. 875, 931–32 (2008); see Sam Bucovetsky & Michael Smart, *The Efficiency Consequences of Local Revenue Equalization: Tax Competition and Tax Distortions*, 8 J. PUB. ECON. THEORY 119, 120–22 (2006) (discussing how a system of federal revenue-equalization grants can address the efficiency problems of decentralization).

64. Louis Kaplow, *Fiscal Federalism and the Deductibility of State and Local Taxes Under the Federal Income Tax*, 82 VA. L. REV. 413, 477–78, 484–90 (1996); Kirk J. Stark, *Fiscal Federalism and Tax Progressivity: Should the Federal Income Tax Encourage State and Local Redistribution?*, 51 UCLA L. REV. 1389, 1425–30 (2004).

65. U.S. DEP'T OF THE TREASURY, TAX REFORM FOR FAIRNESS, SIMPLICITY, AND ECONOMIC GROWTH 63, 78–81 (1984), available at <http://www.ustreas.gov/offices/tax-policy/library/tax-reform/>; Kaplow, *supra* note 64, at 489–90; Michael Smart, *Taxation and Deadweight Loss in a System of Intergovernmental Transfers*, 31 CAN. J. ECON. 189, 205 (1998). R

governments.⁶⁶ Economists have devoted considerable effort to designing fiscal tools to overcome these problems, but so far there seems to be no consensus that any of them succeed.⁶⁷

Thus, putting the local and federal systems together, American tax rules by and large free many firm owners from location-specific rents.⁶⁸ The implication is that redistribution through local taxes will be relatively inefficient. Jurisdictions will struggle to achieve their own citizens' preferences for redistribution, and, if they attempt to do so, may damage the economy in the process.

III. TORT AND CONTRACT AS LOCAL REDISTRIBUTION?

My claims in Part II pose a problem for those urging redistribution only through taxation. The tax system cannot efficiently satisfy society's preferences for redistribution because national redistribution cannot capture all preferences, and local redistribution is impractical and inefficient. The question then becomes one of the second-best. Which system is more costly, a tax system flawed in the way I have described, or redistribution through legal rules?

Kaplow and Shavell argue redistribution through legal rules may encounter many of the same costs as a tax.⁶⁹ Consider table one, below. Kaplow and Shavell's analysis captures the comparison between box one, national tax, and box three, national non-tax. Redistribution through nationwide legal rules will likely fail to fully capture public preferences for distributive fairness, just as national taxation would. The more difficult comparisons are those between box four, local non-tax, and boxes one and two, national and local

66. Brian Galle, *A Republic of the Mind: Cognitive Biases, Fiscal Federalism, and Section 164 of the Tax Code*, 82 *IND. L.J.* 673, 696–700 (2007).

67. See Oates, *supra* note 3, at 1126–30.

68. It is true that redistributive taxes can also be exacted from other sources, such as wealthy individuals who are not business investors. However, one can tell a similar story about wealthy individuals, whose financial resources give them both the opportunity to relocate and also the wherewithal to lobby on their own behalf. Additionally, even if some redistributive taxes were collected from non-business-related sources, an ideally designed redistributive tax would fall at least in part on firm owners. Again, because deadweight losses grow exponentially in proportion to the size of the tax distortion, redistributive taxes should be levied very broadly, such that the marginal deadweight loss from each tax is equal. Sanchirico, *supra* note 22, at 1006–11. That implies that a jurisdiction that could not readily tax business-related sources would have to impose an inefficiently high tax on other sources.

69. Kaplow & Shavell, *Less Efficient*, *supra* note 5, at 667–68.

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tax, respectively. Does local non-tax redistribution create the same deadweight loss and impracticability problems as local taxation? If so, then at a minimum the choice between boxes two and four (accepting Kaplow and Shavell's other arguments) is straightforward: box two is superior. However, I argue that the costs of shifting from box three to four are smaller than the cost of shifting from one to two: non-tax local redistribution has smaller deadweight losses than local taxation.

TABLE 1: POSSIBLE COMBINATIONS OF REDISTRIBUTIVE MECHANISMS

REDISTRIBUTION	NATIONAL	LOCAL
TAX	1. National Tax	2. Local Tax
NON-TAX	3. National Non-Tax	4. Local Non-Tax

Local non-tax redistribution is more efficient than local taxation because it affords greater opportunities for location-specific rents. That is, firms cannot easily reap the benefits of selling in a particular market without being subject to the liability rules of that jurisdiction.⁷⁰ As a constitutional matter, once a firm purposefully avails itself of the opportunity for local sales, the jurisdiction has the power to impose its rules on that firm.⁷¹ And most jurisdictions allow plaintiffs to exercise this power to the fullest extent the Constitution permits.⁷²

To be sure, in the case of defendants with a contractual relationship with prospective plaintiffs, defendants can attempt to specify a more favorable forum for disputes. Mandatory arbitration, waivers of jury trials, and choice-of-law clauses designating a more favorable jurisdiction's rules are all common tactics for mitigating the costs of local consumer protection laws.⁷³ The difficulty for the firm, however, is that a given jurisdiction can simply refuse to give effect to such terms. Courts have found such terms to be unen-

70. See *supra* text accompanying notes 38–42; see also Stephen F. Williams, *Preemption: First Principles*, 103 Nw. U. L. Rev. 323, 327–28 (2009) (making this claim about tort law).

71. 4 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1067.1 (3d ed. 1998) (citing *Hanson v. Denkla*, 357 U.S. 235, 253 (1958); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

72. *Id.* § 1068.

73. See Paul D. Carrington & Paul H. Haagen, *Contract and Jurisdiction*, 1996 SUP. CT. REV. 331, 355–61, 374–78; see also Myriam Gilles, *Opting Out of Liability: The Forthcoming, Near-Total Demise of the Modern Class Action*, 104 MICH. L. REV. 373, 391–98 (2005).

forceable for technical contractual reasons, such as the absence of a genuine agreement, as well as on general public-policy grounds.⁷⁴ Aside from the Federal Arbitration Act and some recently developed rules capping punitive damages, it seems few federal laws limit non-discriminatory state or local rules mandating firms to be bound by the jurisdiction's legal rules.⁷⁵ Thus, a locality seeking to use its tort or contract rules for redistribution probably can do so.

It might also be argued that redistributive legal rules cannot actually work in practice, because the firm will simply include the expected cost of the legal rule in the price of the product. This is the classic "the landlord will raise the rent" problem much debated in the redistribution literature.⁷⁶ Notably, whether redistribution actually increases the welfare of beneficiaries depends in part on the seller's ability to price discriminate. In order to "raise the rent," the merchant must know that a particular customer belongs to the protected class and must be able to charge that customer a higher price. If, in contrast, the merchant can charge only one price to all of its customers, then there may still be redistribution.

It is true, however, that when the merchant "raises the rent" for all its customers at once the resulting redistribution is from unprotected to protected customers, rather than from the firm to poor customers. In other words, rich customers unprotected by the redistributive legal rule pay more to cover the firm's cost of paying out to protected poor customers.⁷⁷ But that is still a form of rich-to-poor redistribution. Similarly, some redistribution is still possible even if merchants can charge more from those protected by a legal rule. Even when the merchant can identify protected class members, the increased price typically represents an ex ante average expected cost. Thus, injured customers who win a judgment obtain a net gain, whereas uninjured customers pay more. In effect, the policy redistributes from lucky (uninjured) customers to the unlucky (injured) customers.⁷⁸ This is essentially the identical structure as

74. See Christopher R. Drahozal, "Unfair" Arbitration Clauses, 2001 U. ILL. L. REV. 695, 697-98 (noting reasons courts have refused to enforce arbitration agreements); Gilles, *supra* note 73, at 399-408.

75. See Williams, *supra* note 70, at 328.

76. E.g., Bruce Ackerman, *Regulating Slum Housing Markets on Behalf of the Poor: Of Housing Codes, Housing Subsidies and Income Redistribution Policy*, 80 YALE L.J. 1093, 1095 (1971); Duncan Kennedy, *Distributive and Paternalist Motives in Contract and Tort Law, With Special Reference to Compulsory Terms and Unequal Bargaining Power*, 41 MD. L. REV. 563, 604 (1982); see Weisbach, *supra* note 6, at 448-49.

77. See Weisbach, *supra* note 6, at 449.

78. See Steven P. Croley & Jon D. Hanson, *The Nonpecuniary Costs of Accidents: Pain-and-Suffering Damages in Tort Law*, 108 HARV. L. REV. 1785, 1793-97 (1995).

personal injury insurance: the customer transfers wealth from her current rich and healthy state to a potential future injured state.⁷⁹ Thus, the “landlord-will-raise-the-rent” problem does not preclude many forms of redistribution, including some that consumers routinely engage in every day.

As a result, whether redistributive taxes are superior to local non-tax redistribution is theoretically indeterminate. We cannot say confidently whether local taxation is superior to local non-tax redistribution. Local non-tax redistribution may well pose the double-distortion problem and other difficulties Kaplow and Shavell point to.⁸⁰ But local taxation creates deadweight losses and losses from incomplete redistribution that local non-tax redistribution does not. Similarly, theory does not clearly tell us whether the double-distortion costs are larger than the losses we would suffer from setting only a single uniform national redistributive tax rule.

IV. EXTERNALITIES AND THE INCIDENCE PROBLEM

One last set of potential arguments against redistribution through local legal rules is worth independent consideration. Professors Issacharoff and Sharkey have explained preemption as a response to over-regulation by states; over-regulation results from the fact that the costs of liability are putatively externalities for each state.⁸¹ The same point could be leveled against tort law as a tool of redistribution; rather than capturing local preferences for redistribution, it simply measures a jurisdiction’s willingness to appropriate the wealth of foreigners. In my view this danger is real, but somewhat overstated.

First, the costs of redistribution are not necessarily borne by out-of-staters. When a firm is liable for a judgment, the economic burden of that judgment is ultimately passed on to real people, whether they are the firm’s owners, its workers, its customers, or even investors in other businesses. Tax scholars call this question of which people bear the burden of an expense the “incidence” of the cost.⁸² Typically, incidence depends on the elasticities of supply and demand for the firm’s products and inputs.⁸³ For example, if demand is highly inelastic, consumers pay virtually any price for the

79. *Id.* at 1794–96.

80. *See supra* text accompanying notes 7–19.

81. Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 *UCLA L. REV.* 1353, 1368–71 (2006).

82. MUSGRAVE & MUSGRAVE, *supra* note 10, at 236–39.

83. *Id.* at 250–62.

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firm's products. The incidence of a tax on such a firm is likely to be borne by its customers because it can easily pass along the costs to them without losing sales.⁸⁴ Given the complexity of these relationships, experts agree that measuring the true incidence of a tax on corporations is a very challenging task.⁸⁵

Thus, the true economic incidence of redistributive tort law might not fall on investors in the liable firms.⁸⁶ If demand is relatively inelastic the firm might charge a higher price for products it sells in the high-cost jurisdiction. In that case the jurisdiction largely internalizes the costs of any redistribution, since it is simply moving money from some of its citizens (unprotected customers) to others (the protected customers). Alternatively, the tax might fall on investors or employees who reside in the taxing jurisdiction, so that again costs are internalized.

In a recent essay, D.C. Circuit Judge Stephen Williams acknowledged a version of this argument, but suggested that firms would be unable to set prices to reflect the costs of a given jurisdiction.⁸⁷ Judge Williams argues:

[I]n our federal system, given (1) the Supreme Court's rather mild limits on in personam jurisdiction, (2) its almost complete laissez faire as to state choice-of-law decisions, (3) the way in which products and buyers wander among the states, and (4) modern courts' virtually complete indifference to contract provisions relating to liability, firms selling in interstate commerce cannot, as a practical matter, match selling prices to varying levels of litigation risk.⁸⁸

In other words, firms cannot price their products according to the legal rule of the consumer's jurisdiction because the consumer can take the product elsewhere, and the seller will still be liable under the rule of this third jurisdiction.

There is certainly some truth to these points, but it is rather overbroad to claim that they apply to all products and all industries. To take an extreme example, homebuilders and other construction contractors probably do not need to worry much that their customers will take their product to a different state. More generally,

84. *Id.* at 254.

85. *Id.* at 264–69.

86. See Charles E. McClure, Jr., *Incidence Analysis and the Supreme Court: An Examination of Four Cases from the 1980 Term*, 1 SUP. CT. ECON. REV. 69, 82 (1982) (arguing that incidence of state-level corporate taxes is unlikely to fall on investors, because they can easily shift their investment to a firm that is not taxed).

87. Williams, *supra* note 70, at 327–28 (2009).

88. *Id.* at 328.

prices should reflect average expected liability, and rational firms ought to be able to predict where their customers will take their products. Most claims will still be in the purchase jurisdiction and many others will be in neighboring locales. It is plausible that firms could price regionally, rather than state-by-state. Moreover, since policies often spread regionally,⁸⁹ a particular liability rule is reasonably likely to hold in any one of the several neighboring jurisdictions where consumers might take their products, further facilitating regional pricing. Yet other services, such as insurance, wireless, and satellite services, could simply add a surcharge (akin to a “roaming” fee) for use in a risky jurisdiction for the seller.

Another internalization mechanism, suggested in recent work by the corporate-law scholar Michal Barzuza, is through the corporate income tax.⁹⁰ If a state imposes taxes based on firms’ net profits and the costs of liability are deductible by firms, then state taxpayers in effect pay a portion of all judgments against the firm through the reduction in revenue resulting from those deductions.⁹¹ In fact, most states have just such a set of corporate tax rules.⁹² In those states, a portion of the costs of liability are spread across all taxpayers, leading to at least partial internalization of the jurisdiction’s liability rule.

On the other hand, whatever the reality of the extent to which the state internalizes the costs of liability, the state’s voters could still *believe* that those costs are externalities.⁹³ In that instance, we might predict that officials will tend to over-produce redistribution because they will not expect to be held accountable by voters for the resulting costs. These officials take the risk, though, that their political rivals will learn the truth and expose the hidden costs to the public.⁹⁴

Another complication raised by these kinds of political considerations is the possibility that outside firms may exert considerable political power despite lacking formal voting representation. This

89. Frances Stokes Berry & William D. Berry, *State Lottery Adoptions as Policy Innovations: An Event History Analysis*, 84 AM. POL. SCI. REV. 395, 399–400 (1990); see Frederick J. Boehmke & Richard Witmer, *Disentangling Diffusion: The Effects of Social Learning and Economic Competition on State Policy Innovation and Expansion*, 57 POL. RES. Q. 39, 40 (2004).

90. Michal Barzuza, *Delaware’s Compensation*, 94 VA. L. REV. 521 (2008).

91. *Cf. id.* at 535–37, 552, 556 (arguing that dependence of state revenues on firm performance gives states incentive to design efficient rules governing firms).

92. JOHN C. HEALY & MICHAEL S. SCHADEWALD, 2009 MULTISTATE CORPORATE TAX GUIDE I-170 to I-177 (2008).

93. See Shaviro, *supra* note 43, at 927–28, 957.

94. See Brian Galle, *Hidden Taxes*, 87 WASH. U. L. REV. 59, 91–93 (2009).

ground has already been thoroughly analyzed, not only in the preemption literature but also in the related field of the dormant Commerce Clause.⁹⁵ The only point to highlight here again is that thorough analysis of the political economy of discrimination against outsiders probably will be highly sensitive to the structure of the industry and the nature of the liability;⁹⁶ generalizations are hazardous.

Overall, the externality problem does not conclusively resolve the debate between taxation and non-tax redistribution. At times it will probably be true that externalities will predictably lead to overproduction of redistribution. At other times externalities may be negligible, or have little effect on the jurisdiction's political actors. Thus, whether taxation is always a superior redistributive mechanism is theoretically uncertain.

CONCLUSION

Current debates over preemption of local consumer protection regimes have over-simplified their analysis by failing to consider the possible use of legal rules as a tool for wealth redistribution. Possibly this omission rests on the strength of a well-established welfarist argument against redistributive legal rules. However, the argument that legal rules are a poor choice of redistributive instrument appears not to have taken federalism considerations into account. I have argued here that theory does not make strong predictions about whether society should prefer taxation, whether at the national or local level, over localized redistribution through legal rules. This finding, if it holds up, has implications not only for the preemption debate but also more generally for the design of our legal system.

95. See, e.g., Jonathan R. Macey, *Federal Deference to Local Regulators and the Economic Theory of Regulation: Toward a Public-Choice Explanation of Federalism*, 76 VA. L. REV. 265, 271–73 (1990).

96. Probably the most forceful version of this claim is Ed Zelinsky's argument that the political economy questions here are so difficult that the Court should just give up. Edward A. Zelinsky, *Restoring Politics to the Commerce Clause: The Case for Abandoning the Dormant Commerce Clause Prohibition on Discriminatory Taxation*, 29 OHIO N.U. L. REV. 29, 32–79 (2002).

THE MEANING OF THE PARALLEL REQUIREMENTS EXCEPTION UNDER *LOHR* AND *RIEGEL*

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INTRODUCTION

In *Riegel v. Medtronic, Inc.*,¹ the Supreme Court held that federal law preempts most product liability claims against manufacturers for medical devices approved through the premarket approval (PMA) process.² The Court declared that 21 U.S.C. § 360k(a)—the express preemption provision added to the Federal Food, Drug, and Cosmetic Act (FDCA)³ by the Medical Device Amendments of 1976 (MDA)⁴—bars state law claims that impose requirements “‘different from, or in addition to, any requirement applicable . . . to the device’ under federal law.”⁵ Because the Riegels’ state law claims were based on supposed manufacturing, design, and warning defects that imposed such requirements, the Court held that they were preempted.⁶

But, *Riegel* went on to discuss a parallel requirements exception to the general rule of preemption. The Court said that § 360k(a) “does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties

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1. 552 U.S. 312 (2008).

2. *Id.* at 321–30. *Riegel* is discussed more fully below. See discussion *infra* Part II.D.

3. See The Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–99 (2006)).

4. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 574 (1976) (codified at 21 U.S.C. § 360k(a)).

5. *Riegel*, 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)).

6. *Id.* at 321–30.

in such a case ‘parallel,’ rather than add to, federal requirements.”⁷ This parallel requirements exception is far from clear.

The Court created the exception twelve years earlier when it first considered the reach of the MDA’s express preemption provision in *Medtronic v. Lohr*.⁸ The *Lohr* Court observed that: “Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.”⁹ And thus began the hotbed of current litigation involving devices approved through the PMA process.¹⁰

Given that the MDA’s express preemption provision affects (or may affect) most state law product liability claims concerning devices approved through the PMA process, the parallel requirements exception described in *Lohr* and *Riegel* is a critical issue in those cases. Unfortunately, although the Court has described the parallel requirements exception in cases where it did not apply, the Court has never addressed the exception’s contours or limits in a case in which it applied.¹¹ Moreover, commentators have focused much of their attention not on explaining how *Riegel* affected medical device cases, but rather on predicting what the case meant for two later prescription drug preemption cases that came before the Supreme Court—*Warner-Lambert Co. v. Kent*¹² and *Wyeth v. Levine*¹³—or ad-

7. *Id.* at 330 (citing *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996)).

8. 518 U.S. 470, 495 (1996).

9. *Id.* at 495. In the concurring portion of her separate opinion, Justice O’Connor (concurring in part and dissenting in part), joined by three justices, added that she “agree[d] that the Lohrs’ claims are not pre-empted by §360k to the extent that they seek damages for Medtronic’s alleged violation of federal requirements.” *Id.* at 513 (O’Connor, J. concurring). Both *Lohr* and *Riegel* are discussed in greater detail below. See *infra* Part II.

10. Cases taking various approaches to the scope of the parallel requirements exception are discussed in Part III.B below.

11. See *Riegel*, 552 U.S. at 330 (“Although the Riegels now argue that their lawsuit raises parallel claims, they made no such contention in their briefs before the Second Circuit, nor did they raise this argument in their petition for certiorari. We decline to address that argument in the first instance here.”).

12. 552 U.S. 440 (2008) (per curiam) (a non-precedential opinion affirming, by an equally divided court, *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2006), which held that the fraud-on-the-FDA exception to Michigan’s immunity statute protecting drug manufacturers from liability in products was not preempted by federal law).

13. 129 S. Ct. 1187, 1204 (2009) (federal law did not preempt state law failure-to-warn claims relating to anti-nausea drug). This Article focuses exclusively on preemption in the context of medical devices approved through the PMA process. Preemption in the context of pharmaceuticals (where there is no express preemption provision), as discussed in *Wyeth*, is left for another day.

dressings preemption more generally.¹⁴ Accordingly, the prevailing thought concerning *Riegel* is that most state law claims involving devices approved through the PMA process are preempted, but plaintiffs may pursue certain, as-yet-undefined, claims under the parallel requirements exception.¹⁵

Not surprisingly, in *Riegel*'s wake, plaintiffs attempt to cast their claims in light of the parallel requirements exception and seek to expand the limits of that exception. But “[l]ittle guidance is provided . . . in *Riegel* in assessing or determining the nature of parallel claims” that survive preemption.¹⁶ Thus, lower courts have struggled to answer the ultimate question: Which state law claims survive preemption under the parallel requirements exception?

This Article attempts to answer that question. Part I briefly explains the FDCA, as amended by the MDA, and its regulation of medical devices. Part II examines the Supreme Court’s medical device preemption trilogy: *Medtronic, Inc. v. Lohr*,¹⁷ *Buckman Co. v. Plaintiffs’ Legal Committee*,¹⁸ and *Riegel v. Medtronic, Inc.*,¹⁹ as well as *Bates v. Dow Agrosciences LLC*,²⁰ which discussed parallel requirements claims in relation to the federal pesticide labeling statute. Part III discusses the three major questions courts must address when faced with supposed parallel requirements claims, namely, whether (1) there was a federal violation; (2) the claims are truly parallel; and (3) punitive damages remedies for otherwise parallel claims conflict with federal law.

Significantly, many purported parallel requirements claims involve situations with no final adjudication of a proceeding initiated by the United States Food and Drug Administration (FDA) that a violation actually occurred. In those instances, the plaintiffs’ attempts to pass the threshold for establishing that a claim survives

14. See, e.g., Richard A. Epstein, *The Case for Field Preemption of State Law in Drug Cases*, 103 NW. U. L. REV. 463 (2009); Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Product Liability Claims*, 103 NW. U. L. REV. 437 (2009).

15. See, e.g., Sharkey, *supra* note 14, at 450–51; see also *The Supreme Court 2007 Term—Leading Cases*, 122 HARV. L. REV. 405, 412, 414–15 (2008) (concluding that *Riegel*'s preemption likely protects only those manufacturers in compliance with FDA regulations).

16. *O’Shea v. Cordis Corp.*, No. 50-2006-CA-013019, 2008 WL 3139428, at *3 (Fla. 4th Dist. Ct. App. May 19, 2008).

17. 518 U.S. 470 (1996).

18. 531 U.S. 341 (2001) (holding that fraud-on-the-FDA claims are impliedly preempted by the FDCA, as amended by the MDA).

19. 552 U.S. 312 (2008).

20. 544 U.S. 431 (2005).

express preemption (i.e., that the claim is based on a federal violation) implicate the concerns that led the *Buckman* Court to find implied preemption.²¹ Ultimately, the Court's dicta in *Lohr* and *Riegel* outlining a parallel requirements exception to express preemption may have been much ado about very little, as few such claims should survive an implied preemption analysis.

I. THE REGULATION OF MEDICAL DEVICES

Before the MDA was enacted in 1976, medical device manufacturers were subject to the varying laws and regulations of the fifty states.²² Through the MDA, Congress unified and centralized the regulation of medical devices under the FDA.²³ To that end, Congress included an express preemption provision in the MDA; 21 U.S.C. § 360k(a):

Except as provided in subsection (b) of this section, 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 Act.²⁴

The FDCA also provides that, with a limited exception for state enforcement of certain food-related statutes, all "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."²⁵

In addition to centralizing the regulation of medical devices, Congress sought to protect consumers from "increasingly complex

21. See *Buckman*, 531 U.S. at 350–51. *Buckman* is discussed in Part II.B below.

22. See *Riegel*, 552 U.S. at 315–16 ("[Before the MDA was enacted in 1976,] [s]everal States adopted regulatory measures [relating to medical devices], including California, which in 1970 enacted a law requiring premarket approval of medical devices. Congress stepped in with the passage of the [MDA], which swept back some state obligations and imposed a regime of detailed federal oversight.") (citations omitted); Mark Herrmann & Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L.J. 1, 4 (1996).

23. See Herrmann & Ritts, *supra* note 22, at 4.

24. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 4(a)(9), 90 Stat. 539, 580 (1976) (codified at 21 U.S.C. § 360k(a)).

25. 21 U.S.C. § 337(a). Section 337(a) was not added to the FDCA by the MDA; instead, it was in the original FDCA. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, § 307, 52 Stat. 1040, 1046 (1938).

devices which posed serious risk if inadequately tested or improperly designed or used,” without stifling medical innovation.²⁶ To assure adequate oversight, the MDA divides medical devices into three categories based on their presumed degree of risk. Class I devices do “not present a potential unreasonable risk of illness or injury” and are subject to only “general controls.”²⁷ Class II devices may involve a higher degree of risk and are subject to “special controls.”²⁸ Class III devices are those involving the highest potential risk and are for “use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health”²⁹ The FDA subjects Class III devices to its most rigorous scrutiny.

The MDA provides that manufacturers may not market Class III devices until they receive FDA approval through the PMA process.³⁰ There are two exceptions to this rule. First, devices sold before the passage of the MDA are grandfathered and may be marketed until the FDA promulgates a regulation requiring approval through the PMA process.³¹ Second, new devices are exempt if the FDA finds them to be “substantially equivalent” to another exempt device.³² This “substantial equivalen[ce]” determination is commonly referred to as the “510(k) notification process” based on the FDCA section requiring limited review before new devices may be

26. S. REP. NO. 94-33, at 5 (1975), *as reprinted in* 1976 U.S.C.C.A.N. 1070, 1075.

27. 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 860.3(c)(1). “Examples of Class I devices include tongue depressors, arm slings, and hand-held surgical instruments.” Overview: FDA Regulation of Medical Devices (May 6, 2003), *available at* http://www.qrasupport.com/FDA_MED_DEVICE.html (last visited Sept. 11, 2009) [hereinafter Overview: FDA Regulation of Medical Devices].

28. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2). “Examples of Class II devices include physiologic monitors, x-ray systems, gas analyzers, pumps, and surgical drapes.” Overview: FDA Regulation of Medical Devices, *supra* note 27.

29. 21 U.S.C. § 360c(a)(1)(C)(ii); 21 C.F.R. § 860.3(c)(3). “Examples of Class III devices . . . are: replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.” Overview: FDA Regulation of Medical Devices, *supra* note 27.

30. 21 U.S.C. § 360e(a); *see also* 21 U.S.C. § 351(f).

31. 21 U.S.C. §§ 360c(f)(1), 360e(b)(1)(A).

32. 21 U.S.C. §§ 360c(f)(4), 360e(b)(1)(B).

sold.³³ Most Class III devices are approved under the 510(k) notification process.³⁴

To obtain approval through the PMA process, the manufacturer must submit an application including, among other things: (1) full reports of all studies regarding the safety and effectiveness of the device that have been published or should reasonably be known to the manufacturer; (2) a full statement of the device's makeup and principle(s) of operation; (3) a description of the methods, facilities, and controls used for manufacturing; (4) samples or components of the device as requested by the FDA; and (5) a specimen of the proposed labeling.³⁵ The FDA may review these materials, employ outside experts to review them, and request any additional information it desires.³⁶ The FDA will approve the device only when it receives "reasonable assurance" that the product is safe and effective.³⁷ Once a manufacturer obtains PMA, it may market the device, but may not change the design, manufacture, label-

33. In 1962, Congress added § 510 to the FDCA. *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 302, 76 Stat. 780 (1962) (codified at 21 U.S.C. § 360c). In 1976, Congress added paragraph (k) to § 510 of the FDCA. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, § 4(a)(9), 90 Stat. 539, 580 (1976) (codified at 21 U.S.C. § 360(k)).

34. In *Riegel*, the Second Circuit noted that in 2005, approximately ninety-nine percent of newly-approved Class III devices were approved through the 510(k) process. *Riegel v. Medtronic*, 451 F.3d 104, 112 (2d Cir. 2006). In 2008, Professor Sharkey suggested that roughly ten percent of available Class III devices were approved through the PMA process. Sharkey, *supra* note 14, at 451. Regardless of the precise percentages, PMA-approved devices appear to be only a relatively small fraction of available medical devices.

35. 21 U.S.C. § 360e(c)(1).

36. 21 U.S.C. § 360e(c)(2), (d); 21 C.F.R. § 814.44(a).

37. 21 U.S.C. § 360e(d)(2).

[T]he safety and effectiveness of a device are to be determined—(A) with respect to the persons for whose use the device is represented or intended, (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21 U.S.C. § 360c(a)(2).

[T]he effectiveness of a device is . . . to be determined . . . on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

21 U.S.C. § 360c(a)(3)(A).

ing, or other attributes that would affect the device's safety or effectiveness without FDA approval.³⁸

After its initial approval, the FDA continually reviews its decisions and imposes stringent reporting requirements on the manufacturers including "continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use."³⁹ The FDA requires reports of adverse events from device user facilities,⁴⁰ manufacturers, and importers,⁴¹ and it receives voluntary reports of adverse events from healthcare providers and patients.⁴² The FDA also conducts on-site inspections of manufacturing facilities "to verify that the device[s are] being manufactured, stored, labeled, and shipped under approved conditions."⁴³

The FDA has broad enforcement authority over medical devices. It may (1) restrict distribution of medical devices;⁴⁴ (2) issue warning letters to device manufacturers for suspected non-compliance with the FDCA;⁴⁵ (3) publish other public reports or disseminate information regarding medical devices or manufacturers;⁴⁶ (4) order corrective actions including notification, repair, modifications, adjustments, destruction, or additional device inspection;⁴⁷ (5) temporarily suspend approval "if [the] FDA determines that there is reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death;"⁴⁸ (6) withdraw approval if the FDA determines that the device is no longer safe and effective or that "[a]ny postapproval requirement imposed by the PMA approval order or by regulation has not been met;"⁴⁹ and (7) order mandatory recalls "where FDA

38. See 21 U.S.C. § 360e(d)(6)(A)(i).

39. 21 C.F.R. § 814.82(a)(2).

40. A "device user facility" is "a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office." 21 U.S.C. § 360i(b)(6)(A).

41. 21 U.S.C. § 360i(a)-(b), (e)-(f); 21 C.F.R. §§ 803.1-58, 814.84.

42. See U.S. DEP'T OF HEALTH & HUMAN SERVS. Form FDA 3500 (Medwatch Form for voluntary reporters, including healthcare professionals and patients), available at <http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf>.

43. 21 C.F.R. § 814.82(b); see also 21 U.S.C. § 374.

44. 21 U.S.C. § 360j(e).

45. See FDA, *Regulatory Procedures Manual* § 4-1-1, at 4-2 (Mar. 2009), available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm> (last visited July 7, 2009).

46. 21 U.S.C. § 375.

47. 21 U.S.C. § 360h(a); 21 C.F.R. §§ 822.1-18 (2009).

48. 21 C.F.R. § 814.47(a)(2) (2009).

49. 21 C.F.R. § 814.46(a)(2) (2009).

finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death.”⁵⁰

Under its own authority the agency may impose civil fines on manufacturers it finds to be noncompliant with the FDCA.⁵¹ Further, the FDA may request that the Department of Justice pursue legal action against manufacturers to (1) seize medical devices that the FDA believes are adulterated or misbranded;⁵² (2) enjoin a manufacturer from manufacturing or distributing medical devices;⁵³ or (3) institute criminal proceedings against a device manufacturer for engaging in a prohibited act.⁵⁴

II. THE MEDICAL DEVICE PREEMPTION TRILOGY AND *BATES*

Against the regulatory backdrop described above, the Supreme Court has addressed the preemptive effect of the FDCA on state law causes of action involving medical devices in three cases: *Medtronic, Inc. v. Lohr*, *Buckman Co. v. Plaintiffs’ Legal Committee*, and *Riegel v. Medtronic, Inc.* These decisions, along with *Bates v. Dow Agrosciences LLC*⁵⁵—which addressed state law claims imposing parallel requirements in the context of the federal pesticide labeling statute⁵⁶—provide the basis for evaluating the scope of state law claims that survive preemption by way of the parallel requirements exception.

A. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr*,⁵⁷ the Court considered the extent to which the MDA’s express preemption provision, § 360k(a), preempts state common law product liability claims relating to medical devices. In the case, Lora Lohr’s Medtronic heart pacemaker failed, allegedly because of a defective lead,⁵⁸ and she suffered “a ‘complete heart block’ that required emergency surgery” to replace

50. 21 C.F.R. § 810.15 (2009).

51. 21 U.S.C. § 333(f) (2007).

52. 21 U.S.C. § 334 (2007).

53. 21 U.S.C. § 332 (2007).

54. See 21 U.S.C. §§ 331, 335, 351–52 (2007). For additional discussion on FDA enforcement authority, see JAMES M. BECK & ANTHONY VALE, *DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK* § 4.01 (2009).

55. 544 U.S. 431 (2005).

56. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136–36y (2000).

57. 518 U.S. 470, 471 (1996).

58. Pacemakers consist of a generator and one or more leads, which are electrical wires that connect the generator to the heart. Based on information about

the pacemaker.⁵⁹ The lead in Ms. Lohr's original pacemaker had not gone through the PMA process but, instead, had been approved under the 510(k) notification process where the FDA found it to be "substantially equivalent" to devices already on the market when the MDA was enacted.⁶⁰

Ms. Lohr and her husband brought a product liability action against Medtronic asserting Florida common law negligence and strict liability claims based on alleged manufacturing, warning, and design defects.⁶¹ After the district court dismissed the action based on federal preemption, the Eleventh Circuit affirmed except with respect to the design defect claims, which it found were not preempted.⁶²

The Supreme Court held that none of the claims before it on appeal were preempted.⁶³ The Court began by noting the "rigorous" PMA process for Class III devices.⁶⁴ The Court also noted, however, that "substantially equivalent" devices marketed under the 510(k) notification process were subjected to scrutiny that was "by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours."⁶⁵

Because the 510(k) notification process allowed devices to be "marketed without running the gauntlet of the PMA process," the Court found that the MDA imposed no "requirements" on their design; instead, the statute merely "maintain[ed] the [pre-MDA] status quo with respect to the marketing of existing medical devices and their substantial equivalents."⁶⁶ Therefore, for lack of a conflicting federal requirement and based on the so-called "presump-

the heart provided through the leads, the generator monitors and, when appropriate, stimulates the heart.

59. *Lohr*, 518 U.S. at 481.

60. *Id.* at 480; *see* 21 U.S.C. §§ 360c(f)(4), 360e(b)(1)(B) (2007).

61. *Lohr*, 518 U.S. at 481.

62. *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1350–52 (11th Cir. 1995).

63. There were opinions by (1) Justice Stevens (joined by Justices Ginsburg, Kennedy, and Souter); (2) Justice Breyer, concurring in part and concurring in the judgment; and (3) Justice O'Connor (joined by Chief Justice Rehnquist and Justices Scalia and Thomas), concurring in part and dissenting in part. Justice Stevens's opinion commanded a majority where joined by Justice Breyer's or Justice O'Connor's opinions and, otherwise, was a plurality opinion. *Lohr v. Medtronic, Inc.*, 518 U.S. 470 (1996).

64. *Id.* at 477.

65. *Id.* at 478–79 (citation omitted).

66. *Id.* at 494.

tion against preemption,⁶⁷ the Lohrs' design defect claims were not preempted.⁶⁸ Further, their manufacturing and warning defect claims survived preemption "because their generality leaves them outside the category of requirements that § 360(k) envisioned to be 'with respect to' specific devices such as pacemakers."⁶⁹

Had the Court issued a narrow ruling on those grounds the controversy over parallel requirements might never have started. Instead, the Court expanded its reasoning, observing that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."⁷⁰ While state common law claims based on alleged violations of FDA regulations might include additional elements and, for that reason, "might be 'different from' the federal rules in a literal sense," they "do[] not amount to the additional or different 'requirement' that is necessary under the statute; rather, [the state law claim] merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."⁷¹ Indeed, all members of the Court agreed that parallel requirements claims survive preemption.⁷²

67. The "presumption against preemption" generally is traced to *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 334 (2008) (Ginsburg, J., dissenting); *Lohr*, 518 U.S. at 485. There, the plaintiffs alleged that Illinois grain warehouse regulations were preempted because they conflicted with federal regulations. The Court began its analysis by articulating what has become the "presumption against preemption;" namely, that, where "Congress legislate[s] . . . in a field which the States traditionally have occupied," the Court should "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." *Rice*, 331 U.S. at 230 (citations omitted). *Rice* said that "[t]he test" for conflict preemption purposes "is whether the matter on which the State asserts the right to act is in any way regulated by the Federal Act" and, applying that standard, found that most of the Illinois regulations at issue were preempted. *Id.* at 236.

68. *Lohr*, 518 U.S. at 492-94.

69. *Id.* at 502.

70. *Id.* at 495.

71. *Id.*

72. *Id.* (portion of Court's opinion authored by Justice Stevens and joined by Justices Kennedy, Souter, Ginsburg, and Breyer); *id.* at 513 (O'Connor, J., concurring in relevant part, joined by Chief Justice Rehnquist and Justices Scalia and Thomas) ("Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to,' requirements under federal law.").

B. Buckman Co. v. Plaintiffs' Legal Committee

Five years after *Lohr*, the Supreme Court revisited the issue of parallel requirements in *Buckman Co. v. Plaintiffs' Legal Committee*.⁷³ In the latter case, the plaintiffs alleged that their injuries resulted from purported defects in orthopedic bone screws implanted in their spines.⁷⁴ The FDA approved the screws under the 510(k) notification process when labeled for use in arm and leg bones but had not approved them when labeled for use in the spine.⁷⁵ The plaintiffs asserted state tort claims based on the manufacturers' supposed fraudulent representations to the FDA about the screws' intended use.⁷⁶ The district court dismissed the fraud-on-the-FDA claims based on federal preemption, and the Third Circuit reversed.⁷⁷

The Supreme Court reversed the Third Circuit,⁷⁸ holding that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law."⁷⁹

The conflict stem[med] from the fact that the federal regulatory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration c[ould] be skewed by allowing fraud-on-the-FDA claims under state tort law.⁸⁰

The Court further explained:

73. 531 U.S. 341 (2001).

74. *Id.* at 343.

75. *Id.* at 346.

76. *Id.* at 346–47. The named defendant in *Buckman* was a consulting company that assisted the device manufacturer in seeking 510(k) clearance from the FDA, not the device manufacturer itself. *Id.* at 343. The Court's decision, however, was not based in any manner on this fact. To the contrary, the Court noted that the 510(k) application, allegedly containing the fraudulent representations, was filed by the defendant and the manufacturer on the manufacturer's behalf. *Id.* at 346–47. Nowhere in the Court's opinion does it suggest that the outcome would have been different had the 510(k) application been filed solely by the manufacturer.

77. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (3d Cir. 1998), *rev'g* No. MDL 1014, 1997 WL 305257 (E.D. Pa. Mar. 28, 1997).

78. Chief Justice Rehnquist wrote the Court's opinion, which was joined by Justices O'Connor, Scalia, Kennedy, Souter, Ginsburg, and Breyer. Justice Stevens wrote an opinion concurring in the judgment, which Justice Thomas joined. *Buckman*, 531 U.S. at 342.

79. *Id.* at 531 U.S. at 348 (footnote omitted).

80. *Id.*

As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA. Would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability. In effect, then, fraud-on-the-FDA claims could cause the Administration's reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, see 21 U.S.C. § 396 (1994 ed., Supp. V), and even though off-label use is generally accepted.

Conversely, fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application.⁸¹

The holding in *Buckman* is clear: "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."⁸² The Court "express[ed] no view on whether these claims [we]re subject to express pre-emption under 21 U.S.C. § 360k."⁸³

Buckman mentioned *Lohr's* dictum regarding parallel requirements claims but did not discuss it in detail. Specifically, the Court rejected the *Buckman* plaintiffs' assertion that their fraud claims escaped preemption as "claims arising from violations of FDCA requirements."⁸⁴ The Court first noted that the *Lohr* plaintiffs' "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements," and then observed that:

[The *Buckman* plaintiffs'] fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although [*Lohr*] can be read to allow certain state-law causes of actions that parallel

81. *Id.* at 350–51 (footnote omitted).

82. *Id.* at 349 n.4.

83. *Id.* at 348 n.2.

84. *Id.* at 352 (citation omitted).

federal safety requirements, it does not . . . stand for the proposition that any violation of the FDCA will support a state-law claim.⁸⁵

C. *Bates v. Dow Agrosciences LLC*

In the 2005 case of *Bates v. Dow Agrosciences LLC*,⁸⁶ the Court interpreted the scope of preemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁸⁷ In *Bates*, Texas farmers alleged that Dow's pesticide, Strongarm, destroyed their crops—due to the soil's high pH—and brought a range of state law damage claims against Dow.⁸⁸ The lower courts found those claims were preempted by FIFRA's express preemption provision, 7 U.S.C. § 136v(b).⁸⁹

The Supreme Court vacated and remanded.⁹⁰ The Court found that state law claims imposing only parallel requirements survive express preemption under FIFRA's express preemption provision, which provides that States “shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.”⁹¹ According to the Court, “[t]he imposition of state sanctions for violating state rules that merely duplicate federal requirements is . . . consistent with the text of” FIFRA's express preemption provision.⁹²

The Court found that § 136v(b) did not preempt the *Bates* plaintiffs' design defect, negligent testing, manufacturing defect, and express warranty claims because § 136v(b) applies only to requirements relating to “labeling or packaging” and those claims “plainly d[id] not qualify as requirements for ‘labeling or packaging.’”⁹³ The *Bates* plaintiffs' fraud and negligent failure-to-warn claims did not escape preemption for that reason because they were

85. *Id.* at 352–53.

86. 544 U.S. 431 (2005).

87. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136–36y (2000).

88. 544 U.S. at 435–36.

89. *See* *Dow Agrosciences, LLC v. Bates*, 205 F. Supp. 2d 623, 626 (N.D. Tex. 2002), *aff'd*, 332 F.3d 323 (5th Cir. 2003).

90. Justice Stevens wrote the Court's opinion, which was joined by Chief Justice Rehnquist and Justices O'Connor, Kennedy, Souter, Ginsburg, and Breyer, who also filed a concurring opinion. Justice Thomas filed an opinion concurring in the judgment in part and dissenting in part, and Justice Scalia joined that opinion.

91. 7 U.S.C. § 136v(b) (2006).

92. 544 U.S. at 442.

93. *Id.* at 444.

“premised on common-law rules that qualify as ‘requirements for labeling or packaging.’”⁹⁴ As to those claims, the Court first observed that “§ 136v(b) prohibits only state-law labeling and packaging requirements that are ‘*in addition to or different from*’ the labeling and packaging requirements under FIFRA”⁹⁵ and then remanded for the lower courts to “decide in the first instance whether these particular common-law duties are equivalent to FIFRA’s misbranding standards.”⁹⁶

Explaining this result, *Bates* first observed that its “‘parallel requirements’ reading of § 136v(b) . . . f[ound] strong support in” *Lohr*.⁹⁷ The Court also noted that unless parallel requirements claims survived express preemption under § 136v(b), there was no “plausible alternative interpretation of ‘in addition to or different from’ that would give that phrase meaning.”⁹⁸ The Court found that this result was consistent with the presumption against preemption.⁹⁹ Furthermore, *Bates* rejected the “greatly overstate[d] need for uniformity and centralization”¹⁰⁰ because, under FIFRA, “[s]tates may ban or restrict the uses of pesticides that EPA has approved; they may also register, subject to certain restrictions, pesticides for uses beyond those approved by EPA.”¹⁰¹ Finally, *Bates* cautioned “that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive preemption” and “must also be measured against any relevant EPA regulations that give content to FIFRA’s misbranding standards.”¹⁰²

However, the substantial differences between FIFRA on the one hand, and the FDCA and MDA on the other, limit *Bates*’s instructive value for interpreting the scope of preemption under the MDA. The scope of express preemption under FIFRA is limited to “labeling or packaging” requirements, whereas the MDA’s express preemption provision, 21 U.S.C. § 360k, applies more broadly to requirements “relat[ing] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.”¹⁰³ Further, the EPA’s review of pesticide labeling is substantially less extensive than the FDA’s review of PMA-approved de-

94. *Id.* at 446.

95. *Id.* at 447 (emphasis in original).

96. *Id.*

97. *Id.*

98. *Id.* at 448.

99. *Id.* at 449.

100. *Id.* at 450.

101. *Id.* (citations omitted).

102. *Id.* at 453.

103. 21 U.S.C. § 360k(a)(2).

vices, and FIFRA contemplates a substantially greater role for state regulation than the FDCA.¹⁰⁴ Nonetheless, *Bates* provides an extended discussion of why parallel requirements claims survive express preemption based on the presence of the words “in addition to or different from” in FIFRA’s § 136v(b) and, for that reason, provides insight into their meaning in the MDA’s § 360k(a).

D. Riegel v. Medtronic, Inc.

In 2008, the Court revisited the issue of express preemption under § 360k in *Riegel v. Medtronic, Inc.*¹⁰⁵ After Charles Riegel suffered a heart attack, his physician inserted a Medtronic balloon catheter into Mr. Riegel’s coronary artery, which was diffusely diseased and calcified.¹⁰⁶ The catheter was contraindicated for patients with diffusely diseased or calcified arteries.¹⁰⁷ Further, despite warnings against overinflation, the physician overinflated the catheter, which then burst.¹⁰⁸ Unlike the pacemaker lead at issue in *Lohr*, which the FDA had approved under the 510(k) notification process, the FDA had approved the catheter in *Riegel* under the “rigorous” PMA process.¹⁰⁹ Mr. Riegel and his wife filed suit against Medtronic asserting New York common law claims based on supposed manufacturing, warning, and design defects.¹¹⁰ The district court dismissed the plaintiffs’ claims based on federal preemption, and the Second Circuit affirmed.¹¹¹

The Supreme Court affirmed.¹¹² Initially, the Court found that the FDA’s approval through the PMA process, unlike approval

104. See *Bates*, 544 U.S. at 440 (“EPA confirmed that it had ‘stopped evaluating pesticide efficacy for routine label approvals almost two decades ago’”) (citation omitted); *id.* at 450 (outlining types of state regulation permitted under FIFRA); see also 7 U.S.C. § 136v(a) (“A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.”); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1990) (saying FIFRA did not expressly or impliedly preempt local ordinance regulating pesticide use);

105. 552 U.S. 312 (2008).

106. *Id.* at 320–21.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Riegel v. Medtronic, Inc.*, No. 99-CV-0649, 2003 U.S. Dist. LEXIS 27454 (N.D.N.Y. Dec. 2, 2003), *aff’d*, 451 F.3d 104 (2d Cir. 2006).

112. Justice Scalia wrote the Court’s opinion, which was joined by Chief Justice Roberts and Justices Kennedy, Souter, Thomas, Breyer, and Alito. Justice Stevens wrote an opinion concurring in part and concurring in the judgment, and Justice Ginsburg dissented. See *Riegel*, 552 U.S. at 314.

under the 510(k) notification process, “imposes [federal] ‘requirements’ under the MDA as [the Court] interpreted it in *Lohr*.”¹¹³ Next, the Court concluded that the Riegels’ New York common law claims imposed requirements that were “different from, or in addition to, any [federal] requirement applicable . . . to the device.”¹¹⁴ The Court “adhere[d] to” its conclusion in *Lohr* “that common-law causes of action for negligence and strict liability do impose ‘requirement[s]’ and would be pre-empted by federal requirements specific to a medical device. . . . Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”¹¹⁵

Further, the Court rejected the plaintiffs’ contention that even if their claims imposed “requirements,” “general common-law duties are not requirements maintained ‘with respect to devices.’”¹¹⁶ That was because the plaintiffs’ claims

depend[ed] upon New York’s ‘continu[ing] in effect’ general tort duties ‘with respect to’ Medtronic’s catheter. Nothing in the statutory text [of the MDA] suggest[ed] that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general.¹¹⁷

Finally, *Riegel* reiterated *Lohr*’s parallel requirements exception: “[Section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”¹¹⁸ Although the *Riegel* plaintiffs argued that they had asserted such parallel claims, the Court declined to address them because the plaintiffs had failed to raise them either before the Second Circuit or in their petition for certiorari.¹¹⁹ Thus, *Riegel*, like *Lohr*, acknowledges (in dictum) the parallel requirements exception to the MDA’s express preemption provision but provides little guidance as to its meaning.¹²⁰

113. *Id.* at 321–23.

114. *Id.* at 323–30.

115. *Id.* at 323–25 (citing *Medtronic v. Lohr*, 518 U.S. 470, 512 (1996)).

116. *Id.* at 327.

117. *Id.* at 328 (emphasis in original).

118. *Id.* at 330 (citations omitted).

119. *Id.*

120. *Riegel*, like *Lohr*, involved *only* express preemption under § 360k. Neither case discussed implied preemption, addressed in *Buckman*, which is based in substantial part on another FDCA section, 21 U.S.C. § 337.

III. WHAT ARE THE PARALLEL REQUIREMENTS CLAIMS THAT ESCAPE PREEMPTION?

Lohr involved a device approved under the 510(k) notification process, which does not trigger preemption.¹²¹ *Lohr* stated that “[n]othing in § 360k(a),” the MDA’s express preemption provision, “denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.”¹²² In *Buckman*, there was no express preemption because the device had been approved through the 510(k) notification process.¹²³ The Court held, however, that the state law fraud-on-the-FDA claims at issue there were impliedly preempted.¹²⁴ *Bates*, although interpreting FIFRA and not the FDCA, reaffirmed *Lohr*’s parallel requirements approach to express preemption and found that the “in addition to or different from” language,¹²⁵ which closely tracks language in the MDA’s express preemption provision, required that approach. And *Riegel*—a case involving a PMA-approved device where the plaintiffs’ claims were preempted but no parallel claims were at issue—observed that “§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”¹²⁶

In short, state law claims paralleling federal requirements appear to survive express preemption under § 360k(a). But this conclusion has become established largely through dicta with little controlling authority outlining either what the un-preempted, surviving state law claims might be, or whether they survive in whole or only in part. Moreover, *Lohr* and *Riegel* said only that these hypothetical parallel claims were not *expressly* preempted.¹²⁷ They said nothing about the extent to which any such claims may be *impliedly* preempted. *Riegel*’s silence on this point, as well as its failure to cite or discuss the Court’s earlier decision in *Buckman*, is particularly puzzling.

121. See discussion *supra* Part II.A.

122. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996).

123. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 346 (2001).

124. *Id.* at 348.

125. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005).

126. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (citations omitted).

127. Similarly, *Bates* addressed only express preemption under 7 U.S.C. § 136v(b).

From the cases discussed, it is possible to discern some general contours of a surviving, parallel requirements state law claim. First, there is little point in assessing whether claims relating to 510(k)-approved devices are “parallel” and survive express preemption given *Lohr*'s holding that, for 510(k) devices, there is no express preemption. Thus, the parallel requirements analysis should begin with claims relating to a PMA-approved device.

Second, the state law claim at issue must be one that both imposes requirements under the MDA and “relates to the safety or effectiveness of the device” or there would be no express preemption and, thus, no meaningful parallel requirements inquiry. Most state law claims based on theories of express warranty, affirmative misrepresentation, and implied warranty impose requirements and are preempted by § 360k(a) because they directly or indirectly challenge the adequacy of FDA-approved labeling or other federal requirements.¹²⁸ However, one could imagine claims unrelated “to the safety or effectiveness of [a] device,” for example, a claim based on representations relating to pricing.¹²⁹ Those claims are not suited to a parallel requirements inquiry.

128. *E.g.*, *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008) (“[T]he better-reasoned approach would find plaintiff’s breach of express warranty claims based on the labeling of [the device at issue] preempted.”); *Lake v. Kardjian*, 874 N.Y.S.2d 751, 754 (Sup. Ct. 2008) (“[A] breach of express warranty claim based upon FDA approved statements in product labeling and advertising is preempted by the MDA.”). *But see* *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009) (finding that express warranty claims that “device implanted in [the plaintiff’s] hip failed to meet the promises of the [device’s] label and package inserts” were not preempted).

129. *See* *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997) (“Express warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted.”); *Hofts*, 597 F. Supp. 2d at 839 (“Because express warranties ‘arise from the representations of the parties and are made as the basis of the bargain between them,’ a ‘state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA’ and therefore may not be preempted.”) (quoting *Mitchell*, 126 F.3d at 915); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 285–86 (E.D.N.Y. 2009) (finding “plaintiff’s breach of express warranty claim [to be] preempted to the extent that it is premised on FDA approved representations made by the manufacturer,” but finding that other express warranty claims failed because “[n]owhere in her amended complaint does plaintiff allege that she relied on defendants’ alleged representations” or “even describe how this representation was made”); *Huber v. Howmedica Osteonics Corp.*, No. 07-2400, 2008 U.S. Dist. LEXIS 106479, at *8–11 (D.N.J. Dec. 21, 2008) (denying motion to dismiss express warranty claim for PMA-approved device). *See generally* *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 526

Third, the requirements imposed by the state law claim must parallel federal requirements or, conversely, cannot be “different from, or in addition to, any” MDA-imposed requirement “relat[ing] to the safety or effectiveness of the device or to any other matter included in [an MDA] requirement applicable to the device.”¹³⁰ This means that at a minimum, state law claims survive express preemption as parallel requirements claims only if they are premised on allegations that the device manufacturer *violated* federal requirements.

But, if a state law claim relates to a PMA-approved device and imposes requirements that relate to supposed violations of federal requirements, this does not end the inquiry. Courts also must decide whether (1) a federal requirement was violated; (2) the requirements the state law claim imposes truly parallel the federal requirement; and (3) all aspects of the claim survive preemption. The following subparts explore these issues.

A. Was A Federal Requirement Violated?

Following *Riegel*, plaintiffs’ attorneys routinely seek to avoid federal preemption by pleading a parallel requirements claim that alleges that the device manufacturer violated a federal requirement.¹³¹ The evidence of the alleged violation can range anywhere from little more than the plaintiff’s allegation to a prior, final judicial or regulatory adjudication that the manufacturer violated the law.

1. The Range of Possible Enforcement Actions

As the federal agency charged with enforcing the FDCA, the FDA brings, or recommends that the Department of Justice should bring, enforcement actions.¹³² If the plaintiff’s claim is based on an instance in which the FDA had previously obtained a final judg-

(1992) (Stevens, J., plurality) (finding express preemption provision in Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334, did not preempt state law express warranty claims because “a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a ‘requirement . . . imposed *under State law*’ within the meaning of” that statute) (emphasis in original).

130. 21 U.S.C. § 360k(a).

131. Cases presenting alleged parallel requirements claims are discussed below in Part III.B.

132. 21 U.S.C. § 337(a) (“Except as provided in subsection (b) [relating to food products], all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”); *see also* 21 U.S.C. §§ 332–334, 352, 355(e).

ment against the defendant manufacturer, the defendant may be effectively precluded from contesting whether a violation of the federal requirement occurred.¹³³ Conversely, if the defendant prevailed in a prior enforcement proceeding, the plaintiff may be similarly barred from arguing that a state law claim survives preemption based on a supposed violation of a federal requirement.¹³⁴

But instances where federal enforcement proceedings have resulted in a final judgment are rare, and there are a range of intermediate possibilities. For example, a tort plaintiff might plead a violation of a federal requirement where the FDA had never identified or spoken about the supposed violation. In that event, there would be no evidence about whether the FDA believed a violation actually occurred.

Moving higher up on the enforcement continuum, the FDA could have sent the manufacturer an untitled letter, which raises alleged “violations that do not meet the threshold of regulatory significance for a Warning Letter.”¹³⁵ Or, the FDA could send the manufacturer a warning letter, which “is informal and advisory” and “communicates the agency’s position on a matter.”¹³⁶ As one court observed, however, even warning letters “merely establish a dialogue between the FDA [and the recipient] and do not necessarily lead to further sanctions.”¹³⁷ As another court noted, a warning letter is “a statement by the FDA . . . of what its position is on an issue, along with a threat of enforcement that does not arise to a promise to enforce,” but sending such a letter “standing alone, has no effect until and unless the FDA takes enforcement action.”¹³⁸

133. The manufacturer could also be legally precluded from contesting the violation based on issue preclusion. See RESTATEMENT (SECOND) OF JUDGMENTS §§ 39–62 (1980).

134. While a defendant that did not prevail in enforcement proceedings might, depending on the particular facts and the applicable law, be collaterally estopped from later contesting that a violation occurred, a plaintiff presumably would not have been a party to the FDA enforcement proceeding and, therefore, would not be collaterally estopped by a judgment for the defendant in the enforcement proceeding. But, even though collateral estoppel would not bar a plaintiff from claiming that the conduct at issue in the enforcement proceeding violated federal requirements, the fact that the defendant prevailed in those proceedings nonetheless should preclude such a claim.

135. FDA, REGULATORY PROCEDURES MANUAL § 4-2-1, at 4-26 (2009), available at http://www.fda.gov/ora/compliance_ref/rpm/.

136. *Id.* § 4-1-1, at 4-2.

137. *Prof'ls & Patients For Customized Care v. Shalala*, 847 F. Supp. 1359, 1365 (S.D. Tex. 1994) (citation omitted), *aff'd*, 56 F.3d 592 (5th Cir. 1995).

138. *Den-Mat Corp. v. FDA*, No. MJG-92-444, 1992 U.S. Dist. LEXIS 12233, at *12 (D. Md. Aug. 17, 1992) (citation omitted); *accord* *Biotics Research Corp. v.*

Thus, neither an FDA untitled nor an FDA warning letter, by itself, establishes that a violation actually occurred. In response to such a letter the manufacturer may, for instance, prove to the FDA's satisfaction that there was no violation. Or, while not agreeing that a violation occurred, it may take any requested remedial actions to avoid the expense of contesting the issue or the perceived risks of prolonging a dispute with the manufacturer's primary regulator.

Even when more formal enforcement steps have been taken the FDA's determination that a violation occurred is not necessarily the last word.¹³⁹ The FDA could commence litigation accusing the manufacturer of having violated the FDCA, and the manufacturer could nonetheless win at trial. As the Supreme Court recently observed in *Wyeth v. Levine*, the FDCA's misbranding statute "contemplates that federal juries will resolve most misbranding claims" and, therefore, "the FDA's belief that a drug is misbranded is not conclusive."¹⁴⁰

2. The Burdens Presented by Pursuing Non-Final Federal Violations in the Course of Adjudicating Whether State Law Claims Survive Preemption

In situations where FDA enforcement proceedings have not reached a final result that can be "imported" into the action in which the state law claim is asserted, there are likely questions about whether a violation of federal requirements in fact occurred and, if so, on what terms and to what extent the FDA would have pursued an enforcement action. To resolve the threshold "was there a violation" issue in the parallel requirements preemption in-

Heckler, 710 F.2d 1375, 1378 (9th Cir. 1983) (saying warning letters "do not commit the FDA to enforcement action," and the recipient may not bring an action to challenge a Warning Letter); *see also* 21 C.F.R. § 10.85 (2009) ("A statement or advice given by an FDA employee . . . in writing . . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.").

139. For example, in *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777, 2008 U.S. Dist. LEXIS 62131 (N.D. Tex. Aug. 13, 2008), the FDA had issued reports and warnings letters regarding violations of FDA current good manufacturing practices (CGMP) regulations and filed suit against the defendant's president and chief executive officer for violations of CGMP and premarket approval requirements. *Id.* at *3-4.

140. 129 S. Ct. 1187, 1197 (2009); *see also* *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005) ("In criminal prosecutions for violations of FIFRA's provisions, *see* [7 U.S.C.] § 136l(b), juries necessarily pass on allegations of misbranding.").

quiry, the parties must litigate (without FDA involvement) the question of whether the manufacturer violated a federal requirement.¹⁴¹ As *Buckman* recognized, doing that creates a raft of problems.

First, litigating the issue of whether there was a federal violation ignores § 337(a) of the FDCA, which provides that “all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”¹⁴² The Court noted in *Buckman* that “[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions,” and “[t]he FDA . . . has at its disposal a variety of enforcement options that allow it to take a measured response to suspected” FDCA violation.¹⁴³

Having private tort plaintiffs rather than the FDA select which alleged violations to pursue undermines the FDA’s ability to “make

141. Theoretically, courts could, based on the doctrine of primary jurisdiction, stay an action or dismiss it without prejudice pending the FDA’s resolution of whether violations occurred. Primary jurisdiction:

“[A]pplies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.” The contours of primary jurisdiction are not fixed by a precise formula. Rather, the applicability of the doctrine in any given case depends on “whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application.” Among the reasons and purposes served are the promotion of consistency and uniformity within the areas of regulation and the use of agency expertise “in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion.”

When it is determined that primary jurisdiction to resolve an issue lies with an agency, a court otherwise having jurisdiction over the case may stay or dismiss the action pending the agency’s resolution of the question. The doctrine is to be “invoked sparingly, as it often results in added expense and delay.”

Alpharma Inc. v. Pennfield Oil Co., 411 F.3d 934, 938 (8th Cir. 2005) (citations omitted). Given the volume of claims relating to medical devices, the range of supposed FDCA violations alleged in those actions, and the fact that primary jurisdiction is to be “invoked sparingly,” it is unlikely that courts would routinely find that primary jurisdiction should be invoked in this context.

142. 21 U.S.C. § 337(a).

143. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001); *see, e.g., Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (“[E]very federal court that has addressed the question has held that the FDCA does not create a private right of action to enforce or restrain violations of its provisions.” (quoting *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 WL 94237, at *3 (D. Kan. Feb 26, 1997)); *see also* JAMES M. BECK & ANTHONY VALE, *DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK* § 4.01 (2009).

a measured response” to suspected FDCA violations.¹⁴⁴ It also eliminates the resulting “flexibility [that] is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives.”¹⁴⁵ As with the state law fraud-on-the-FDA claims in *Buckman*, adjudicating FDCA violations in actions brought by private plaintiffs “inevitably conflict[s] with the FDA’s responsibility to police” manufacturers “consistently with the Administration’s judgment and objectives.”¹⁴⁶

Second, tort plaintiffs would “prosecute” supposed FDCA violations in courts without the FDA’s direct involvement and without the benefit of the Agency’s substantial expertise. The FDA is the federal agency responsible for regulating medical devices; it defines and interprets the PMA requirements on which a state law claim must be based.¹⁴⁷ If private plaintiffs may, in effect, become prosecutors of supposed FDCA violations, the FDA will be glaringly absent from nearly all cases interpreting what its regulations mean.

Instead of having the true expert—the FDA—in the courtroom, trials will turn on the testimony of privately-retained experts. Experience and common sense suggest that in general, plaintiffs’ experts will testify that the requirements imposed by the FDA either compelled the device manufacturer to do something it allegedly did not do, or prohibited the manufacturer from doing something it allegedly did. The reverse is also true; defense experts generally testify that the FDA requirements allowed the manufacturers to do whatever they did or precluded them from doing what plaintiffs allege they should have done. In the end, juries will be left to choose between the parties’ retained experts’ competing (and sometimes extreme) opinions, and there is little reason to expect the resulting verdicts to reflect the FDA’s actual views.

Third, having juries rather than the FDA pass on alleged FDCA violations may create a systemic bias in favor of finding that the violations occurred and might result in over-deterrence. As *Riegel* explained, the FDA must, by statute,¹⁴⁸ “apply cost-benefit analysis,” while “[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped the

144. *Buckman*, 531 U.S. at 349.

145. *Id.*

146. *Id.* at 350.

147. See *Medtronic v. Lohr*, 518 U.S. 470, 496 (1996) (“[T]he FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [FDCA] . . .”) (citation omitted).

148. 21 U.S.C. § 360c(a)(2)(C).

benefits are not represented in court.”¹⁴⁹ In *Warner-Lambert*, Justice Breyer made the same point during his questioning at oral argument:

Now, who would you rather have make the decision as to whether this drug is, on balance, going to save people or, on balance, going to hurt people? An expert agency, on the one hand, or 12 people pulled randomly for a jury role who see before them only the people whom the drug hurt and don't see those [other people] who need the drug to cure them?¹⁵⁰

Juries also have been reported to suffer from substantial hindsight bias and according to some, reach decisions that have little relation to the scientific evidence presented.¹⁵¹

Thus, juries may see only the injured plaintiffs before them, not the systemic costs that may result from finding that the FDCA prohibits conduct. For that reason, juries may find violations based on conduct that the FDA would permit because that conduct is beneficial from a larger societal perspective. For example, fearing that judges or juries may conclude that legitimate and useful activities, such as advertising that appraises physicians about a product, nonetheless violate federal requirements, manufacturers might refrain from engaging in those activities.¹⁵²

Fourth, having private litigants in effect prosecuting alleged FDCA violations creates substantial uncertainty. In many situations multiple plaintiffs sue a medical device manufacturer, which means there would be multiple fact-finders assessing a single alleged violation. There is no assurance that those fact-finders will (1) condemn only conduct that the FDA considers to violate federal requirements; (2) produce the results that an FDA enforcement action

149. 552 U.S. 312, 325 (2008).

150. Transcript of Oral Argument at 30:22–31:3, *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006) (No. 06-1498), available at http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-1498.pdf. *Warner-Lambert* is described *supra* note 12.

151. Reid Hastie & W. Kip Viscusi, *What Juries Can't Do Well: The Jury's Performance as a Risk Manager*, 40 ARIZ. L. REV. 901, 917 (1998) (“[T]he typical juror appears to be subject to a massive hindsight bias.”); Ross P. Laguzza, *Science Doesn't Matter: A Blasphemer's View of How To Win A Causation Battle*, 31 THE BRIEF 55, 55 (2002) (“[I]n most cases, [] scientific evidence has little bearing on jurors' decisions.”).

152. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (noting that, if private plaintiffs could pursue state law fraud-on-the-FDA claims, “[w]ould-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer . . . to unpredictable civil liability”).

would; or (3) agree with one another—a concern that is absent when there is but a single enforcement authority.¹⁵³ Just as *Buckman* expressed concern that “fraud-on-the-FDA claims would . . . cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court,”¹⁵⁴ so too would private enforcement actions cause device manufacturers to fear that an unknown judge or jury would find fault with conduct the FDA would allow.¹⁵⁵

For these reasons, the universe of claims that may survive express preemption under the parallel requirements exception for PMA-approved devices outlined in *Lohr* and *Riegel* should include only instances where there is a prior, final determination that a violation actually occurred. That is because establishing a necessary predicate to pursuing those claims—that there was a violation of a federal requirement—runs into the implied preemption principles articulated in *Buckman*.

Certainly the fact that there is an express preemption provision in a federal statute does not prohibit engaging in an implied preemption inquiry. Since *Freightliner Corp. v. Myrick*,¹⁵⁶ it has been clear that the fact that a statute has an express preemption provision does not bar the ordinary working of implied preemption principles.¹⁵⁷ And, as *Buckman* explained, there is “no presumption against pre-emption” when assessing whether a manufacturer violated a federal requirement because “the relationship between a

153. Product liability cases involving medical devices are also dominated by complex questions of causation and the adequacy of particular warnings. The FDA’s absence in deciding these, and other, questions introduces additional risk of misinterpretation or misapplication of its requirements.

154. *Buckman*, 531 U.S. at 351.

155. In *Bates*, however, the Court dismissed this concern:

While it is true that properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding, there is no reason to think such occurrences would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that everyday bear the risk of conflicting jury verdicts.

Bates v. Dow Agrosiences LLC, 544 U.S. 431, 452 (2005).

156. 514 U.S. 280 (1995).

157. *Id.* at 288. As the Court explained in *Freightliner*, “[t]he fact that an express definition of the pre-emptive reach of a statute “implies”—i.e., supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied preemption.” 514 U.S. at 288–89. Indeed, even the presence of a savings clause—a provision the FDCA does not contain for medical devices—“does not bar the ordinary working of conflict pre-emption principles.” *Geier v. Amen. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (emphasis in original).

federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.”¹⁵⁸

Thus, even if a plaintiff’s claims are premised on state law requirements that “parallel” federal requirements and, for that reason, survive express preemption under the dicta in *Lohr* and *Riegel*, those claims nonetheless are impliedly preempted under *Buckman* absent a prior, final determination that there was a violation of a federal requirement. In the real world this is a very significant limitation on the parallel requirements exception as comparatively few state law claims are based on prior, final determinations that a violation occurred.

3. A Hypothetical: Assume *Buckman* Involved a PMA-Approved Device

One way to demonstrate that *Buckman* and implied preemption limit the parallel requirements claims that survive express preemption under *Lohr* and *Riegel*’s dicta is to take the fraud-on-the-FDA claims at issue in *Buckman* and assess whether, if permitted to proceed, they would have imposed such “parallel requirements.” To do so, one must hypothesize that *Buckman* involved a PMA-approved device because there was no express preemption for the 510(k)-approved device at issue in *Buckman* and, therefore, no need to examine the parallel requirements exception.

These hypothetical fraud-on-the-FDA claims appear to be parallel requirements claims under *Lohr* and *Riegel*. They would “provide a traditional damages remedy for violations of common-law duties [that] parallel federal requirements;”¹⁵⁹ namely the federal requirements that require manufacturers to provide the FDA with truthful and complete data when seeking PMA approval.¹⁶⁰

For purposes of assessing whether these fraud-on-the-FDA claims are impliedly preempted under *Buckman*, however, the underlying device’s method of approval is irrelevant. Notwithstanding the shift from a 510(k)-approved device (as in *Buckman*) to a PMA-approved device (as in our hypothetical), these claims create essentially the same problems that the *Buckman* plaintiffs’ claims created. As *Buckman* found, the federal enforcement scheme does not contemplate or permit private plaintiffs enforcing FDCA requirements when there is no underlying FDA enforcement action. Thus, al-

158. *Buckman*, 531 U.S. at 347, 348.

159. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996).

160. *See, e.g.*, 21 U.S.C. § 331(p) (2007) (prohibiting “the failure to provide any information required by” 21 U.S.C. § 360(j) or (k)).

though the hypothetical fraud-on-the-FDA claims would escape express preemption because they impose only state law requirements that “parallel” federal ones, these claims should be impliedly preempted under *Buckman*.

Not surprisingly, the *Buckman* plaintiffs argued that their claims imposed only parallel requirements and, therefore, survived preemption under *Lohr*'s dictum.¹⁶¹ *Buckman* characterized this argument as one that both the *Buckman* and *Lohr* plaintiffs' claims arose from “violations of FDCA requirements,” and rejected it because the claims in *Lohr* “arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements,” while those in *Buckman* “exist[ed] solely by virtue of the FDCA disclosure requirements.”¹⁶²

The *Buckman* plaintiffs, however, did not compare their claims to the *Lohr* plaintiffs' actual claims; instead, they compared them to the hypothetical claims that survive express preemption because they impose only parallel requirements as provided in *Lohr*'s dictum. The reason the *Lohr* plaintiffs' claims survived preemption was unrelated to the fact that they were based on common law obligations and not “solely” based on “violation[s] of the FDCA requirements.” Instead, the *Lohr* plaintiffs' claims escaped express preemption largely because the device at issue had been approved under the 510(k) notification process and, thus, there simply were no applicable federal requirements.

Further, the reason the *Lohr* plaintiffs' claims survived preemption had nothing to do with parallel requirements. Indeed, those claims properly were never subjected to a parallel requirements inquiry. That inquiry addresses which claims survive express preemption—an issue that was irrelevant in *Lohr*—where there was no express preemption because the device at issue had been approved under the 510(k) notification process. As *Riegel* demonstrated, however, the *Lohr* plaintiffs' claims were not ones that, for a PMA-approved device where express preemption applies, could have survived preemption as claims imposing only parallel requirements. Putting aside the device's approval method, the *Lohr* plaintiffs' claims, like the *Riegel* plaintiffs' claims, were premised on supposed breaches of common law obligations *without* accompanying breaches of federal requirements.

161. Brief for Respondent at 37–38, *Buckman*, 531 U.S. 341 (Oct. 23, 2000) (No. 98-1768), 2000 U.S. S. Ct. Briefs LEXIS 540, at *37–38.

162. *Buckman*, 531 U.S. at 352–53 (citation omitted).

A more responsive answer to the *Buckman* plaintiffs' assertion that their fraud-on-the-FDA claims survived preemption because they imposed only parallel requirements under *Lohr*'s dictum might have been that, although possibly not expressly preempted, their claims were nonetheless impliedly preempted. For the reasons detailed at length in *Buckman*, even claims that survive express preemption by imposing only parallel requirements may nonetheless be impliedly preempted when, as in *Buckman*, they require private plaintiffs to usurp the FDA's role as the sole enforcer of the FDCA—a scenario unrelated to the approval method.¹⁶³

B. Does The State Law Claim Impose Requirements That "Parallel" Federal Requirements?

A state law claim that purportedly escapes preemption under the parallel requirements exception faces a second hurdle: establishing that in fact, the state law claim *parallels* federal requirements. Under *Lohr*, mere similarity between the state and federal requirements is not enough; instead, parallel requirements claims escape express preemption because they "merely provide[] another reason for manufacturers to comply with *identical* existing 'requirements' under federal law."¹⁶⁴ This subpart details the extent to which each of the various types of supposedly "parallel" claims actually track a federal requirement.

1. Negligence Per Se Claims

The most directly parallel state law claim that a medical device plaintiff can assert is a negligence per se claim premised on a violation of an underlying federal requirement. As one court observed, "[a] claim of negligence per se simply adopts the standard of care imposed by a statute or regulation as the standard against which the defendant's conduct is evaluated."¹⁶⁵ Such claims should meet *Riegel*'s definition of a parallel state law claim: a claim "providing a damages remedy for claims premised on a violation of FDA regulations."¹⁶⁶

163. Along those lines, the Sixth Circuit found that a plaintiff's claims alleging failure to comply with FDA regulations amounted to "a disguised fraud on the FDA claim" and thus were preempted under *Buckman*. *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005).

164. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996) (emphasis added).

165. *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1163 (D. Minn. 2009) (citing RESTATEMENT (SECOND) OF TORTS § 286 (1965)) (emphasis in original).

166. 552 U.S. 312, 330 (2008).

But negligence per se claims also may, for reasons discussed in Subpart III.A above, be impliedly preempted under *Buckman*. For example, the *Buckman* plaintiffs' "fraud-on-the-FDA" claims presumably could have been, for a PMA-approved device, recast as "failure-to-submit-the-required-information" negligence per se claims. Yet a court should still find claims recast in this manner to be impliedly preempted for the reasons detailed at length in *Buckman*. Indeed, the District of Minnesota recently held that broad-ranging negligence per se claims failed because, among other reasons, they were "impliedly preempted under 21 U.S.C. § 337(a) and *Buckman*."¹⁶⁷

Negligence per se claims also may face other legal obstacles. Many states do not permit negligence per se claims where, as with the FDCA, the underlying statute or regulation does not permit a private right of action.¹⁶⁸ Most states have adopted some sort of legislative purpose limitation on the use of negligence per se.¹⁶⁹ As

167. *In re Medtronic*, 592 F. Supp. 2d at 1163 n.19.

168. RESTATEMENT (SECOND) OF TORTS § 286, cmt. d (1965) (saying when "the legislature has indicated no intention that [a statutory provision] shall be so applied" in a tort suit, courts may "treat the provision as inapplicable"); *see also* RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY § 4, comment *d* (1997) ("[P]urpose" is to be taken "into account in determining whether noncompliance . . . renders the product defective.").

169. Arkansas: *Branscumb v. Freeman*, 200 S.W.3d 411, 416–17 (Ark. 2004); Colorado: *Bittle v. Brunetti*, 750 P.2d 49, 58 (Colo. 1998); *Gerrity Oil & Gas Corp. v. Magness*, 946 P.2d 913, 930 (Colo. 1997); Connecticut: *Ward v. Greene*, 839 A.2d 1259, 1272 (Conn. 2004); *Gore v. People's Sav. Bank*, 665 A.2d 1341, 1351–52 (Conn. 1995); Florida: *White v. NCL America, Inc.*, No. 05-22030-CIV, 2006 WL 1042548, at *5 (S.D. Fla. Mar. 8, 2006); *Labzda v. Purdue Pharm., L.P.*, 292 F. Supp. 2d 1326, 1355 (S.D. Fla. 2003); *Freehauf v. Sch. Bd. of Seminole County*, 623 So. 2d 761, 763 (Fla. Dist. Ct. App. 1993); Georgia: *Spivey v. Sellers*, 363 S.E.2d 856, 858 (Ga. Ct. App. 1987); Idaho: *O'Guin v. Bingham County*, 72 P.3d 849, 856 (Idaho 2003); Illinois: *Magna Trust Co. v. Ill. Cent. R.R.*, 728 N.E.2d 797, 805 (Ill. App. Ct. 2000); Kansas: *Alumbaugh v. Union Pac. R.R.*, 322 F.3d 520, 524–25 (8th Cir. 2003); *Bland v. Scott*, 112 P.3d 941, 947–48 (Kan. 2005); *Pullen v. West*, 92 P.3d 584, 593–94 (Kan. 2004); *OMI Holdings, Inc. v. Howell*, 918 P.2d 1274, 1296 (Kan. 1996); Kentucky: *T & M Jewelry, Inc. v. Hicks*, 189 S.W.3d 526, 530 (Ky. 2006); Massachusetts: *Swift v. United States*, 866 F.2d 507, 509 (1st Cir. 1989); Missouri: *Lowdermilk v. Vescovo Blg. & Realty Co.*, 91 S.W.3d 617, 629 (Mo. App. 2002); *Imperial Premium Fin. v. Northland Ins. Co.*, 861 S.W.2d 596, 599 (Mo. Ct. App. 1993); Nebraska: *Holmes v. Circo*, 244 N.W.2d 65, 69–70 (Neb. 1976); Nevada: *Texas Int'l Airlines, Inc. v. Bryan*, 857 F. Supp. 838, 848 (D. Nev. 1981); New Mexico: *F.D.I.C. v. Schuchmann*, 235 F.3d 1217, 1223 (10th Cir. 2000) (citing *Valdez v. Gillessen & Son, Inc.*, 734 P.2d 1258, 1261 (N.M. 1987)); *Ray v. Aztec Well Serv. Co.*, 748 F.2d 888, 890 (10th Cir. 1984) (finding liability because the plaintiff was in the class of people the legislature intended to protect and the injury was of the sort that the legislature intended to protect them from); *Jaramillo v. Fisher Controls Co.*, 698 P.2d 887, 892 (N.M. 1985); New York: *German v. Fed. Home Loan Mortgage Corp.*, 885 F. Supp. 537, 567 (S.D.N.Y. 1995); *Sheehy v. Big Flats*

the Tenth Circuit explained, “[w]here a statute creates legal duties and provides a particular means for their enforcement, *the designated remedy excludes all others.*”¹⁷⁰ Moreover, there are other state-imposed limitations that may prohibit a particular negligence per se claim relating to a medical device.¹⁷¹ However, when negligence

Cmty. Day, Inc., 541 N.E.2d 18, 21 (N.Y. 1989); Gain v. E. Reinforcing Serv., Inc., 603 N.Y.S.2d 189, 191 (App. Div. 1993); North Carolina: Hall v. Toreros, II, Inc., 626 S.E.2d 861, 867–69 (N.C. Ct. App. 2006), *review allowed*, 642 S.E.2d 248 (N.C. 2007); Williams v. City of Durham, 473 S.E.2d 665, 667 (N.C. Ct. App. 1996); Ohio: Hernandez v. Martin Chevrolet, Inc., 649 N.E.2d 1215, 1217 (Ohio 1995); Oklahoma: Gorton v. Mashburn, 995 P.2d 1114, 1117 (Okla. 1999); Oregon: Scovill v. City of Astoria, 921 P.2d 1312, 1316 (Or. 1996); Pennsylvania: Frederick L. v. Thomas, 578 F.2d 513, 517 n.8 (3d Cir. 1978); South Carolina: Hurst v. Sandy, 494 S.E.2d 847, 851 (S.C. App. 1997); Tennessee: Rains v. Bend of the River, 124 S.W.3d 580, 589–91 (Tenn. App. 2003); Utah: Rollins v. Petersen, 813 P.2d 1156, 1163–64 (Utah 1991); Wisconsin: Cooper v. Eagle River Mem’l Hosp., Inc., 270 F.3d 456, 460 (7th Cir. 2001); Chapman v. Mutual Ser. Cas. Ins. Co., 35 F. Supp. 2d 699, 705 (E.D. Wis. 1999).

170. Gammill v. United States, 727 F.2d 950, 953 n.3 (10th Cir. 1984) (emphasis added) (quoting Silverstein v. Sisters of Charity of Leavenworth, 559 P.2d 716, 718 (Colo. App. 1976)).

171. For example, several states do not allow negligence per se claims based on the violation of a regulation, as opposed to a statute. *See, e.g.*, LA. CIV. CODE ANN. art. 2317 (1997 & Supp. 2009); California Serv. Station & Auto. Repair Ass’n v. Am. Home Assurance Co., 73 Cal. Rptr. 2d 182, 188 (Cal. Ct. App. 1998); Murray v. Briggs, 569 So. 2d 476, 480 (Fla. Dist. Ct. App. 1990); Town of Kirklin v. Everman, 29 N.E.2d 206, 206–07 (Ind. 1940); Harwood v. Glacier Elec. Coop., 949 P.2d 651, 656 (Mont. 1997); Price v. Sinnott, 460 P.2d 837, 840 (Mont. 1969); McKinney v. H.M.K.G. & C., Inc., 123 S.W.3d 274, 280–81 (Mo. Ct. App. 2003); Elliott v. City of New York, 747 N.E.2d 760, 763–64 (N.Y. 2001); Chambers v. St. Mary’s Sch., 697 N.E.2d 198, 202–03 (Ohio 1998); Ridgecrest Retirement & Healthcare v. Urban, 135 S.W.3d 757, 763 (Tex. Ct. App. 2004). Moreover, negligence per se claims have been held improper where based upon the violation of FDA guidance, advisory, draft documents, or other pronouncement not having the force of law. *See* Flechsig v. United States, 991 F.2d 300, 304 (6th Cir. 1993); Jacobo v. United States, 853 F.2d 640, 641 (9th Cir. 1988); Gatter v. Nimmo, 672 F.2d 343, 347 (3d Cir. 1982); Smith v. Pulaski County, 501 S.E.2d 213, 214 (Ga. 1998); Schaeffer v. Stewart’s Plaza Pharmacy, Inc., 79 P.3d 922, 931–33 (Utah 2003); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. d (1997); RESTATEMENT (SECOND) OF TORTS §§ 288–288C (1965). Additionally, FDCA-based negligence per se claims have been rejected in cases where the standard allegedly imposed by the FDCA was held impermissibly vague. *See, e.g.*, Talley v. Danek Med., Inc., 179 F.3d 154, 161 (4th Cir. 1999); McNeil Pharm. v. Hawkins, 686 A.2d 567, 582 (D.C. Cir. 1996); Baraukas v. Danek Med., Inc., No. 97-613, 2000 WL 223508, at *4 n.2 (M.D. N.C. Jan. 13, 2000); Shanks v. Upjohn Co., 835 P.2d 1189, 1200–01 (Alaska 1992); *In Re* Shigellosis Litig., 647 N.W.2d 1, 10–12 (Minn. Ct. App. 2002); Goodman v. Wenco Foods, Inc., 423 S.E.2d 444, 452 (N.C. 1992); Jones v. GMRI, Inc., 551 S.E.2d 867, 873 (N.C. Ct. App. 2001); Messer Griesheim Indus., Inc. v. Eastman Chem. Co., 194 S.W.3d 466, 483 (Tenn. Ct. App. 2005); King v. Danek Med., Inc., 37 S.W.3d 439, 458 (Tenn. Ct. App. 2000). For a thorough discussion of these, and other

per se claims are permitted on these facts—that is, an established violation of a federal requirement proximately caused the injury at issue—they do not suffer from being insufficiently “parallel” to a federal requirement.

2. Design Defect, Failure-To-Warn, Breach of Implied Warranty of Merchantability, and Other Labeling-Based Claims

At the other extreme from negligence per se claims, in terms of their “parallelism,” are design defect, failure-to-warn, breach of implied warranty of merchantability, and various labeling-based claims, including those crafted as claims for express warranty, affirmative misrepresentation, and breach of implied warranty of fitness for purpose.¹⁷² Theoretically, one or more of these claims could be founded on an underlying violation of federal requirements if, for example, a device manufacturer did not use the FDA-approved design or labeling. However, those claims are rare in practice because manufacturers typically use the design and labeling the FDA approved.¹⁷³

Traditional product liability claims are expressly preempted because the state law requirements they impose are “different from, or in addition to, any requirement” imposed by the FDCA.¹⁷⁴ As Justice Breyer observed in his concurrence in *Lohr*, “a federal MDA regulation [that] requires a 2-inch wire” in a device, preempts not only a state agency regulation that requires a 1-inch wire, but also “a state-law tort action that premises liability upon the defendant manufacturer’s failure to use a 1-inch wire (say, an award by a jury per-

FDCA-based negligence per se claim issues, see JAMES M. BECK & ANTHONY VALE, DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK § 4.02 (2009) and James M. Beck & John A. Valentine, *Challenging the Viability of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience*, 55 FOOD & DRUG L. J. 389 (2000).

172. As noted previously *supra* note 129, it is conceivable that express warranty, affirmative misrepresentation, and implied warranty of fitness for purpose claims could be based on statements wholly unrelated to a medical device’s labeling. In that event, federal requirements might not be implicated and, for that reason, an express preemption analysis might not apply.

173. *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777, 2008 U.S. Dist. LEXIS 62131 (N.D. Tex. Aug. 13, 2008), may have involved such an instance. There, the plaintiffs alleged that the defendant’s implantable cochlear ear device was manufactured with a defective feed-through device the FDA had not approved that caused the device to be ineffective. *Id.* at *5. Purcel found those plaintiffs’ strict liability and implied warranty of merchantability claims survived preemption as parallel requirements claims. *Id.* at *7–8, *11–12.

174. 21 U.S.C. § 360k(a)(1).

suaded by expert testimony that use of a more than 1-inch wire is negligent).¹⁷⁵

These types of claims were at issue in *Riegel* where the Court affirmed the lower courts' preemption findings with respect to those plaintiffs' claims that relied on multiple legal theories—strict liability, negligence, and breach of implied warranty—and a wide range of supposed defects, including alleged defects in “design, testing, inspection, distribution, labeling, marketing, and sale” of the device.¹⁷⁶ Both before and after *Riegel*, courts have routinely dismissed these claims relating to PMA-approved devices routinely as expressly preempted because they plainly impose state law requirements that are “different from, or in addition to” federal requirements and, therefore, are not parallel claims.¹⁷⁷

175. *Medtronic v. Lohr*, 518 U.S. 470, 504 (1996) (Breyer, J., concurring in part and concurring in the judgment).

176. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320–21 (2008).

177. Some cases involve design defect claims. *See, e.g.*, *Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 930 (5th Cir. 2006); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009); *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161–62 (D. Minn. 2009). Some involve failure-to-warn claims. *See, e.g.*, *Gomez*, 442 F.3d at 931; *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 490 (7th Cir. 2005); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286–87 (E.D.N.Y. 2009); *In re Medtronic*, 592 F. Supp. 2d at 1159–61. Some involve implied warranty of merchantability claims. *See, e.g.*, *Mitchell v. Collagen Corp.*, 126 F.3d 902, 914–15 (7th Cir. 1997); *Horowitz*, 613 F. Supp. 2d at 284–85; *In re Medtronic*, 592 F. Supp. 2d at 1164. Some involve other labeling-based claims. *See, e.g.*, *Gomez*, 442 F.3d at 932 (express warranty claim based on representations in label, warnings, and instructions for use was preempted); *Bencomo v. Guidant Corp.*, No. 06-2473, 2009 U.S. Dist. LEXIS 55504, at *16 (E.D. La. June 30, 2009) (holding that a breach of express warranty claim “when the representations at issue are approved by the FDA through the premarket approval process” was preempted); *Horowitz*, 613 F. Supp. 2d at 285 (“Plaintiff’s breach of express warranty claim is preempted to the extent that it is premised on FDA approved representations made by the manufacturer.”) (citation omitted); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008) (“Plaintiff’s express warranty claim would contradict the FDA’s determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements. Therefore, that claim is preempted by section 360k(a).”); *Lake v. Kardjian*, 874 N.Y.S.2d 751, 754 (Sup. Ct. 2008) (“[A] breach of express warranty claim based upon FDA approved statements in product labeling and advertising is preempted by the MDA . . .”).

Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 839–40 (S.D. Ind. 2009), denied a motion to dismiss implied warranty of merchantability claims with respect to a PMA-approved device because, in 21 C.F.R. § 808.1, the MDA exempts from preemption regulations of general applicability, which the *Hofts* court found an implied warranty of merchantability claim to be. But *Hofts* did not address, much less distinguish, *Riegel*’s rejection of this interpretation of 21 C.F.R. § 808.1.

3. Manufacturing Defect Claims

Manufacturing defect claims lie between the extremes of state law negligence per se claims and common law claims asserting design and warnings defects. A claim that a plaintiff's injury was caused by a medical device that was manufactured improperly and in violation of a federal requirement seems like a prime candidate for being a non-preempted parallel claim. Some courts have held that these claims are indeed parallel and are not preempted, although some of those rulings were in the context of motions to dismiss where the factual record was undeveloped.¹⁷⁸

But connecting a supposed manufacturing defect—typically, an isolated instance where the device was not manufactured in the way the manufacturer intended—to a violation of a federal requirement can be daunting, particularly because of prevailing standards regarding the specificity of pleading.¹⁷⁹ For example, in *In re Sprint Fidelis Leads Product Liability Litigation*,¹⁸⁰ the plaintiffs alleged a “manufacturing defect” based on supposedly inadequate welding techniques that purportedly did not comply with the FDA’s Current Good Manufacturing Practices (CGMP) and Quality System Regulation (QSR). In finding these claims insufficiently parallel to survive preemption, that court found that the applicable FDA regulations “serve only as ‘an umbrella quality system,’ providing ‘general objectives’ medical device manufacturers must seek to achieve.”¹⁸¹ Because of the “flexibility inherent in the CGMPs and QSR,” the plaintiffs’ manufacturing defect claims were “not ‘parallel.’”¹⁸² “In the absence of any specific requirement in the CGMPs/QSR that [the manufacturer] weld the . . . leads in a certain fashion, holding [the manufacturer] liable for such a welding ‘defect’ would impose requirements ‘different from, or in addition to’ those under federal law.”¹⁸³

Riegel, 552 U.S. at 328–29. *In re Medtronic*, relying on *Riegel*, rejected this interpretation of 21 C.F.R. § 808.1. 592 F. Supp. 2d at 1164.

178. *E.g.*, *Gomez*, 442 F.3d at 933 (where manufacturing defect claims had proceeded to jury trial, the court noted that “[t]he district judge properly limited [the plaintiff’s] negligence claim to a claim that the [device] used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications.”) (citation omitted); *Hofst*, 597 F. Supp. 2d at 836–37 (denying motion to dismiss).

179. See the discussion of recent Supreme Court decisions addressing pleading standards *infra* at text accompanying notes 189–91.

180. 592 F. Supp. 2d 1147 (D. Minn. 2009).

181. *Id.* at 1157.

182. *Id.* at 1158.

183. *Id.*

For example, in *Parker v. Stryker Corp.*,¹⁸⁴ the plaintiff “allege[d] that the [device] was defective because ‘the manufacturing processes for the device and certain of their [*sic*] components did not satisfy the [FDA’s] Pre-Market Approval standards for the devices.’”¹⁸⁵ In rejecting that claim, the court noted that, “[a]lthough such a claim appears to constitute the type of parallel claim the *Riegel* Court found to be outside the preemptive reach of section 360k, nowhere does plaintiff’s complaint provide any factual detail to substantiate that crucial allegation.”¹⁸⁶

Similarly, the plaintiff in *Clark v. Medtronic, Inc.*¹⁸⁷ attempted to pursue a manufacturing defect claim relating to an implantable cardioverter-defibrillator (ICD) based on *res ipsa loquitur*, arguing that, because the device malfunctioned, it must have had a manufacturing defect. The court in *Clark* assumed without discussion that this claim survived preemption, but nonetheless rejected it because an “ICD is a complex device which ‘can fail for a variety of reasons, including medical complications, body rejection phenomena, allergic reaction, and surgical techniques, all of which occur without someone acting in a negligent manner.’”¹⁸⁸

In re Medtronic, Inc., Parker, and Clark highlight the need for a plaintiff’s complaint to tie a manufacturing defect claim to supposed violations of specific federal requirements. These decisions are consistent with the Supreme Court’s recent focus in *Bell Atlantic Corp. v. Twombly*¹⁸⁹ and *Ashcroft v. Iqbal*¹⁹⁰ on the need for plaintiffs

184. 584 F. Supp. 2d 1298 (D. Colo. 2008).

185. *Id.* at 1301–02 (citation omitted).

186. *Id.* at 1302. Other courts have reached the same conclusion with respect to attempts to assert manufacturing defect claims for the device at issue in *Parker*, an artificial replacement hip. *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 280–84 (E.D.N.Y. 2009); *Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 U.S. Dist. LEXIS 99118, at *6 (N.D. Ill. Dec. 9, 2008).

187. *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008).

188. *Id.* at 1094 (quoting *Mozes v. Medtronic, Inc.*, 14 F. Supp. 2d 1124, 1129 (D. Minn. 1998)).

189. 550 U.S. 544 (2007). *Twombly* affirmed the dismissal of a complaint alleging antitrust conspiracy claims, observing that “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.” *Id.* at 555 (citations omitted).

190. 129 S. Ct. 1937 (2009). In *Iqbal*, a Pakistani Muslim who had been arrested in connection with the investigation into the September 11, 2001, terrorist attacks filed a *Bivens* action against federal officials. The trial court denied the federal officials’ motion to dismiss based on qualified immunity, and the Second Circuit affirmed. In reversing, the *Iqbal* Court observed that “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do

to provide a non-speculative factual basis for claims in their complaints. The decisions rejected *Conley v. Gibson*'s permissive pleading standard, which allowed claims to proceed "unless it appear[ed] beyond doubt that the plaintiff c[ould] prove no set of facts . . . which would entitle him to relief."¹⁹¹ In short, manufacturing defect claims may, at least in theory, "parallel" federal requirements. But connecting the supposed device's alleged manufacturing defect to a concrete violation of an actual federal requirement often may be an insurmountable hurdle for plaintiffs to overcome.

C. Preemption and Punitive Damages

Lohr and *Riegel* stated, respectively, that § 360k(a) does not bar plaintiffs from pursuing a "traditional damages remedy" or a "damages remedy for claims premised on a violation of FDA regulations."¹⁹² As Justice O'Connor's concurrence in *Lohr* explained:

Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to," requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements.¹⁹³

But what if, even though the federal and state duties arguably parallel one another, other aspects of the state law claim conflict

not suffice" and that "Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at 1949–50 (citation omitted). Further, *Iqbal* made clear that *Twombly* is not limited to antitrust actions; instead, the "decision in *Twombly* expounded the pleading standard for 'all civil actions' . . ." *Id.* at 1953 (citation omitted).

191. *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957). *Twombly* found that: this phrase is best forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint. *Conley*, then, described the breadth of opportunity to prove what an adequate complaint claims, not the minimum standard of adequate pleading to govern a complaint's survival.

550 U.S. at 563 (citations and footnote omitted).

192. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

193. 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part) (emphasis in original); see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447–48 (2005) (quoting this portion of Justice O'Connor's opinion in *Lohr* with approval).

with provisions contained in the FDCA's enforcement scheme? Punitive damages are a particularly potent method of governing conduct and, as the Supreme Court stated in *Exxon Shipping Co. v. Baker*,¹⁹⁴ "the consensus today is that punitives are aimed not at compensation but principally at retribution and deterring harmful conduct."¹⁹⁵ In that sense, a punitive damages remedy is an enforcement action. For that reason, punitive damages may not merely "impose[e] different or additional remedies" for violating federal requirements but may instead constitute "different or additional requirements." Further, state law punitive damages awards that exceed the FDCA's express limitations on federal civil penalties may expressly or implicitly conflict with federal law.

These are relatively uncharted waters in the context of medical devices. There do not appear to be any decisions considering whether, for claims that survive express preemption under *Lohr* and *Riegel* because they impose only parallel requirements, accompanying punitive damages demands are, for other reasons, either expressly or impliedly preempted. Nonetheless, as explained below, awarding punitive damages in connection with state law parallel requirements claims may run afoul of federal law.

First, Congress created a detailed federal enforcement scheme for the FDCA that includes civil penalties, criminal penalties, seizure, and injunctive relief,¹⁹⁶ but not punitive damage awards to private plaintiffs. Furthermore, Congress has stated that enforcing the FDCA is an exclusively federal task: "[A]ll . . . proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."¹⁹⁷ Superimposing state law punitive damage remedies "aimed at deterrence and retribution" on top of the federal enforcement scheme lacking those remedies necessarily readjusts Congress's calculus regarding the appropriate penalties for violating federal law.¹⁹⁸ Accordingly, state law punitive

194. 128 S. Ct. 2605 (2008).

195. *Id.* at 2621 (footnote omitted).

196. 21 U.S.C. §§ 331–34 (2007).

197. 21 U.S.C. § 337(a) (emphasis added).

198. In *Baker*, the Supreme Court rejected Exxon's claim that, in light of the federal enforcement scheme established in the Clean Water Act, 33 U.S.C. § 1251–1387 (CWA), substantial awards of punitive damages to persons whose property was damaged by the Exxon Valdez oil spill were preempted. 128 S. Ct. at 2618–19. But the CWA is substantially different from the MDA and the FDCA. Specifically, (1) the CWA has no express preemption provision analogous to the MDA's § 360k(a) and the FDCA's § 337(a); (2) the CWA has a broad savings provision, 33 U.S.C. § 1321(o), that *Baker* found relegated Exxon to the "untenable claim that the CWA somehow preempts punitive damages, but not compensatory

damage claims, even if they are imposed for violating federal requirements, may be (1) expressly preempted by (i) § 360k(a) because they impose additional state requirements that do not “parallel” federal ones, or (ii) § 337(a) because they are state-based enforcement actions; and (2) impliedly preempted because, by increasing the penalties for violating federal law above what Congress intended, they conflict with the federal enforcement scheme.¹⁹⁹

Second, in the context most analogous to punitive damage awards in civil litigation—civil penalties under the FDCA—Congress has stated that the FDA *must* be involved and consider specified factors when assessing those civil penalties for violations of federal device requirements. The civil penalty provision provides:

*[T]he Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.*²⁰⁰

In a civil action between a private plaintiff and a medical device manufacturer, the FDA is not present to make any of these determinations. Accordingly, such awards may conflict with § 333(f)(5) and may thus be preempted.

Third, the FCDA’s civil penalty provisions for devices set maximums that limit the total penalties that may be imposed.²⁰¹ As the Supreme Court observed in *Baker*, “a penalty should be reasonably predictable in its severity, so that even Justice Holmes’s ‘bad man’ can look ahead with some ability to know what the stakes are in choosing one course of action or another.”²⁰² Section 333(f)(1)(A) provides that “any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount *not to exceed* \$15,000 for each such violation, and *not to exceed* \$1,000,000 for all such violations adjudicated in a

damages” when “nothing in the statutory text points to fragmenting the recovery scheme this way,” 128 S. Ct. at 2619; and (3) there does not appear to be authority under the CWA that, as *Buckman* found for the FDCA, it was important to preserve a federal agency’s “enforcement options that allow it to make a measured response to suspected” violations. *Buckman v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 349 (2001).

199. To the extent that there is express preemption of punitive damage awards under 21 U.S.C. § 337(a) or implied conflict preemption, then such preemption would not be limited to litigation relating to parallel requirements claims or to PMA-approved devices and, instead, would apply more broadly.

200. 21 U.S.C. § 333(f)(5)(B) (2007) (emphasis added).

201. 21 U.S.C. § 333(f)(1)(A), (B) (2007).

202. *Baker*, 128 S. Ct. at 2627.

single proceeding.”²⁰³ If a court in which such a parallel requirements claim is pending permits a punitive damages award on that claim of more than \$15,000 per violation or a total of \$1 million, that exceeds § 333(f)(1)(A)’s cap.²⁰⁴ As the Supreme Court explained in *BMW of North America, Inc. v. Gore*,²⁰⁵ courts “should ‘accord ‘substantial deference’ to legislative judgments’” that are reflected in statutory civil and criminal penalties when considering “‘appropriate sanctions for the conduct at issue.’”²⁰⁶

Finally, § 333(f) provides that, for some violations, civil penalties may not be awarded in certain circumstances.²⁰⁷ Specifically, § 333(f)(1)(B) provides that, for certain types of violations, the civil penalty provision does not apply if (1) there was not “a significant or knowing departure from such requirements” or “a risk to public health;”²⁰⁸ (2) the violation was a “minor violation[]” if the defendant demonstrates “substantial compliance;”²⁰⁹ and (3) when the violation related to “one or more devices which are not defective.”²¹⁰ Significantly, the first item limits penalties for violations of

203. 21 U.S.C. § 333(f)(1)(A) (2007) (emphasis added).

204. Also, shifting from the currently-prevailing paradigm of the FDA as the sole enforcement authority to one where multiple private plaintiffs may pursue “parallel claims” would mean that there could be many more “single proceeding[s]” and, therefore, much greater potential exposure.

205. 517 U.S. 559 (1996). In *Gore*, the Supreme Court found that a state law punitive damages award was excessive and violated the Due Process Clause.

206. *Id.* at 583 (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 301 (1989) (O’Connor, J., concurring in part and dissenting in part)). In the context of assessing whether punitive awards are excessive, *State Farm Mut. Ins. Co. v. Campbell*, 538 U.S. 408, 428 (2003), also recognized the importance of “disparit[ies] between . . . punitive damages award[s] and the ‘civil penalties authorized or imposed in comparable cases.’” (Citation omitted). Punitive damage awards for state-claims imposing parallel requirements would, of course, be subject to federal and state due process limitations and, in some instances, additional common law and statutory limitations.

207. 21 U.S.C. § 333(f)(1)(B) (2007).

208. 21 U.S.C. § 333(f)(1)(B)(i) (2007) (which applies to violations of FDA regulations implementing (1) the records and reporting requirements established by § 360i(a), including adverse event reporting; and (2) the good manufacturing practices requirements in § 360j(f)).

209. 21 U.S.C. § 333(f)(1)(B)(ii) (2007) (which applies to “minor violations” when the violator “demonstrates substantial compliance” for violations of (1) 21 U.S.C. § 360i(e), which relates to device tracking; or (2) § 360i(g), which relates to reporting removals and corrections).

210. 21 U.S.C. § 333(f)(1)(B)(iii) (2007) (which applies to devices that are adulterated because they were “prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health” in violation of 21 U.S.C. § 351(a)(2)(A)).

“good manufacturing practices requirements,”²¹¹ a basis that medical device plaintiffs frequently allege as the grounds for supposed parallel requirements claims.²¹² If a jury assessing punitive damages relating to a state law claim that parallels federal good manufacturing requirements is not required to assess whether there was “a significant and knowing departure from [those] requirements” or “a risk to public health,” then the state law damages remedy may impose requirements that go beyond federal requirements, and § 333(f)(1)(B)(i)’s “safe harbor” is nullified. Furthermore, even if the jury does make those assessments, there is no guarantee that the jury’s determinations will track what the FDA’s decisions would have been.

IV. CONCLUSION

Courts assessing whether state law claims asserted by product liability plaintiffs against medical device manufacturers escape express preemption under § 360k(a) should focus on whether (1) a federal requirement was violated; (2) the requirements imposed by the plaintiff’s state law claims actually parallel federal requirements; and (3) punitive damages remedies appended to those claims survive preemption. As to the first question, absent a prior, final determination that the manufacturer actually violated a federal requirement, establishing this predicate for avoiding express preemption implicates the concerns that led the Court in *Buckman* to find there was implied preemption; namely, the specter of private plaintiffs usurping the FDA’s ability “to achieve a somewhat delicate balance of statutory objectives” in enforcing the FDCA.²¹³ With respect to the second question, most courts have found that only negligence per se and manufacturing defect claims parallel federal requirements. And those claims often suffer from other infirmities, including plaintiffs’ inability to sufficiently tie their claims to supposed violations of federal requirements. As to the final question, even if a state law claim imposes only parallel requirements for violating a federal requirement, an accompanying punitive damage award may be either expressly or impliedly preempted, although courts have yet to grapple with those issues.

211. 21 U.S.C. § 360j(f).

212. *E.g.*, *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282–84 (E.D.N.Y. 2009); *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157–58 (D. Minn. 2009).

213. *Buckman v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 348 (2001).

FRUSTRATED WITH PREEMPTION: WHY COURTS SHOULD RARELY DISPLACE STATE LAW UNDER THE DOCTRINE OF FRUSTRATION PREEMPTION

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INTRODUCTION

In recent years, the Supreme Court's docket has been replete with preemption cases.¹ Indeed, it is fair to say that the preemption of state law by federal law has become the preeminent federalism issue in our courts. But the topic of preemption implicates far more than federalism; it also raises important separation of powers concerns and does so in at least two ways. First, when courts imply that federal statutes preempt state law, despite having no explicit preemption provisions, the courts risk judicial lawmaking. In Justice Thomas's words, it "leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies."² Second, when administrative agencies claim state laws are preempted, it raises the question of whether unelected executive branch officials can displace state law. Agencies often claim that state laws are preempted based either on their construction of an express preemption provision or their conclusion that the state law frustrates the achievement of federal statutory objectives.³

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1. See, e.g., *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Chamber of Commerce v. Brown*, 128 S. Ct. 2408 (2008); *Cuomo v. Clearing House Ass'n*, 129 S. Ct. 2710 (2009); *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008); *Rowe v. N.H. Motor Transp. Ass'n*, 552 U.S. 364 (2008); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1 (2007).

2. *Wyeth*, 129 S. Ct. at 1217 (Thomas, J., concurring).

3. See, e.g., Average Fuel Economy Standards for Light Trucks Model Years 2008–2011, 71 Fed. Reg. 17,566, 17,667 (Apr. 6, 2006) (to be codified at 16 C.F.R. pt. 163) (conclusion by the National Highway Traffic Safety Administration that

This Article explores how separation of powers concerns and related principles of statutory construction bear on the preemption inquiry. Our specific focus is on the type of preemption that presents the greatest separation of powers risks, namely, preemption based on the conclusion that state law frustrates “the accomplishment and execution of the full purposes and objectives of Congress.”⁴ The Article first explains why principles of statutory construction, separation of powers, and federalism require that courts should rarely displace state law under frustration preemption. When reasonable policy grounds both support and oppose preempting state law, courts should construe Congress’s decision *not* to include an express preemption provision as a decision *not* to displace state law. And when Congress did not intend to preempt state law on frustration preemption grounds, federal agencies lack the authority to decree otherwise.

Next, this Article explores the Supreme Court’s recent decision in *Wyeth v. Levine*,⁵ in which the Court’s reasoning aligned with many of the contentions in this Article. In *Wyeth*, the Court addressed the preemptive scope of the Federal Food, Drug, and Cosmetic Act (FDCA), which, as amended, does not contain an express preemption provision.⁶ The Court rejected the defendant’s frustration preemption argument that the FDCA displaced the plaintiff’s state tort law action because it presented an obstacle to the FDCA’s regulatory regime.⁷

state greenhouse gas standards “frustrate the objectives of Congress” in establishing the Corporate Average Fuel Economy program); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601) (conclusion by the Food and Drug Administration 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 [pharmaceutical] firm from including in labeling or advertising a statement that is included in prescription drug labeling”); Final Rule: Standard for the Flammability (Open Flame) of Mattress Sets, 71 Fed. Reg. 13,472, 13,496–97 (Mar. 15, 2006) (to be codified at 49 C.F.R. pts. 523, 533, and 537) (conclusion by Consumer Product Safety Commission that “all non-identical state requirements which seek to reduce the risk of death or injury from mattress fires” are expressly preempted); *see also* Catherine M. Sharkey, *Preemption By Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 230–42 (2007).

4. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Preemption under *Hines* has several names, including “obstacle,” “frustration,” and “purposes and objectives” preemption. We will call it “frustration” preemption.

5. 129 S. Ct. 1187.

6. *Id.* at 1191.

7. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–97 (2006).

The concurring opinion of Justice Thomas more closely adopts the ideas set forth here, such as our argument that courts should not assume that Congress intends to accomplish its objectives at all costs. But the majority opinion of Justice Stevens accepts that the key inquiry in the frustration preemption analysis is whether Congress intended such preemption, and not whether courts can discern some tension between the federal and state schemes. The majority also recognized that, given the existence of express preemption provisions in other statutes, courts can, and should, view Congress's failure to include an express preemption provision as strong evidence that Congress did not intend it to preempt state law.

I.
PREEMPTION AND PRINCIPLES OF STATUTORY
CONSTRUCTION, SEPARATION OF
POWERS, AND FEDERALISM

When analyzing whether a federal statute displaces state law, the Supreme Court recognizes that the question is an issue of congressional intent.⁸ Thus, when defendants allege frustration preemption, the key inquiry is whether Congress intended to displace state laws that frustrate the full accomplishment of federal objectives.⁹ The answer is that Congress *sometimes* intends to remove every obstacle to federal objectives as quickly and completely as possible. But Congress often has competing objectives and crafts legislation as a product of compromise. For instance, Congress might conclude that a particular type of state tort action should proceed in order to provide remedies for injured consumers, even if it “frustrates” to some degree the federal goal of uniformity. Similarly, Congress might retain a state tort action as a compromise for having a less strict federal standard.

In the end, this paradigmatic policy decision is for Congress, not the courts, to make. Congress knows how to express its intent to displace state laws that it believes stand as obstacles to federal objectives. Hundreds of federal statutes contain express preemption provisions.¹⁰ Courts should respect Congress's decision not to

8. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (“[T]he purpose of Congress is the ultimate touchstone in every pre-emption case.”) (internal quotation marks omitted); see also *Retail Clerks Int'l Ass'n v. Schermerhorn*, 375 U.S. 96, 103 (1963).

9. *Hines*, 312 U.S. at 67.

10. See JAMES T. O'REILLY, *FEDERAL PREEMPTION OF STATE AND LOCAL LAW* 2 (2006).

include such a provision. Adherence to the plain language of federal statutes requires no less. Just as the Supreme Court no longer finds implied private rights of action—except in rare cases¹¹—courts should no longer find frustration preemption (except in rare cases).

Several commentators have observed that the Supreme Court's implied preemption jurisprudence is in tension with its plain-language approach to statutory construction. For example, Professor John F. Manning notes that “the Court's approach to implied federal preemption of state law generally reflects premises more akin to those evident in its former purposivism.”¹² Likewise, Professor Daniel J. Meltzer argues that contrary to its default approach to statutory interpretation, the Court engages in significant interpretive lawmaking in implied preemption cases.¹³ This Article suggests that the Court should bring these two areas of the law into alignment.

Principles of federalism buttress this conclusion. The Commerce Clause gives Congress broad authority to preempt state law.¹⁴ If the political process is to serve as a genuine check on that power, states must receive notice when their authority is at risk. Frustration preemption undermines that check. It also amounts to a presumption *in favor* of preemption as courts presume Congress intended to displace state law. Our federal system should not countenance such a disregard of the states' reserved powers.

A. *Whether a federal statute preempts state law under the doctrine of frustration preemption depends on whether Congress intended it to displace state law.*

The Supremacy Clause¹⁵ is the constitutional choice-of-law provision which declares that federal law trumps state law when the two are in direct conflict. But the clause itself resolves few, if any, preemption disputes. Rather, as the Supreme Court has stated, the question in preemption cases “is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exer-

11. *Cort v. Ash*, 422 U.S. 66, 79–80 (1975); *see also infra* notes 42–48 and accompanying text.

12. John F. Manning, *Competing Presumptions about Statutory Coherence*, 74 *FORDHAM L. REV.* 2009, 2034 n.114 (2006).

13. Daniel J. Meltzer, *The Supreme Court's Judicial Passivity*, 2002 *SUP. CT. REV.* 343, 364–68 (2002).

14. *Gregory v. Ashcroft*, 501 U.S. 452, 501 (1991).

15. U.S. CONST. art. VI, cl. 2.

cise its constitutionally delegated authority to set aside the laws of a State?”¹⁶

That general statement masks critical nuances because the precise target of the statutory inquiry varies greatly depending on the type of preemption at issue. In particular, the inquiry differs depending on whether preemption allegedly arises from (1) a statutory provision that expressly preempts state laws; (2) a direct conflict between federal and state law such that it would be impossible to comply with both; or (3) the claim that operation of state law would frustrate achievement of the federal statute’s objectives.¹⁷ When a party claims a federal statute preempts state law based on frustration preemption, the key statutory construction inquiry is whether Congress—notwithstanding its silence on the issue—intended to displace state laws that frustrate certain purposes or objectives of the federal act.¹⁸

1. Express Preemption

When preemption is asserted based on an express preemption provision, the statutory construction inquiry concerns the meaning and scope of the provision. The presence of a saving clause, which preserves certain types of state laws from the force of the preemption provision, sometimes complicates this inquiry.¹⁹ But, critically, the inquiry in an express preemption case is *not* whether Congress intended to displace state law in the first place. The presence of an express preemption provision answers that question.

2. Impossibility Preemption

Preemption also occurs when “compliance with both federal and state regulations is a physical impossibility.”²⁰ The paradigmatic case of “impossibility preemption” occurs when a federal statute says “private entities must do X” and a state law says “private entities may not do X.” In this situation, direct operation of the Supremacy Clause gives the federal law precedence over a state law that would have nullified its operation. The statutory construction inquiry concerns the substantive meaning of the federal statute: What is the meaning of X? The inquiry, again, is *not* whether Congress intended to displace certain state laws.

16. *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996).

17. *See infra* text accompanying notes 19–32.

18. *See infra* note 31.

19. *See, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867–74 (2000).

20. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963).

For example, to borrow from Professor Hart's famous example,²¹ if a federal statute declares that "no vehicles shall be permitted in public parks," and a state law provides that "bicycle riding is permitted in parks," the sole statutory construction inquiry would be the meaning of the substantive term "vehicles." If "vehicles" includes bicycles, the state law is preempted by operation of the Supremacy Clause—without any need for Congress to have specifically stated "we intend to displace state laws that directly contradict this statute."

3. Frustration Preemption

Even where there is no express preemption provision and it is possible to comply with both federal and state law, the Supreme Court asks whether the federal law nonetheless preempts the state law because it frustrates the full achievement of the federal objectives.²² In answering that question the statutory construction inquiry has two distinct focuses.

The first inquiry is the same one undertaken in impossibility preemption cases: What is the substantive meaning of the federal statute?²³ But, even if the court knows exactly what federal standards and rules Congress intended to adopt, there remains the separate question of whether Congress intended to displace state laws to better effectuate those standards and rules and their underlying purposes.

The Supremacy Clause tells us that *if* Congress intended to displace state laws when they frustrate the achievement of certain federal objectives, that federal command controls.²⁴ The predicate question of whether Congress intended such an effect is a matter of statutory construction.

Critically, Congress does not always, or even usually, intend to preempt any and all state laws that might somehow "frustrate" achievement of one of its objectives. For example, one goal of Congress might be to foster uniformity in regulations, but that objective

21. See H.L.A. Hart, *Positivism and the Separation of Law and Morals*, 71 HARV. L. REV. 593, 607 (1958).

22. See *Sprietsma v. Mercury Marine*, 537 U.S. 51, 70 (2002); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

23. See *Perez v. Campbell*, 402 U.S. 637, 644 (1971) ("Deciding whether a state statute is in conflict with a federal statute and hence invalid under the Supremacy Clause is essentially a two-step process of first ascertaining the construction of the two statutes and then determining the constitutional question whether they are in conflict.").

24. *Hines*, 312 U.S. at 66–68.

may not be “unyielding.”²⁵ For instance, a state tort action frustrating the goal of uniformity might possess the redeeming quality of advancing Congress’s expectation that injured consumers have access to remedies.²⁶ Similarly, Congress might conclude that state tort liability provides a necessary supplement to a regulatory regime by “spurring change in regulatory or corporate procedures, as well as extending knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators.”²⁷ Or a statute might reflect a compromise in which legislators who wanted stricter federal standards settled for laxer standards in exchange for *not* displacing state tort actions.²⁸

These examples, however, assume that courts can derive a single congressional intent. As Professor Nelson has explained, even if we “suppose that all members of Congress can agree on the ‘full purposes and objectives’ behind a particular federal statute[,] [t]here still is no reason to assume that they would want to displace whatever state law makes achieving those purposes more difficult.”²⁹ The Supreme Court “has acknowledged outside the realm of preemption, [that] ‘no legislation pursues its purposes at all costs,’ and ‘it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute’s primary objective must be the law.’”³⁰

In short, sometimes Congress decides as a policy matter that certain statutory ends warrant casting aside all state laws that hinder attainment of those ends. Sometimes, however, Congress decides as a policy matter (or as a compromise) that the competing interests served by state law outweigh the costs imposed on a particular federal objective. When assessing whether a federal statute

25. *Sprietsma*, 537 U.S. at 70.

26. *Id.* at 64 (saying state tort actions, “unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims”).

27. Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. AM. MED. ASS’N 308, 310 (2007); see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) (saying “tort suits can serve as a catalyst” to improve industry and federal regulatory practices).

28. See *Landgraf v. USI Film Prods.*, 511 U.S. 244, 286 (1994) (“Statutes are seldom crafted to pursue a single goal, and compromises necessary to their enactment may require adopting means other than those that would most effectively pursue the main goal.”).

29. Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 280 (2000).

30. *Id.* (quoting *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987)).

preempts a state law based on frustration preemption, a court must decide how Congress resolved that policy question.³¹

As we explain below, ordinary tools of statutory construction dictate that when Congress has not spoken to the issue of preemption, courts should rarely conclude that Congress nonetheless intended to displace state laws that purportedly frustrate achievement of one of the federal statutory goals.³²

B. Standard tools of statutory construction militate against finding frustration preemption.

Statutory interpretation begins with the text. “When the statutory language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.”³³ Statutes, like the FDCA, that contain no preemption provisions express no apparent intent to displace state law.

When Congress wishes to displace state law to achieve federal objectives more efficiently, it knows how to do so. By one count, Congress has enacted 350 statutes that contain express preemption provisions.³⁴ The *absence* of a preemption provision is therefore telling and should create a strong presumption that Congress intended no preemption. Indeed, the Supreme Court routinely infers meaning from Congress’s failure to address a particular issue in

31. Some parties have asserted that congressional intent to displace state law is irrelevant to the frustration preemption inquiry. Brief of Prod. Liab. Advisory Council, Inc., as Amicus Curiae Supporting Petitioner at 3, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) (“[C]onflict preemption analysis does not require a court to infer Congress’s preemptive intent.”). To be sure, it is irrelevant when a frustration preemption argument is premised on the impossibility of complying with both state and federal law. At that point, the Supremacy Clause kicks in and nullifies state law. But short of this type of impossibility preemption, the implied displacement of state law is not necessary; rather, it is a policy judgment. And Congress, not the courts, is the appropriate institution to make that policy judgment.

32. We recognize that the Supreme Court stated in *Geier v. Am. Honda Motor Co.* that it did not wish to “drive[] a legal wedge” between impossibility and frustration preemption. 529 U.S. 861, 873–74 (2000). But *Geier* cannot reasonably be construed as suggesting that there are no differences whatsoever between how the two types of preemption are analyzed.

33. *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (internal quotation marks omitted).

34. See O’REILLY, *supra* note 10, at 2.

a statute where Congress has expressly spoken on a similar issue in other statutes.³⁵

And when courts decline to read unexpressed preemptive intent into federal statutes, they act in a manner consistent with well-established statutory canons. First, one “cardinal principle of statutory construction” is that “a statute ought . . . to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.”³⁶ Although courts typically employ the anti-surplusage canon to understand the meaning of a single statute, its logic applies to construing separate statutes. Inferring frustration preemption makes surplusage out of many of Congress’s express preemption provisions.

Second, “[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”³⁷ Although, as with the anti-surplusage canon, this principle speaks to the “inclusion or exclusion” within a statute, its logic also applies when comparing statutes. When Congress includes preemption provisions in more than 350 statutes and does not include such provisions in other statutes, courts should presume Congress acted intentionally and purposefully.

35. *See, e.g.*, *Kimbrough v. United States*, 552 U.S. 85, 103 (2007) (“Drawing meaning from silence is particularly inappropriate here, for Congress has shown that it knows how to direct sentencing practices in express terms.”); *Whitfield v. United States*, 543 U.S. 209, 216–17 (2005) (“Congress has included an express overt-act requirement in at least 22 other current conspiracy statutes, clearly demonstrating that it knows how to impose such a requirement when it wishes to do so. Where Congress has chosen *not* to do so, we will not override that choice. . . .” (citation omitted)); *Dole Food Co. v. Patrickson*, 538 U.S. 468, 476 (2003) (“Where Congress intends to refer to ownership in other than the formal sense, it knows how to do so. Various federal statutes refer to ‘direct and indirect ownership.’ The absence of this language in 28 U.S.C. § 1603(b) instructs us that Congress did not intend to disregard structural ownership rules.” (citations omitted)); *Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc.*, 484 U.S. 49, 57 (1987) (“Congress has demonstrated in . . . other statutory provisions that it knows how to avoid this prospective implication by using language that explicitly targets wholly past violations.”); *see also* *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1, 38 (2007) (Stevens, J., dissenting) (“To begin with, Congress knows how to authorize executive agencies to preempt state laws. It has not done so here.” (footnote omitted)).

36. *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (quotation marks and citations omitted).

37. *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation marks and citations omitted).

A further reason not to infer that Congress intended to displace certain state laws in the absence of a preemption provision is the difficulty of discerning Congress's precise goals and purposes in enacting a statute. Frustration preemption assumes the state law at issue is an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress."³⁸ What if, however, the federal statute was the product of a compromise or contains multiple "purposes and objectives" in some tension with each other?³⁹ A state law might simultaneously frustrate accomplishment of the "general objective," yet further the achievement of other desirable ends.⁴⁰ Only the statutory text can resolve whether Congress intended to preempt state law in such circumstances. Given these considerations, it is not surprising that members of the Supreme Court have expressed concern with the concept of frustration preemption.⁴¹

This approach to frustration preemption—focusing on text, not on furthering perceived congressional purpose—parallels the Supreme Court's approach to implied rights of action. Before 1975, the Court "placed considerable emphasis upon the desirability of implying private rights of action in order to provide remedies thought to effectuate the purposes of a given statute."⁴² As a result, the Court's "probe of the congressional mind . . . never focused squarely on private rights of action, as distinct from the substantive

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

39. See *Fitzgerald v. Racing Ass'n of Cent. Iowa*, 539 U.S. 103, 108 (2003) (noting that the state law under review, "like most laws, might predominantly serve one general objective . . . while containing subsidiary provisions that seek to achieve other desirable (perhaps even contrary) ends as well, thereby producing a law that balances objectives but still serves the general objective when seen as a whole").

40. *Id.*

41. See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part) (approving "th[e] Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 907 (2000) (Stevens, J., dissenting) (discussing the importance of "prevent[ing] federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes"); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part, concurring in judgment) ("A free-wheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law.").

42. *Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11, 15 (1979).

objects of the legislation.”⁴³ This changed in a series of cases beginning with *Cort v. Ash*.⁴⁴

The key inquiry now is whether Congress specifically intended to create a private right of action.⁴⁵ And “unless this congressional intent can be inferred from the language of the statute, the statutory structure, or some other source, the essential predicate for implication of a private remedy simply does not exist.”⁴⁶ Although not dispositive, “congressional silence . . . is thus a serious obstacle” to finding private rights of action.⁴⁷

The Supreme Court changed its approach to implying private rights of action for many reasons, one of which has particular resonance here. The Court observed in *Virginia Bankshares* that, while the text and legislative history of § 14(a) of the Securities Exchange Act of 1934 “carry the clear message that Congress meant to protect investors from misinformation[,] . . . it is just as true that Congress was reticent with indications of how far this protection might depend on self-help by private action.”⁴⁸ As this case indicates, Congress does not always pursue its objectives at all costs and through all means. It is up to Congress, not the courts, to specify the means, whether they be private rights of action or the displacement of state law.

C. Principles of federalism further militate against finding frustration preemption.

The Supreme Court has frequently recounted the reasons why the Framers adopted a federal structure of government and the advantages that accrue from it. Allowing states to exercise continued power ensures that government is

more sensitive to the diverse needs of a heterogeneous society[,] . . . increases opportunity for citizen involvement in democratic processes[,] . . . allows for more innovation and experimentation in government[,] . . . and makes government more responsive by putting the States in competition for a mobile citizenry.⁴⁹

43. *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1103 (1991).

44. 422 U.S. 66 (1975).

45. See *Virginia Bankshares*, 501 U.S. at 1104; *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 812 n.9 (1986) (collecting cases).

46. *Nw. Airlines, Inc. v. Transp. Workers*, 451 U.S. 77, 94 (1981).

47. *Virginia Bankshares*, 501 U.S. at 1104.

48. *Id.* at 1103–04; 15 U.S.C. § 78n(a) (1947).

49. *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

Preempting state laws, however, serves none of those interests. This concern may not have been paramount earlier in the Republic, when Congress's powers were viewed as narrower and federal law was "generally interstitial in its nature."⁵⁰ Now, however, with Congress's vast authority under the Commerce Clause,⁵¹ it has correspondingly broad opportunities to preempt state law.

Recognizing this concern, the Supreme Court adopted a series of clear-statement rules applicable when Congress encroaches upon state powers.⁵² These rules serve a crucial structural function: "[I]nasmuch as th[e] Court in *Garcia [v. San Antonio Metropolitan Transit Authority]*, 469 U.S. 528 (1985) has left primarily to the political process the protection of the States against intrusive exercises of Congress'[s] Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise."⁵³ In *Garcia*, the Court overruled *National League of Cities v. Usery*⁵⁴ and stated that the key mechanism to "ensure[] that laws that unduly burden the States will not be promulgated" is the states' participation in federal governmental action.⁵⁵ But states cannot protect their interests through the political process if Congress has not signaled that it intends to encroach on the states' domain.

The doctrine of frustration preemption is irreconcilable with that principle. Indeed, after the court concludes there is a conflict, the doctrine amounts to a presumption *in favor* of preemption because the court presumes that Congress, although silent on the issue, would have wanted state law displaced. This not only conflicts with basic canons of statutory construction and the judiciary's institutional role,⁵⁶ but also undermines the protections the political process affords the states. As then-Justice Stone wrote,

50. RICHARD H. FALLON, JR. ET AL., *THE FEDERAL COURTS AND THE FEDERAL SYSTEM* 494 (5th ed. 2003).

51. See *Gonzales v. Raich*, 545 U.S. 1, 17 (2005) (confirming "Congress'[s] power to regulate purely local activities" that substantially affect interstate commerce).

52. See, e.g., *Gregory*, 501 U.S. at 460–61 (adopting "plain statement" rule when Congress "would upset the usual constitutional balance of federal and state powers"); *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985) (requiring plain statement before construing statute to abrogate states' sovereign immunity); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (stating "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").

53. *Gregory*, 501 U.S. at 464.

54. 426 U.S. 833 (1976).

55. *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 556 (1985).

56. See *supra* notes 32–48 and accompanying text.

At a time when the exercise of the federal power is being rapidly expanded through Congressional action, it is difficult to overstate the importance of safeguarding against such diminution of state power by vague inferences as to what Congress might have intended if it had considered the matter or by reference to our own conceptions of a policy which Congress has not expressed and which is not plainly to be inferred from the legislation which it has enacted.⁵⁷

The longstanding presumption against preemption is one tool for protecting the states' status as "independent sovereigns in our federal system."⁵⁸ "This assumption provides assurance that the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts."⁵⁹ The arguments set forth above are independent from, but complementary to, the presumption against preemption. Principles of statutory construction and the proper institutional roles of Congress and the courts dictate that frustration preemption should rarely be found; federalism principles reinforce that conclusion. The federalism-based presumption against preemption, and its concomitant clear-statement rule, leads to the same result.

D. Inferring frustration preemption is only proper when no reasonable policy ground supports applying state law.

We do not suggest courts can *never* find frustration preemption. A state law might so undermine the achievement of manifest federal objectives that no reasonable legislator would have voted for the bill knowing that such a state law would continue to operate. Conversely, however, courts should not displace a state law when a reasonable policy ground supports its application. In other words, if a court can identify a legitimate reason why Congress would have *not* wanted a state law to be preempted, the court would be bound to uphold the state law.

This "reasonable policy ground" rule accounts for the statutory construction, separation-of-powers, and federalism concerns discussed above. The choice whether to preempt state law is for Congress to make. It knows how to express its intent to displace state laws; courts undermine the interests served by our federal system when they conclude federal acts implicitly preempt state laws.

57. *Hines v. Davidowitz*, 312 U.S. 52, 75 (1941) (Stone, J., dissenting).

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

59. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quotation marks and citation omitted).

Taken together, the general rule must be that courts should not “expand federal statutes beyond their terms through doctrines of implied pre-emption.”⁶⁰ If reasonable policy arguments can be asserted both for and against displacement of state law, congressional silence is properly construed as a decision *not* to displace state law.

E. Federal agencies lack the authority to deem state laws preempted under the doctrine of frustration preemption.

When the ordinary tools of statutory construction reveal Congress did not intend to displace state law, the frustration preemption inquiry ends. As occurred in *Wyeth*,⁶¹ however, sometimes courts consider the federal agency’s conclusions that a state law frustrates the achievement of federal objectives.⁶² Several scholars have comprehensively addressed the deference, if any, an agency should receive when it opines on preemption.⁶³ For present purposes, an additional observation is in order.

In *Alexander v. Sandoval*, the Supreme Court held that “it is most certainly incorrect to say that language in a regulation can conjure up a private cause of action that has not been authorized by Congress. Agencies may play the sorcerer’s apprentice but not the sorcerer himself.”⁶⁴ That holding fully applies to agency efforts to “conjure up” frustration preemption. It is one thing for an agency to exercise statutorily-delegated authority by promulgating a substantive regulation, and for that substantive regulation to preempt

60. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part).

61. *Wyeth v. Levine*, 129 S. Ct. 1187, 1201–04 (2009).

62. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601).

63. Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 Nw. U. L. REV. 695, 699 (2008) (suggesting that “especially with respect to a statute that contains no explicit preemptive language . . . courts should apply not only a presumption against preemption, but also an additional presumption against *agency* preemption”); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. REV. 727, 759–79 (2008) (concluding that agency interpretational rulings about the preemptive effect of federal law should be subject to a deference doctrine that is *sui generis* to preemption law); Ernest A. Young, *Executive Preemption*, 102 Nw. U. L. REV. 869, 891–93 (2008) (suggesting a preemption-specific version of *Skidmore* deference to prescribe deference to an agency’s interpretation of federal law); *see also* Mendelson, *supra*, at 698 (“Despite agencies’ expertise in implementing their own programs, no presumptive deference should be due because agencies lack both institutional expertise on important issues of state autonomy and federalism and adequate statutory guidance regarding preemption questions.”).

64. 532 U.S. 275, 291 (2001).

state laws that directly contradict it.⁶⁵ But, it is quite another thing for an agency to declare that, even though Congress did not intend to displace state laws that could frustrate full achievement of the federal objectives, the agency has authority to declare state laws preempted on that ground. In the former action, the agency is the sorcerer's apprentice; in the latter action, it is improperly playing the sorcerer. Put another way, "if Congress does not intend [frustration] preemption, Congress should be held not to intend agency [frustration] preemption."⁶⁶

For precisely this reason, an agency cannot manufacture preemption by declaring a standard it has adopted is both a "floor" and a "ceiling."⁶⁷ Such assertions are invariably followed by the contention that these standards preempt any state measures that impose stricter standards or additional requirements because they directly conflict with the federal ceiling.⁶⁸ The problem with this approach is that the agency's declaration that its standard is a ceiling is nothing more than a declaration that it is invoking frustration preemption.

As Professor Mendelson observes, Congress commonly charges agencies with accomplishing primary goals (e.g., providing a safe workplace, ensuring that drinking water is healthy, making automobiles safer) as well as "countervailing or moderating goals" (e.g., reducing costs to employers, increasing flexibility for manufacturers).⁶⁹ If agencies can declare their standards to be both floors (to achieve the primary goals) and ceilings (to achieve the countervailing secondary goals), "federal agencies would have the power to preempt nearly any state law operating in the same arena as the federal law."⁷⁰ For "[a]n agency can nearly always identify some statutory goal—perhaps opposed to or in tension with the statute's primary goal—with which the state law will conflict."⁷¹

65. See *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152–55 (1982) (agency rule permitting federal savings and loan associations to use "due-on-sale" clauses in mortgage contracts preempts California's prohibition of such clauses).

66. Mendelson, *supra* note 63, at 707.

67. See, e.g., 71 Fed. Reg. at 3935 (FDA's assertion that its labeling requirements "establish both a 'floor' and a 'ceiling'").

68. See, e.g., Brief of the United States as Amicus Curiae Supporting Petitioner at 19, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

69. Mendelson, *supra* note 63, at 711–14.

70. *Id.* at 714.

71. *Id.* at 713; see also *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646 (1990) ("[T]here are numerous federal statutes that could be said to embody countless policies.").

If Congress intends to grant agencies that massive power, it generally may do so. But where Congress does not express the intent to preempt state laws merely because those laws might frustrate the full accomplishment of a federal objective, Congress also does not intend to grant federal agencies the authority to do precisely that under the guise of setting floors and ceilings.

II. FRUSTRATION PREEMPTION UNDER THE FDCA: *WYETH V. LEVINE*

This part applies the reasoning set forth in Part I to demonstrate why the FDCA,⁷² which has no express preemption provision, does not impliedly preempt state tort actions. It then shows that the majority opinion of the Supreme Court and the concurring opinion of Justice Thomas in *Wyeth v. Levine*⁷³ reached the same conclusion through reasoning similar to that in this Article.

A. *Background of Wyeth v. Levine*

In 2001, Diane Levine sued Wyeth for its failure to warn of the dangers of injecting its nausea medication, Phenergan, directly into a patient's vein.⁷⁴ As a result of a direct injection, Ms. Levine suffered gangrene that required the amputation of part of her arm.⁷⁵

After a favorable verdict at the trial court, the Vermont Supreme Court affirmed Ms. Levine's jury award of \$7.4 million.⁷⁶ Throughout the litigation, Wyeth maintained that Ms. Levine's lawsuit was preempted under various theories, including frustration preemption. The question presented to the United States Supreme Court was "whether federal law preempt[ed] Levine's claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration."⁷⁷

Wyeth presented two preemption arguments. It first argued that "it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law."⁷⁸ Second, Wyeth maintained that "recognition of Levine's

72. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–97 (2006).

73. *Wyeth*, 129 S. Ct. at 1204 (Thomas, J., concurring).

74. Joint Appendix at 14, *Wyeth*, 129 S. Ct. 1187 (2009).

75. *Wyeth*, 129 S. Ct. at 1191.

76. *Levine v. Wyeth*, 944 A.2d 179, 182–83 (Vt. 2006) (award reduced to \$6,774,000 by party stipulation).

77. *Wyeth*, 129 S. Ct. at 1194.

78. *Id.* at 1193 (citing *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)).

state tort action creates an unacceptable ‘obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’ because it substitutes a lay jury’s decision about drug labeling for the expert judgment of the [Federal Drug Administration].”⁷⁹ Our focus is on that second argument.

With respect to frustration preemption, Wyeth’s argument was (1) that the FDCA, which broadly regulates foods, drugs, and cosmetics, operates identically to the Medical Device Amendments of 1976 (MDA),⁸⁰ which expressly preempts “different” or “addition[al]” state requirements with respect to medical devices;⁸¹ and (2) that Congress implicitly intended to preempt all state requirements “different from, or in addition to” the federal regulatory regime governing prescription drugs.⁸² Thus, Wyeth’s implied preemption argument boiled down to the proposition that the Supreme Court should construe the FDCA as though it had an express preemption provision like the MDA.

B. The principles set forth above demonstrate that state tort law does not frustrate Congress’s objectives in enacting the FDCA.

Because the FDCA does not contain an express preemption provision, the principles of statutory construction, separation of powers, and federalism set forth in Part I weigh heavily against inferring that Congress intended to displace state tort actions that do not present an “impossibility” conflict.

Congress’s treatment of state law as applied to other products regulated by the FDA reinforces this conclusion. Congress expressly preempted certain state actions based on injuries arising from medical devices⁸³ and vaccines,⁸⁴ and has preempted state re-

79. *Id.* at 1193–94 (citation omitted) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

80. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k (2006).

81. Brief for the Petitioner at 31, *Wyeth*, 129 S. Ct. 1187 (2009) (No. 06-1249).

82. 21 U.S.C. § 360k; Brief for the Petitioner, *supra* note 81, at 40–41. Under the FDCA, a drug manufacturer may not market a new drug before first submitting a new drug application to the FDA and receiving the agency’s approval. *See* § 355a. Essentially, Wyeth maintained that because the process for approving new drugs is at least as rigorous as the premarket approval process for medical devices and because the Court had already held that the MDA preempts state law tort suits as being an impermissible “addition[al]” or “different” state requirement, Ms. Levine’s claim should similarly be preempted. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 343 (2008) (Ginsburg, J., dissenting).

83. 21 U.S.C. § 360k(a).

84. 42 U.S.C. §§ 300aa–22(b)(1) and (e) (2006).

quirements with respect to over-the-counter drugs.⁸⁵ In addition, Congress failed to include an express preemption provision in the FDCA despite the long history of state tort actions against drug manufacturers.⁸⁶ Indeed, Congress adopted a saving clause in 1962 to limit the FDCA's preemptive scope.⁸⁷ Congress's decision not to include an express preemption provision in the FDCA is therefore properly viewed as a decision not to displace state tort actions.

Congress's failure to include an express preemption provision combined with its decision to include a saving clause has additional implications. We noted earlier the principle that "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."⁸⁸ Moreover, "[t]he long history of tort litigation against manufacturers" of prescription drugs, and Congress's refusal to amend the FDCA in response, adds force to the conclusion that Congress did not intend to preempt such litigation.⁸⁹ Drug manufacturers have been obligated to comply with both federal drug labeling obligations and state common law for seventy years.⁹⁰

When Congress crafted the preemption provision in the MDA, it was surely aware that "[j]udgments against manufacturers of various FDA-approved products were by no means rare."⁹¹ Nevertheless, Congress opted to preempt only state requirements with respect to medical devices—not state requirements with respect to

85. 21 U.S.C. § 379r(a).

86. *Wyeth*, 129 S. Ct. at 1200.

87. Drug Amendment of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) (current version at 21 U.S.C. §§ 301–99(2006)). *See also Wyeth*, 129 S. Ct. at 1196 ("The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA.").

88. *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation marks and citations omitted).

89. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

90. *See, e.g., Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 981, 991–94 (8th Cir. 1969); *Abbott Labs. v. Lapp*, 78 F.2d 170, 175 (7th Cir. 1935); *Valmas Drug Co. v. Smoots*, 269 F. 356, 360 (6th Cir. 1920); *Tinnerholm v. Parke Davis & Co.*, 285 F. Supp. 432, 451–52 (S.D.N.Y. 1968); *Incollingo v. Ewing*, 282 A.2d 206, 212, 219–20 (Pa. 1971); *Phillips v. Roux Labs.*, 145 N.Y.S.2d 449, 451–52 (App. Div. 1955); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 341 n.11 (2008) (Ginsburg, J., dissenting) (listing 14 state law tort actions brought between 1968 and 1975 involving FDA-approved drugs).

91. Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims after Medtronic*, 64 TENN. L. REV. 691, 704 (1997).

drugs. As the Supreme Court observed in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, “[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.”⁹²

Wyeth’s frustration preemption arguments should therefore prevail only if no reasonable policy arguments can be asserted against the displacement of state law. In *Riegel*, the Court “speculate[d]” that the reason Congress probably wanted the MDA’s preemption provision to cover state tort actions was “solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.”⁹³ That is a plausible policy justification for preempting state tort actions against prescription drug manufacturers as well. But there are plenty of plausible policy justifications for *not* preempting such actions.

Specifically, Congress may have wanted injured consumers to retain the right to bring tort actions against prescription drug manufacturers:

- to avoid the “harsh implications of foreclosing all judicial recourse for consumers injured” by defective drugs or inadequate drug labels;⁹⁴
- because tort suits “aid in the exposure of new dangers,” which leads manufacturers and federal regulators to address the problems;⁹⁵
- based on the concern that “pre-approval testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies . . .”;⁹⁶

92. 489 U.S. 141, 166–67 (1989) (quotation marks omitted; second alteration in original).

93. *Riegel*, 552 U.S. at 326.

94. Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 9 (1997); see also *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (saying state tort actions, “unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims”).

95. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005).

96. 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, 471 (2008).

- based on the concern that the FDA is overworked and underfunded, and therefore cannot ensure that defective and dangerous devices will not reach consumers;⁹⁷ or
- based on the concern that the post-approval monitoring system is not up to the task of protecting consumers from drugs whose defects become apparent only after initial FDA approval.⁹⁸

In the end, Congress decides whether the policy considerations noted in *Riegel* outweigh the policy considerations outlined above. Congress's decision not to include an express preemption provision in the FDCA reflects a decision to accept the policy arguments opposed to displacing state tort actions against prescription drug manufacturers.

*C. The Majority Decision on Frustration Preemption
in Wyeth v. Levine*

Justice Stevens, joined by Justices Kennedy, Souter, Ginsburg, and Breyer, issued the opinion of the Court, rejecting Wyeth's preemption claims.⁹⁹ Significantly, as in this Article, the majority concluded that in conflict preemption cases congressional intent matters and the presumption against preemption applies.

The Court first recognized that to answer the question "whether federal law preempts Levine's claim that Phenergan's label did not contain an adequate warning" it "must be guided by two cornerstones of [the Court's] pre-emption jurisprudence."¹⁰⁰ First, "the purpose of Congress is the ultimate touchstone in every pre-emption case,"¹⁰¹ and second, the presumption against preemption applies "[i]n all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied."¹⁰²

In holding that congressional intent is the key inquiry in implied preemption cases, the Court rejected the position set forth in Justice Alito's dissent (and advanced by several amici) that "the sole question is whether there is an 'actual conflict' between state and

97. See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 499 (1997).

98. See Kessler & Vladeck, *supra* note 96, at 483–95.

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

100. *Id.* at 1194.

101. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

102. *Id.* at 1194–95 (quoting *Lohr*, 518 U.S. at 485) (quotation marks and ellipses omitted, second alteration in original).

federal law; if so, then pre-emption follows automatically by operation of the Supremacy Clause.”¹⁰³

In addition, it reaffirmed that the “presumption against pre-emption” applies in conflict preemption cases.¹⁰⁴ In doing so, the Court rejected the theory presented in several amicus briefs, such as those by the Chamber of Commerce and the Product Liability Advisory Council, that the presumption against preemption does not apply in conflict preemption cases.¹⁰⁵ These parties argued that to determine whether state law conflicts with federal law, courts must interpret the *substantive* meaning of those laws without applying any such presumption.¹⁰⁶ The Court definitively rejected that argument, stating that “this Court has long held to the contrary.”¹⁰⁷

After rejecting Wyeth’s argument that it was impossible to comply with “both the state-law duties underlying [Levine’s] claims and its federal labeling duties,” the Court turned to Wyeth’s frustration preemption arguments.¹⁰⁸ Wyeth’s primary contention was that “the FDCA establishes both a floor and a ceiling for drug regulations” and that “[o]nce the FDA has approved a drug’s label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered [a] stronger warning.”¹⁰⁹ The Court squarely rejected this theory on the basis that “all evidence of Congress’[s] purposes is to the contrary.”¹¹⁰ Of significant importance to its conclusion that state tort suits did not frustrate federal objectives was the Court’s recognition that Congress “surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history.”¹¹¹

103. *Id.* at 1228 (Alito, J., dissenting); *see also* Brief of Prod. Liab. Advisory Council, Inc., *supra* note 31, at 3.

104. *Wyeth*, 129 S. Ct. at 1194–95.

105. Brief of Prod. Liab. Advisory Council, Inc., *supra* note 31, at 5–19; Brief of Chamber of Commerce of the United States as Amicus Curiae Supporting Petitioner at 27, *Wyeth*, 129 S. Ct. 1187 (No. 06-1249).

106. Brief of Prod. Liab. Advisory Council, Inc., *supra* note 31, at 16 (“Interpreting the federal statute’s substantive meaning is an inquiry that does not bring into play the presumption against preemption.”) (quotation marks omitted); Brief of Chamber of Commerce of the United States, *supra* note 105, at 23–24.

107. *Wyeth*, 129 S. Ct. at 1195 n.3 (citing cases). *But see id.* at 1229 n.14 (Alito, J., dissenting) (stating that it “remained an open question—before today—whether” the presumption against preemption “applied in conflict pre-emption cases”).

108. *Id.* at 1196–2000.

109. *Id.* at 1199.

110. *Id.*

111. *Id.* at 1200.

The Court highlighted that Congress had indeed enacted an express preemption provision for medical devices in its 1976 amendments of the FDCA, but had not done so for prescription drugs, such as Phenergan.¹¹² “Its silence on the issue, coupled with its awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”¹¹³ The majority reinforced its conclusion by citing to the presumption again preemption.¹¹⁴

Lastly, the Court addressed the impact of the FDA’s assertion that Levine’s claim is preempted. Although the Court recognized that agencies, such as the FDA, “do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an ‘obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’”¹¹⁵ it found that the weight of the FDA’s view received the deference accorded by *Skidmore v. Swift & Co.*,¹¹⁶ and thus depended on its “thoroughness, consistency, and persuasiveness.”¹¹⁷ Under this standard, the FDA’s view did not merit deference.¹¹⁸ The Court noted that not only was the FDA’s view (which was set forth in the preamble of an FDA final rule) “inherently suspect” because of its procedural failure to provide states and other parties with notice of its federalism impacts, but it was also at odds with Congress’s intent and the FDA’s previous long-standing position on the issue.¹¹⁹

The majority also cited several of the “reasonable policy arguments” identified above. For example, the Court noted that based on the FDA’s “limited resources” to monitor drugs, state tort actions could serve to uncover unknown drug hazards.¹²⁰ In addition, the majority suggested that state tort suits could “provide incentives for drug manufacturers to disclose safety risks promptly,” and such

112. *Id.* (citing *Riegel*, 552 U.S. at 327 (2008) (“Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.”)).

113. *Id.*

114. *Id.*

115. *Id.* at 1201 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

116. 323 U.S. 134 (1944).

117. *Wyeth*, 129 S. Ct. at 1201; *see also Skidmore*, 323 U.S. at 140.

118. *Wyeth*, 129 S. Ct. 1203.

119. *Id.* at 1199.

120. *Id.* at 1202.

suits “serve a distinct compensatory function that may motivate injured persons to come forward with information.”¹²¹

It concluded its decision by rejecting Wyeth’s (and the dissent’s) contention that the Court’s previous ruling in *Geier v. American Honda Motor Co.*¹²² compelled preemption here.¹²³ Distinguishing that case, it found that Wyeth had not persuaded the Court that “failure-to-warn claims like Levine’s obstruct the federal regulation of drug labeling.”¹²⁴

Thus, the majority did not fully embrace the arguments set forth here: that frustration preemption may only be found when no reasonable policy ground supports applying state law. It did, however, adopt the key test that congressional intent matters in conflict preemption cases and that Congress’s continued refusal to enact an express preemption provision is a significant element in determining whether Congress intended to displace state law.

D. *The Concurring Opinion of Justice Thomas*

Justice Thomas concurred in the judgment, agreeing with the Court that the FDA’s approval of the Phenergan label “does not pre-empt the state-law judgment” at issue.¹²⁵ He wrote separately, however, because he could not “join the majority’s implicit endorsement of far-reaching implied pre-emption doctrines.”¹²⁶ In fact, Justice Thomas rejected those doctrines altogether.

Justice Thomas identified many of the concerns presented in Part I, including that under our federalist system “the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause”¹²⁷ and that the Supremacy Clause thus ensures that “the Federal Government does not amass too much power at the expense of the States.”¹²⁸ The Court’s broad frustration preemption precedents, and particularly its frustration preemption jurisprudence, he reasoned, have “expanded federal statutes beyond their terms.”¹²⁹

In his view, this “potentially boundless” doctrine of frustration preemption, where the Court looked to “broad federal policy objec-

121. *Id.*

122. 529 U.S. 861 (2000).

123. *See Wyeth*, 129 S. Ct. at 1203.

124. *Id.* at 1204.

125. *Id.* at 1205 (Thomas, J., concurring).

126. *Id.*

127. *Id.*

128. *Id.* at 1206.

129. *Id.* at 1207.

tives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law,” does not satisfy constitutional requirements.¹³⁰ He explained that the Supremacy Clause only grants “supreme” status to federal laws “made in [p]ursuance”¹³¹ of the Constitution, and that the Constitution’s Bicameral and Presentment Clauses¹³² “prescribe and define the respective functions of the Congress and of the Executive in the legislative process.”¹³³ Because “[c]ongressional and agency musings . . . do not satisfy Art. 1, § 7 requirements for enactment of federal law . . . [they] do not pre-empt state law.”¹³⁴ Therefore, according to Justice Thomas (and as we posit above), “evidence of pre-emptive purpose must be sought in the text and structure of the provision at issue” when analyzing the preemptive effect of federal statutes and regulations.¹³⁵ Citing his concurring opinion in *Bates*, he asserted that the “[p]re-emption analysis should not be ‘a free-wheeling judicial inquiry into whether a state statute is in tension with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict.’”¹³⁶ In short, “[p]re-emption must turn on whether state law conflicts with the text of the relevant federal statute or with the federal regulations authorized by that text.”¹³⁷

For these reasons, Justice Thomas views the “Court’s entire body of [frustration] pre-emption jurisprudence [a]s inherently flawed” because the cases “improperly rely on legislative history, broad atextual notions of congressional purpose, and even congressional inaction in order to pre-empt state law.”¹³⁸ As we propose here, “when statutory language is plain, it must be enforced according to its terms.”¹³⁹ Thus, the lack of an express preemption provision in the FDCA demonstrates it does not preempt state tort actions.

130. *Id.*

131. U.S. CONST. art. 6, cl. 2.

132. *Id.* art 1, § 7, cls. 2–3.

133. *Wyeth*, 129 S. Ct. at 1207 (Thomas, J., concurring) (quoting *INS v. Chadha*, 462 U.S. 919, 945–46 (1983)).

134. *Id.*

135. *Id.* (alterations in original) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)).

136. *Id.* at 1208 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005)).

137. *Id.*

138. *Id.* at 1211.

139. *Id.* at 1215; *see also id.* (“[N]o agency or individual Member of Congress can preempt a State’s judgment by merely musing about goals or intentions not found within or authorized by the statutory text.”).

Likewise, Justice Thomas recognized that attempting “to divine the broader purposes of the statute” leads courts “to assume that Congress wanted to pursue those policies ‘at all costs’—even when the text reflects a different balance.”¹⁴⁰ Because “[f]ederal legislation is often the result of compromise between legislators and ‘groups with marked but divergent interests,’ . . . a statute’s text might reflect a compromise between parties who wanted to pursue a particular goal to different extents.”¹⁴¹ Consequently, “it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute’s primary objective must be the law,”¹⁴² and preemption can only apply to “policies that are actually authorized by and effectuated through the statutory text.”¹⁴³

With respect to the FDCA, Justice Thomas agreed with the majority that it did not displace state tort law.¹⁴⁴ But he disagreed with the majority’s reliance on congressional silence to derive the motivations and policies of Congress.¹⁴⁵ To him, the relevance was that “no statute explicitly pre-empts the lawsuits.”¹⁴⁶ He concluded his concurrence with the warning that he “can no longer assent to a doctrine that pre-empts state laws merely because they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of federal law.”¹⁴⁷

In this respect, his opinion is significant because absent an express preemption provision, Justice Thomas will not find a state statute preempted unless it is “impossible” to comply with both state and federal law. This approach to frustration preemption therefore closely resembles the position advocated here—indeed, it goes further by not allowing frustration preemption even in the rare case where no plausible policy would justify the state law’s interference with federal objectives.

140. *Id.*

141. *Id.* (citing *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 93–94 (2002)).

142. *Id.*

143. *Id.* at 1216.

144. *Id.* at 1204.

145. *Id.* at 1216.

146. *Id.*; *see also id.* at 1217 (Court’s role “is merely to interpret the language of the statutes enacted by Congress”) (quotation marks and brackets omitted).

147. *Id.* at 1217 (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (quotation marks and brackets omitted).

CONCLUSION

In *Wyeth*, the Supreme Court made clear that the question whether a federal statute displaces state law is an issue of congressional intent—even in frustration preemption cases. With this in mind, courts should look to principles of statutory construction, separation of powers, and federalism when determining whether a federal law preempts state law. As we have shown above, these principles dictate that courts should rarely displace state law under the doctrine of frustration preemption.

WHO DECIDES WHO DECIDES: FEDERAL REGULATORY PREEMPTION OF STATE TORT LAW

*MARK SEIDENFELD**

INTRODUCTION

In this paper, I contend that there is no universal answer to whether common law courts provide a valuable function as a backstop to agency regulation for setting standards of care within an industry, with which a provider of goods or services must comply.¹ Rather, the potential benefits of having courts as a backstop will depend on particular characteristics of the market in which a producer operates. These include, among other things, efficiencies of uniformity of production, the risks of uncertainty facing the producer about the standard of care, the information reasonably available prior to the producer's commitment to market a product, and the likely reaction of consumers to knowledge about the product if they are fully informed of its risks.

Given this premise about the value of tort law as a regulatory backstop, the crucial question becomes: Which institution is best suited to decide, in the context of a particular regulatory action, whether tort suits are preempted? Here the choice is not only between agency and court, but also Congress, which can, if it chooses, preclude state tort suits with respect to virtually any mass tort. My thesis is that agencies are the preferable institution for deciding whether state tort law should be preempted by regulation and that

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1. This paper limits its consideration to regulation of consumer goods and services which can threaten health and safety, which are the kinds of commercial activity that generate the mass tort actions that have garnered the attention of the public, regulators and scholars alike.

therefore courts should recognize agencies' authority to preempt state law under general rulemaking authority granted by Congress.²

At the outset, I need to clarify the scope of this thesis. I do not address directly the question that has arisen of late in tort preemption cases—the role of agencies in determining whether a statute itself preempts common law tort suits either directly or by occupying the regulatory field. Others have thoughtfully written on this question, addressing whether agency input is appropriate and, if so, how best to structure that input in the context of interpreting potentially preempting statutes.³ Instead, this paper addresses the issue of agency preemption in the absence of statutory instruction.⁴

My proposal may seem radical because it unmoors preemption from any reliance, whether actual or imagined, on a congressional decision on this issue. Those who value federalism for its own sake might therefore find my proposal disconcerting as it facilitates preemption by circumventing the checks of the legislative process.⁵ Of

2. I am not alone in having reached this conclusion. Cathy Sharkey recently advocated a similar switch in focus from Congress to agencies for preemption decisions. See Catherine Sharkey, *Federalism Accountability: "Agency-Forcing" Measures*, 58 DUKE L.J. 2125, 2129 (2009) [hereinafter Sharkey, *Federalism Accountability*]. See generally William W. Buzbee, *Preemption Hard Look Review: Regulatory Interaction, and the Quest for Stewardship and Intergenerational Equity*, 77 GEO. WASH. L. REV. 1521 (2009) (accepting that agencies can preempt state law but arguing that such action should be subject to hard look review).

3. See generally Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004). See also Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 491–502 (2008) [hereinafter Sharkey, *Products Liability Preemption*]; Thomas Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 769–79 (2008) [hereinafter Merrill, *Preemption*]; cf. Gillian E. Metzger, *Administrative Law as the New Federalism*, 57 DUKE L.J. 2023, 2069–72 (2008) (discussing the role of ordinary doctrines of administrative law as a means of implementing federalism concerns in preemption cases).

4. My conclusion that agencies should have primary responsibility for deciding when tort suits are preempted does bear on the question of whether a statute calls for preemption. In order to preserve room for the agency to exercise this responsibility, I conclude that courts should not interpret statutes definitively either to preempt or to save tort suits except when the statute so provides explicitly and clearly. See discussion *infra* Section IIIA.

5. See William N. Eskridge, *Vetogates, Chevron, Preemption*, 83 NOTRE DAME L. REV. 1441, 1470 (2007) (opining that because agency rulemaking circumvents the vetogates involved in the legislative process, "the Court should require a targeted (preemption-specific) statement from Congress when it is delegating preemptive authority to an agency"); Merrill, *Preemption*, *supra* note 3, at 750–51 (2008). Those concerned with circumvention of the limits on preemption often call for "presumptions against preemption" or "clear statement rules." See Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1425 (2001); Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the*

course, courts ultimately rejected that concern with respect to rulemaking in general, allowing broad delegations by Congress.⁶ If one values federalism instrumentally, rather than as an end in itself, the same arguments for allowing the regulatory process to be more flexible than the legislative process also support allowing such flexibility for preemption decisions.⁷ Even unabashed federalists might take heart, however, because my proposal reduces the pressure on courts to find statutory preemption on the slimmest of interpretive reeds⁸ and imposes significant procedural and substantive burdens before an agency could preempt tort law. The hope is that this proposal will encourage wiser preemption, not simply more preemption.

I. COMPARATIVE ADVANTAGES OF PREEMPTIVE REGULATION

Agencies can act in a variety of ways to establish regulation. If authorized by Congress they can adopt rules that govern industry

National Legislative Process, 82 N.Y.U. L. REV. 1, 17, 32–39 (2007); Earnest A. Young, *Federal Preemption and State Autonomy*, in *FEDERAL PREEMPTION: STATE'S POWERS, NATIONAL INTERESTS* 249, 254 267–68 (Richard A. Epstein & Michael S. Greve eds., 2007). Such doctrines are examples of “resistance norms”—rules that discourage particular government action by raising the cost of that action. See Ernest A. Young, *Constitutional Avoidance, Resistance Norms, and the Preservation of Judicial Review*, 78 TEX. L. REV. 1549, 1585 (2000).

6. See Heidi Kitrosser, *The Accountable Executive*, 93 MINN. L. REV. 1741, 1756 (2009) (stating that “the Court has come to accept broad policymaking delegations from Congress to the administrative state”).

7. For some, like Brad Clark and Cass Sunstein, the non-delegation doctrine remains vital in theory, foundering only in the lack of administrability of a distinction between enacting and executing the law. See Clark, *supra* note 5, at 1374; Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 338 (2000). For them, the canon requiring a statutory clear statement of intent to preempt state law would reflect a limit on Congress’s authority to delegate preemption power to agencies. Hence, presumably they would find my proposal unconstitutional. For those who take the more usual view that Congress can delegate legislative functions to agencies as long as it does so with sufficient safeguards, duly adopted regulations are laws enacted pursuant to the Constitution and hence can preempt state law under the Supremacy Clause.

8. See Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437, 438–41 (2009) [hereinafter Sharkey, *What Riegel Portends*] (criticizing the Supreme Court Justices’ approaches to interpreting preemption provisions as removed from analysis of statutory text, and perhaps outcome driven).

conduct.⁹ Some agencies are also charged with the responsibility to approve products before they come on the market.¹⁰ Approval is often based on imprecise standards set by statute or regulation, with the agency filling gaps in the standards on a case-by-case basis¹¹ or by interpretive rule or policy statement.¹² At times agencies regulate ex post by monitoring industry conduct and ordering a regulated entity to cease and desist from conduct that the agency determines to be contrary to statutory or regulatory standards.¹³ Regardless of how an agency sets initial standards, it usually has significant enforcement discretion that allows it to refrain from penalizing an entity that has transgressed an agency standard. To the extent enforcement discretion is exercised in accordance with predictable criteria, it modifies any regulatory standard because those criteria define the conduct that will trigger a regulatory response.¹⁴

Tort suits, like agency regulatory action, come in a variety of forms and can develop in a variety of manners. Some suits result from isolated events that cause the conduct of one person to harm

9. See 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 6.2, at 306 (4th ed. 2002).

10. The FDA (Food and Drug Administration) has recently been highlighted as an agency with such authority in several recent Supreme Court preemption decisions. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 87 (2d Cir. 2006), *aff'd per curiam* *Warner-Lambert & Co. v. Kent*, 552 U.S. 440 (2008) (evenly divided court); *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009); see also Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–99 (2006).

11. See *SEC v. Chenery*, 332 U.S. 194, 201–03 (1947) (approving SEC authority to establish policy by adjudication as well as rulemaking).

12. See Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 808 (2001) [hereinafter Strauss, *Publication Rules*]. The extent to which interpretive rules and statements of policy have “legal effect” is controversial, although it is clear that they do not have the same binding force of law of legislative rules. See Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1315 (1992).

13. See, e.g., 15 U.S.C. § 45(b) (2006) (authorizing the Federal Trade Commission to order a company to cease and desist from unfair trade practices).

14. See Jeannette L. Austin, Comment, *The Rise of Citizen-Suit Enforcement in Environmental Law: Reconciling Private and Public Attorneys General*, 81 NW. U. L. REV. 220, 234–35 (1987) (articulating a sophisticated view of administrative law in which “[e]nforcement efforts . . . are an integral part of the policymaking process”); cf. Matthew C. Stephenson, *Public Regulation Of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 VA. L. REV. 93, 116 (2005) (noting that agencies often adopt overly broad regulations and use enforcement discretion to tailor them to optimize the social goals of the agency’s regulatory program).

another in a manner that is unique to their precise interaction;¹⁵ others may involve isolated incidents that injure numerous people.¹⁶ Of late, tort suits that have generated the most controversy about preemptive regulation have been products liability cases—based on injuries, either realized or latent, caused by the use of a product which may be a good or a service.¹⁷ Injuries in such cases are traceable to similar causes and threaten similar potential injuries to each victim.¹⁸

Along another dimension, tort suits can go to trial where a jury ultimately may decide whether the injurers' conduct was unreasonable, thereby establishing the standard of care to the extent the case provides controlling or persuasive precedent.¹⁹ Alternatively, suits can settle, in which case the attorneys play a more significant role in determining what conduct is reasonable and the cost the defendant bears for its actions.²⁰ To be sure, the strength of the attorneys' positions will depend on their predictions of how a jury is

15. These correspond to typical tort suits, like automobile accidents. See Byron G. Stier, *Resolving the Class Action Crisis: Mass Tort Litigation as Network*, 2005 UTAH L. REV. 863, 932–33 (distinguishing the typical tort involving an automobile accident from mass tort cases).

16. See, e.g., *Arce v. Burrow*, 958 S.W.2d 239, 243 (Tex. App. 1997) (stating that the case involved a plant explosion killing 23 people and injuring hundreds), *aff'd in part, rev'd in part*, *Burrow v. Arce*, 997 S.W.2d 229 (Tex. 1999) (remanded to trial court for determination of the existence of damages).

17. The Supreme Court has decided ten products liability preemption cases since 1992: *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Warner-Lambert & Co. v. Kent*, 552 U.S. 440 (2008); *Bates v. Dow Agrosciences LLC.*, 544 U.S. 431 (2005); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

18. For a description of the various types of mass tort suits, see L. Elizabeth Chamblee, *Unsettling Efficiency: When Non-Class Aggregation of Mass Torts Creates Second-Class Settlements*, 65 LA. L. REV. 157, 164–70 (2004).

19. Cf. W. Kip Viscusi et al., *Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1467–68 (“Application of broad liability rules and the application of 20-20 hindsight often places juries in the position of second guessing the FDA on the types of warnings that should be provided with prescription drug products and which products should be marketed.”).

20. See RICHARD A. NAGAREDA, *MASS TORTS IN A WORLD OF SETTLEMENT* 219–33 (2007) (describing how lawyers use the pathologies of settlement in class actions strategically, and how that influences the resulting settlements); Guy Halfteck, *Legislative Threats*, 61 STAN L. REV. 629, 643–45, nn.56–57 (2008) (describing the traditional view of litigation as regulation, which the author ultimately questions).

likely to come out were the case to proceed to trial.²¹ In that sense, the attorneys' determination of reasonableness should track those that would have been made by juries. But there are a host of other factors such as the cost of litigation facing each side, technical questions of procedure, and predictions about the extent of liability and how the remedy will be allocated among plaintiffs, all of which bear on the ultimate settlement of the matter.²²

Judges also can considerably influence whether a product liability suit succeeds or fails, or more significantly in the context of aggregated claims, whether it settles and on what terms.²³ Judges rule on outcome-determinative motions such as those for dismissal for failure to state a claim or summary judgment. These rulings allow them direct input into determining the standard of care for the defendant in a particular context. Judges also decide whether to certify a class, which greatly affects the potential liability threat faced by the defendant and thereby influences the likelihood that the defendant will settle.²⁴

Also, the choice between agencies and courts arises in the context where an agency has already acted, thereby setting some default standard of care. The question then is whether to allow courts to assess the reasonableness of industry conduct that has been approved by, or has complied with, the standards set by the relevant agency. When evaluating the institutional competence of the tort system, I therefore assume that the courts will have the information generated by the prior regulatory action.²⁵ Regulators, however, may or may not have information generated by tort suits depending on whether such suits have been preempted, or whether the cases have settled under agreements that restrict access to information. Aside from these assumptions, it is important to understand that

21. See NAGAREDA, *supra* note 20, at 14–15 (noting that for a mass tort to develop to a stage where defendants are apt to settle requires that plaintiffs' attorneys have a credible threat to prevail in individual cases).

22. See Roger C. Crampton, *Individualized Justice, Mass Torts, and "Settlement Class Actions": An Introduction*, 80 CORNELL L. REV. 811, 822 (1995).

23. See NAGAREDA, *supra* note 20, at 7 (stating that the prospect of settlement turns judges "from neutral umpires at trial to 'managerial' figures who oversee deals and administer their implementation over time").

24. See Robert G. Bone, *Securing the Normative Foundations of Litigation Reform*, 86 B.U. L. REV. 1155, 1169 (2006).

25. This may not be true if the information within the agency is deemed a trade secret or otherwise within an exception to the Freedom of Information Act. See Gardiner Harris, *Drug Agency May Reveal More Data on Actions*, N.Y. TIMES, June 2, 2009, at A10 (reporting on establishment of a task force to address FDA policy of withholding drug safety information that drug manufacturers claim to be trade secrets).

regulations always provide a floor for the standard of care. Allowing tort suits leaves the ultimate regulatory standard to the common law process only for conduct above the regulatory floor.²⁶

There are numerous potential benefits to authorizing agencies to preempt by regulation. As described below, they include: institutional advantages of agencies in setting an efficient level of care; reduction in uncertainty that could otherwise discourage production of useful products; national uniformity, which can reduce overall costs of production; prevention of states from cost exporting; and transparency and political accountability.

A. *Setting the Standard of Care*

Regardless of the precise criteria one advocates for setting the standard of care applicable to producers of goods and services, the incremental costs and benefits will have a bearing on the optimal level of care. Under either a negligence or regulatory standard that results in violators bearing significant costs, the standard of care provides a strong economic signal of the level of care for a producer. If that standard is set at a point other than where the marginal cost of care equals the marginal benefit from care—however society chooses to evaluate those costs and benefits—then producers will face a strong economic incentive to invest in an inefficient amount of care.²⁷ Under a strict liability system, the producer internalizes both the costs and benefits of care. Therefore, the incentive it faces to invest in care will depend on the marginal cost versus the liability that will be created by limiting care. As such, the manufacturer's level of diligence will depend on the regulator's or jury's assessment of the compensable costs of accidents.²⁸ There are reasons to expect that agencies will provide more accurate signals to manufacturers about their optimal level of care. Agency staff members come from professions that are often trained in matters relating to the industry they regulate.²⁹ Juries, however, are not only untrained but subject to biases that tend to overinflate the costs of accidents and understate the costs of care.³⁰

26. Richard A. Epstein & Michael S. Greve, *Conclusion: Preemption Doctrine and Its Limits*, in *FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS* 309, 311 (Richard A. Epstein & Michael S. Greve, eds., 2007).

27. A negligence standard, however, will be fairly insensitive to the accuracy of the assessment of damages. See ROBERT COOTER & THOMAS ULEN, *LAW & ECONOMICS* 353–56 (5th ed. 2008); Josh Teitelbaum, *A Unilateral Accident Model under Ambiguity*, 36 J. LEG. STUD. 431, 459–60 (2007).

28. See COOTER & ULEN, *supra* note 27, at 338–41.

29. See B. GUY PETERS, *THE POLITICS OF BUREAUCRACY* 96 (4th ed. 1995).

30. See *infra* notes 35–39 and accompanying text.

Agency staff members have knowledge and experience that make them superior to juries in evaluating the harms likely to be caused by provision of a product or service and the costs of forcing entities to meet a particular level of care. Agencies employ professionals specialized in predicting the effects of products, or byproducts of their use, at various points along the chain of causation. These employees have no direct stake in the ultimate standard of care that is adopted by rule.³¹ Moreover, they are capable of learning about a problem and reaching fairly accurate conclusions about costs and benefits relatively quickly.³² The tort system, in contrast, uses an adversarial process that has been criticized for allowing hired guns to confuse even fairly accepted issues of scientific fact.³³ Moreover, the tort system often sets the standard of care by looking at how those other than the defendant have acted in similar situations, which sets up a feedback loop that can induce the establishment of non-optimal standards.³⁴

In addition, juries have been accused of caprice and bias in placing dollar values on life and health.³⁵ In part, this may stem

31. See Mark Seidenfeld, *Why Agencies Act: A Reassessment of the Ossification Critique of Judicial Review*, 70 OHIO ST. L.J. 251, 268–81 (2009) [hereinafter Seidenfeld, *Why Agencies Act*].

32. See Peter H. Schuck, *Some Reflections on the Future of Mass Torts*, 12 CONN. INS. L.J. 505, 511–12 (2006).

33. See, e.g., JOSEPH SANDERS, *BENEDICTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION* 110–15, 195–97 (1998); Susan Haack, *What's Wrong with Litigation-Driven Science? An Essay in Legal Epistemology*, 38 SETON HALL L. REV. 1053, 1054 (2008); cf. E. Donald Elliott, *Toward Incentive Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U. L. REV. 487, 489 (1989) (describing how clinical ecologists' testimony about causation of harm from exposure to minute quantities of a wide range of chemicals has unduly influenced toxic tort litigation).

34. See James Gibson, *Doctrinal Feedback and (Un)Reasonable Care*, 94 VA. L. REV. 1641, 1653 (2008) (stating that “a legal standard that defers to custom can create systemic departures from efficient behavior and then allow those departures to infect custom”).

35. See Mark Geistfeld, *Constitutional Tort Reform*, 38 LOY. L.A. L. REV. 1093, 1106–07 (2005) (reporting that jury awards of pain and suffering are aptly criticized as “subjective, unpredictable and substantial”); Lars Noah, *Comfortably Numb: Medicalizing (and Mitigating) Pain-And-Suffering Damages*, 42 U. MICH. J. L. REFORM 431, 442–44 (2009). *But cf.* Deborah R. Hensler, *Jurors in the Material World: Putting Tort Verdicts in Their Social Context*, 13 ROGER WILLIAMS U. L. REV. 8, 27–28 (2008) (noting that jury awards for physical injuries in products liability cases are not particularly large compared to salaries of corporate executives). Without opining on the propriety of huge compensation packages for corporate executives, the victims of products liability most certainly would not have generated increases in social wealth anywhere near the dollar values reported in Professor Hensler's survey of jury awards in product liability cases.

from an offer-asking price conundrum.³⁶ The tort system generally seeks to compensate the victim to the extent that he is indifferent between receiving damages and not having been injured by the defendant's conduct.³⁷ This essentially requires that the plaintiff be awarded damages equal to the amount of money he would require to allow the defendant to injure him.³⁸ But this may be a far greater amount than the actual total wealth the individual would ever generate even if he was never injured. As such, it is as if each healthy individual has a potentially infinite reservoir of value greater than the earnings he will actually create by his labors. Tortious conduct depletes this reservoir and, accordingly, juries require tortfeasors to replenish it.³⁹ But the actual money that is awarded must come from somewhere. This can put a significant strain on society, particularly, on producers of products that create risks of harm and must generate dollars to pay claims. I do not mean to imply that agencies act in an ideal manner when putting an implicit value on safety when setting standards of care.⁴⁰ Analyses of the costs and benefits of regulation have revealed that there is a wide disparity between the implicit value of a life under different regulatory schemes and, under some schemes, these values may be as high as the jury awards that capture the attention of critics of the

36. The offer-asking price is "the amount one would be willing to pay for something given one's existing wealth versus the amount one would be willing to accept to give up something to another." Joseph William Singer, *Normative Methods for Lawyers*, 56 *UCLA L. REV.* 899, 918 (2009).

37. See Heidi M. Hurd, *Death to Rapists: A Comment on Kennedy v. Louisiana*, 6 *OHIO ST. J. CRIM. L.* 351, 362 (2008) (stating that in principle, tort law fixes damages at the point where the plaintiff would have been indifferent "between the harm done to her and a given cash payment").

38. See Jennifer Arlen, Note, *An Economic Analysis of Tort Damages for Wrongful Death*, 60 *N.Y.U. L. REV.* 1113, 1119–20, 1124 (1985) (noting the problems caused by the asking-offer price differential in wrongful death cases).

39. The reservoir idea is similar to the quantum theory concept of the electron which finds that a vacuum is comprised of an infinite number of electrons filling energy states up to a certain level that characterizes the vacuum. When a particle gets excited out of one of these base states, the result is the creation of an electron/positron pair. The theory works well, but essentially requires a renormalization of the energy in the universe to subtract off the energy of the infinite number of particles in the base states. See P.A.M. DIRAC, *THE PRINCIPLES OF QUANTUM MECHANICS* 273–75, 295–96 (4th ed. 1958). The jury when awarding damages essentially never fully subtracts off the virtually infinite wealth each individual enjoys simply by living in a healthy state.

40. See STEPHEN BREYER, *BREAKING THE VICIOUS CYCLE: TOWARD EFFECTIVE RISK REGULATION* 21 (1993) (noting that "agencies use different methods for estimating the effects of their regulations").

tort system.⁴¹ But, at least regulatory programs are not committed to a compensation principle that assumes a level of personal wealth that is inconsistent with the actual ability of individuals to generate wealth.

Another problem that plagues the tort system is the fact that once liability is imposed, the damage award often fails to take into account harms that would occur even if the defendant never put the product or service on the market. For example, suppose a plaintiff is suffering from shock and is prescribed a drug to maintain his blood pressure at a level that reduces his risk of dying from the shock. Suppose further that the manufacturer knows and does not reveal that some individuals overreact to the drug and risk vascular constriction that might threaten some of their extremities. It turns out that the plaintiff is one of those individuals, and the drug causes him to lose the last digit of one of his fingers. He sues, claiming that the drug company was negligent in failing to warn of the potential hazards of the drug. He may win his suit, in which case he would receive damages equal to the amount a jury determines sufficient to compensate him for the loss of his fingertip.⁴² It may well be, however, that without the drug, he would have died, but the tort system does not subtract from its damage award the value the drug provided by increasing the chance of his survival. In contrast, an agency evaluating the costs and benefits of the drug will explicitly consider the value of lives it is expected to save.⁴³

One might counter that the market implicitly takes the value of the drug into account. If there is no equivalent drug without the

41. *See id.* at 22 (reporting that the value that regulators implicitly attach to a statistical life vary from about \$100,000 to \$125 million). *But see* CASS R. SUNSTEIN, *THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION* 77 (2002) (reporting that agencies' explicit valuation of a life, used in CBA's required for major rules varies from \$1.5 to \$6.1 million). The difference between these figures may reflect that agency programs that save lives provide other benefits as well, so that a simple comparison of the cost of the program to lives saved may not represent an agency's valuation of a life saved.

42. Essentially, the problem is the converse of the controversy surrounding the "lost chance" tort doctrine. Under that doctrine, a tortfeasor pays the full cost of injury even though it only increased the probability that the injury would occur. *See* Todd S. Aagaard, Note, *Identifying And Valuing the Injury in Lost Chance Cases*, 96 MICH. L. REV. 1335, 1351 (1998). The problem I identify results from the tortfeasor's conduct being charged with all the harm it causes but not being credited with benefits it bestows.

43. *See* Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 77 (1995) (reporting that the FDA calculated benefits from drugs it evaluated by using a range between \$1.5 to \$3.0 million per life the drug was anticipated to save).

same potential side effects, and the tort system holds the manufacturer liable, then the manufacturer should be able to price the drug to cover the negative costs of the injuries it causes because of the great positive value it provides to its users. But markets do not work perfectly and consumers are not always rational, especially when it comes to actions to which they attribute subsequent harm.⁴⁴ First, consumers usually will not have sufficient information to determine the value of a product that helps prevent injuries or diseases. Second, as I just discussed, damage awards reflect an asking price that is above the price consumers are willing to offer for added safety and may reflect a premium for insurance that consumers do not wish to purchase.⁴⁵ Thus, profits from sales of a product or service may not cover tort liability even if its availability increases social wealth. Third, a manufacturer may decide not to continue producing a product even if it provides net benefits to society because consumers often overreact to fears of potential harm from a product, especially when that harm has been publicized due to a high profile tort suit.⁴⁶ This is of special concern when a tort claim is based on a manufacturer's failure to warn adequately about risks created by a product.⁴⁷ Jurors presented with the facts of a particular case are apt to focus on whether the warning was sufficient to discourage use by a person for whom risk from the product was great. Jurors are unlikely to consider situations not before them, such as when the warning might have discouraged use by a person who would have benefited from the product. Unlike juries, regulators know to

44. See, e.g., Ilana Ritov & Jonathon Baron, *Reluctance to Vaccinate: Omission Bias and Ambiguity*, 3 J. BEHAV. DECISION MAKING 263, 275 (1990) (reporting that parents say they would not vaccinate their children against an imminent epidemic because of a risk that the vaccine might kill their children, even if the risk of death from the vaccine is less than from the disease).

45. Thus, critics of products liability note that such liability essentially forces users of a product to pay for insurance that compensates for pain and suffering and other non-pecuniary harms that people rationally do not insure against. See Robert Cooter, *Towards a Market in Unmatured Tort Claims*, 75 VA. L. REV. 383, 391-92 (1989); George L. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1547, 1553 (1987).

46. Although peer-reviewed analyses of the morning sickness drug Bendectin found the drug to be effective and no evidence that the drug increases the risk of birth defects, its manufacturer took the drug off the market in response to the outcome of tort suits. See SANDERS, *supra* note 33, at 19-20, 61.

47. See W. KIP VISCUSI & WESLEY A. MAGAT, LEARNING ABOUT RISK: CONSUMER AND WORKER RESPONSES TO HAZARD INFORMATION 96 (1987); Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 ECONOMETRICA 263, 263-73 (1979) (discussing how consumers overweigh the risks of losses); W. Kip Viscusi & Richard J. Zeckhauser, *Hazard Communication: Warnings and Risk*, 545 ANNALS AM. ACAD. POL. & SOC. SCI. 106, 111 (1996).

assess all the costs of a warning, including the likelihood that warnings may discourage use that would provide net benefits.⁴⁸ Thus, regulators can modify the warning to minimize this problem. Fourth, for some products such as vaccines against easily transmitted diseases that do not work perfectly, there is an external public benefit provided by each individual who gets vaccinated. The more people who get vaccinated, the less likely everyone is to be exposed to the disease and therefore to contract the disease if the vaccine happens not to be effective for them. In that situation, the tort system and the market may drive the vaccine maker out of business even though the vaccine provides significant net benefits to society.

The over-deterrence that may be caused when tort actions are filed in response to alleged injury may be counter-balanced by the likelihood that in many situations in which producers may fail to take reasonable care, they will still escape suit. A person injured by a product may have to expend significant resources to learn that the producer failed to take adequate care or that use of the product likely caused him injury.⁴⁹ There are also costs to bringing suit even once the victim learns this information.⁵⁰ Such transaction costs pose less of a barrier if victims can band together to sue. Recent changes to federal law, however, may have significantly increased the difficulty of getting a national product liability class action certified.⁵¹ Moreover, for some mass tort claims, coordinat-

48. *See, e.g.*, Brief for the United States as Amici Curiae Supporting Defendant-Appellee and Cross-Appellant, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2001) (Nos. 02-55372, 02-55498, at 23–24) (making the FDA’s argument for pre-emption—that a stronger warning on the drug Zolofit would be non-optimal because it would unreasonably discourage use).

49. *See infra* note 50.

50. *See* Jeremy D. Fraiberg & Michael J. Trebilcock, *Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform*, 43 *MCGILL L.J.* 835, 840 (1998). For a detailed discussion of the impediments to litigation, see DON DEWEES, DAVID DUFF & MICHAEL TREBILCOCK, *EXPLORING THE DOMAIN OF ACCIDENT LAW: TAKING THE FACTS SERIOUSLY* (1996).

51. The Class Action Fairness Act (CAFA) generally allows removal to federal court of certain class claims with minimal diversity. *See* 28 U.S.C. § 1332(d)(2) (2006) (granting original jurisdiction to federal courts for certain class actions with minimal diversity and more than \$5 million in controversy). Any significant national class action will therefore be removable to federal court. CAFA, however, did not alter the preexisting choice of law regime, which leads to the potential that individual plaintiffs’ claims may be governed by the law in the state in which the injury or transaction occurred. This effectively means that the law will differ for plaintiffs from different states, which in turn may render the class action unmanageable. *See* Byron G. Stier, *Resolving the Class Action Crisis: Mass Tort Litigation as Network*, 2005 *UTAH L. REV.* 863, 883–89 (2005). For a discussion of the possible effects of CAFA on choice of law in class actions, see generally Samuel Issacharoff,

ing the trial of numerous independent cases may prove prohibitively burdensome.⁵²

If in fact the difficulties of bringing tort actions discourage them except when a producer engages in a blatant dereliction of the duty to exercise care, then there is little detriment to allowing tort suits as a backup to regulation. Torts suits will then only be brought in those cases where regulation proves to have grossly mis-specified the standard of care. This is precisely when such suits will have a salutary effect. It may be, however, that the ability of a lawyer to overcome the barriers to mass tort actions will depend not only on the egregiousness of the defendant's conduct, but also on such factors as the saliency of the injuries, the extent to which easily obtained data from the regulatory agency shows a causal connection between use of the product and injury—even if such use still does not explain most of the injuries—and the extent to which the producer has an interest in keeping aspects of its conduct secret. The problem with the under-deterrence argument is that once a lawyer can credibly threaten class certification or a multitude of independent suits in which the issue of liability poses identical factual issues, he will be better able to persuade the producer to settle, usually for more than the expected value that would result from going to trial.⁵³ A priori, it is not clear how strongly failure of regulation to prevent grossly inadequate care by a producer will correlate with a credible threat of a potentially ruinous tort suit. In short, whether allowing torts as a backup to regulation will beneficially influence the conduct of producers depends on the precise regulation at issue and the conduct it means to induce.

B. Certainty

Producers prefer certainty for at least two reasons: first, they are risk averse, and second, they seek to protect reliance interests. Regulations by themselves tend to serve both interests well. Once a regulation is adopted it remains the binding standard of conduct until it is repealed or amended by the agency or overridden by stat-

Settled Expectations in a World of Unsettled Law: Choice of Law After the Class Action Fairness Act, 106 COLUM. L. REV. 1839 (2006).

52. See Elizabeth Chamblee Burch, *Litigating Groups*, 61 ALA. L. REV. 1, 16 (2009) (noting the problems of “disunity” that plaintiffs face in organizing aggregate non-class action litigation).

53. The potential for plaintiffs' attorneys to extract greater value than the expected value from trial results from the different strategic interests of plaintiffs and defense lawyers with respect to the risk of going to trial. Chris Guthrie, *Framing Frivolous Litigation: A Psychological Theory*, 67 U. CHI. L. REV. 163, 169 (2000).

ute. For matters in which producers have significant reliance interests, it is likely to take several years for an agency to amend or repeal a regulation.⁵⁴ Agencies can react by amending rules more quickly, however, when post-adoption events clearly demonstrate that a regulation is counterproductive.⁵⁵ Sometimes regulations are far from pellucid and agencies give meaning to them by subsequent interpretation or application.⁵⁶ Interpretations issued outside of agency adjudications can be adopted without prior notice and procedure.⁵⁷ Once adopted, however, they only apply prospectively.⁵⁸ An agency can fill in the meaning of a regulation by applying it to a particular set of facts in an adjudication, but will be unable to impose liability or fines on a regulated entity unless that entity was on notice at least that the rule could reasonably be read to prohibit the conduct in which it engaged.⁵⁹ The worst case scenario for regulatory interference with reliance interests occurs when a producer invests significant resources in developing a product it thinks will meet regulatory standards, only to find after development that an agency is unwilling to approve the product.⁶⁰ This threatens significant loss of investment, but still leads to a fairly cer-

54. Amendment or repeal requires that the agency go through a full rulemaking proceeding, which for contested rules generally takes several years. See Cornelius M. Kerwin & Scott R. Furlong, *Time and Rulemaking: An Empirical Test of Theory*, 2 J. PUB. ADMIN. RES. & THEORY 113, 134 (1992) (reporting an average of 3 years from the time a rulemaking entered the Environmental Protection Agency's (EPA) regulatory development management system and time it was finally adopted).

55. See Michael Kolber, *Rulemaking without Rules: An Empirical Study of Direct Final Rulemaking*, 72 ALB. L. REV. 79, 82–83 (2009) (describing how the FDA has used “direct final rulemaking” to expedite the rulemaking process for some rules, but also how the agency has improperly attempted to get controversial rules approved without meaningful comment using this approach).

56. See, e.g., *Air Transp. Ass'n of Am. v. F.A.A.*, 291 F.3d 49, 53–54 (D.C. Cir. 2002) (clarifying that a regulation limiting maximum flight times for commercial airline crew members required airlines to use expected flight times based on actual conditions on the day of the flight rather than scheduled flight times). Agency interpretations of their own regulations enjoy great deference on judicial review. See *Auer v. Robbins*, 519 U.S. 452, 461 (1997); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945) (“[T]he administrative interpretation . . . [is] of controlling weight unless it is plainly erroneous or inconsistent with the regulation.”).

57. 5 U.S.C. § 553(b) (2006).

58. Such interpretations are rules under the APA, and hence apply prospectively. 5 U.S.C. § 551(4) (2006).

59. See *Epilepsy Found. of Ne. Ohio v. N.L.R.B.*, 268 F.3d 1095, 1102–03 (D.C. Cir. 2001).

60. Often the preemption question arises when an agency has to approve a product before it is sold, e.g., FDA approval of drugs. But even after an agency approves the product, the agency usually has authority to continue monitoring the

tain outcome after the agency decision: If the product is approved the producer can market it; if it is not approved, the producer cannot market it.

Tort suits, in contrast, create significant potential to interfere with reliance interests and to generate continuing uncertainty about the costs a producer will incur. The very nature of tort law requires suit after the injury has occurred. By necessity, it takes an ex post perspective on the conduct at issue when assessing whether it was reasonable.⁶¹ The availability of class actions and other mechanisms for consolidating claims allows tort suits to be settled en masse helping to create certainty of outcome after the alleged injury occurs.⁶² Hence, even tort law may allow for considerable future certainty. But it does so well after the producer has made significant investment in the product, and most importantly after the producer has already sold the product, thereby incurring potential liability. Tort law's potential disruption of reliance interests occurs even if tort law is merely a backup to regulation. Therefore, without preemption, tort law can threaten to destroy much of the certainty that regulation creates.

C. *Uniformity and State Cost Exporting*

Another concern of producers is the prospect of having to comply with a multitude of conflicting state standards imposed by the various state tort systems. Faced with conflicting standards of care, producers who wish to avoid liability have no choice but to differentiate their products to meet the standards of each jurisdiction or forbear from participating in some markets.⁶³

This concern about state standards that actually conflict—standards such that compliance with one means non-compliance with the other—does not arise in situations where the sole issue is how much care to take rather than the precise form in which care must

product and to order the producer to cease marketing it if the agency finds that the product fails to meet governing safety standards.

61. See Jeffrey J. Rachlinski, *Regulating in Foresight Versus Judging Liability in Hindsight: The Case of Tobacco*, 33 GA. L. REV. 813, 824 (1999).

62. See Samuel Issacharoff & Richard A. Nagareda, *Class Settlements Under Attack*, 156 U. PA. L. REV. 1649, 1651 (2008).

63. Producers can choose to market their product and pay damages for the violation of state tort standards. See Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1138 (2007). In many cases, however, this is not feasible because the cost of the product will not be sufficient to cover the liability plus the costs of resolving claims. See *supra* notes 35–39 and accompanying text.

be exercised.⁶⁴ Thus, the nature of the alleged violation of the duty of care greatly affects whether uniformity is an issue. In addition, the costs of producing products that vary state by state will differ depending on the product. For example, the cost of modifying the production lines for automobiles to meet standards of individual states would seem, at least on first reflection, to be much greater than the cost of labeling a drug to meet state by state differences regarding warnings of side effects or dangers.

Nonetheless, even state-by-state standards that simply hinge on the level of care create potential problems because manufacturers can avoid the costs of non-uniformity only by producing products that comply with the most stringent state standard. This essentially allows the tort system in a single state to set a national standard of care. Assuming that the standards set by the states vary around the actual optimal level of care, the fact that the most stringent standard will prevail effectively results in an overly strict standard of care. This tendency toward strict tort standards is exacerbated by the potential for juries to relate more to their “neighbor” plaintiffs rather than to out-of-state commercial entities that defend the injuring product.⁶⁵ Juries are unlikely to understand that imposing liability will raise the cost of the product to all who use it and, in extreme cases, might cause the producer to pull the product from the market altogether. Moreover, the fact that trial judges in many states are elected could further magnify the over-regulation tendency because judges may feel pressure to deliver verdicts in favor of local citizens.⁶⁶

64. If the issue is one of how stringent a standard is, then a manufacturer can meet all standards by meeting the most stringent one. Technically, the various standards do not conflict.

65. See Laura G. Dooley, *National Juries for National Cases: Preserving Citizen Participation in Large-Scale Litigation*, 83 N.Y.U. L. REV. 411, 437 (2008) (proposing a national jury system to overcome local nature of local jury values). *But cf.* Edward A. Purcell, Jr., *The Class Action Fairness Act in Perspective: The Old and The New in Federal Jurisdictional Reform*, 156 U. PA. L. REV. 1823, 1848 (2008) (“Except in the most obvious and egregious cases, charges of ‘bias’ and ‘local prejudice’ were exceptionally difficult—if not impossible—to prove.”).

66. See RICHARD NEELY, *THE PRODUCT LIABILITY MESS: HOW BUSINESS CAN BE RESCUED FROM THE POLITICS OF STATE COURTS* 62 (1988) (stating that where judges are elected, “it should be obvious that the in-state local plaintiff, his witnesses, and his friends, can all vote for the judge, while the out-of-state defendant can’t even be relied upon to send a campaign contribution”); Alexander Tabarrok & Eric Helland, *Court Politics: The Political Economy of Tort Awards*, 42 J.L. & ECON. 157, 158–59 (1999) (positing that voters will support judges who redistribute income to in-state plaintiffs from out-of-state defendants); *id.* at 186 (reporting strong empirical evidence that where judges are elected awards against out-of-state plaintiffs are

D. Transparency

The transparency of agency standard setting depends on whether the agency proceeds by rulemaking, adjudication or simply by ad hoc enforcement policy. Agency rulemaking is fairly transparent. An agency generally must use notice-and-comment rulemaking to adopt, amend or repeal a legislative rule.⁶⁷ Critics of administrative government have objected that the agency often is committed to the basic framework of a rule even before it publishes the Notice of Proposed Rulemaking (NOPR) that triggers the notice-and-comment process.⁶⁸ Current executive orders, however, require agencies to file regulatory plans that reveal intentions to adopt rules to address particular problems well in advance of the actual development of proposed rules.⁶⁹ Also, the structure of an agency rulemaking team helps ensure that groups with an interest in the subject of the rulemaking are informed about and provide input into the NOPR.⁷⁰ The transparency of the rulemaking process is further enhanced by judicially imposed requirements that an agency reveal in the NOPR any information on which it relies in developing the rulemaking proposal.⁷¹ Ultimately, judicial review requires the agency to explain how it reached its decision to adopt a rule given relevant statutory provisions and data.⁷²

Outside of the notice-and-comment rulemaking paradigm, transparency of agency standard setting declines, potentially precipitously. Standards that are announced in agency guidance docu-

much higher than those against in-state plaintiffs). It is informative that even Tabarrok and Helland fail to mention that the bias against out of state producers imposes costs on in state users of products. *Cf.* Saul Levmore, *Interstate Exploitation and Judicial Intervention*, 69 VA. L. REV. 563, 570–73 (1983) (distinguishing between state exploitation of other states, which create inefficiencies by exporting costs to other states, and state interferences with activities in other states, which may create inefficiencies, but do so at least partially at the expense of the adopting state).

67. 5 U.S.C. § 553 (2006).

68. *See* Stephanie Stern, *Cognitive Consistency: Theory Maintenance and Administrative Rulemaking*, 63 U. PITT. L. REV. 589, 600 (2002) (presenting evidence of agency “lock-in” to a rule once it is proposed).

69. Exec. Order. No. 12,866, § 4(c), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

70. *See* Brian Galle & Mark Seidenfeld, *Administrative Law’s Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933, 1956–57 (2008) [hereinafter Galle & Seidenfeld, *Administrative Law’s Federalism*].

71. *See* Portland Cement Ass’n v. Ruckelshaus, 486 F.2d 375, 392–93 (D.C. Cir. 1973); Engine Mfrs. Ass’n v. EPA, 20 F.3d 1177, 1181 (D.C. Cir. 1994); Am. Med. Ass’n v. Reno, 57 F.3d 1129, 1132–33 (D.C. Cir. 1995).

72. *See* Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483, 491–92 (1997) [hereinafter Seidenfeld, *Demystifying Deossification*].

ments must be published in the Federal Register if the agency is to rely on them,⁷³ which affords public notice before they are applied. Such standards are not rules with the force of law, however, so courts often find that these standards are not final agency action or are unripe for review.⁷⁴ Hence, standards often evade judicial review that would force the agency to reveal the information on which it relied in formulating them. Standards that are created via approval of specific products or enforcement actions are subject to judicial review but may be sufficiently obscure to elude public notice. Such proceedings are also frequently handled by informal procedures and therefore, unlike rulemaking, are less likely to be subject to scrutiny by staff members who bring varying professional perspectives.⁷⁵

To the extent enforcement affects regulatory standards, the information and criteria underlying agency policy may be far from clear. Agency personnel may not apply enforcement criteria consistently and the agency often does not reveal what drives decisions not to prosecute a violation of a regulation or statute unless the enforcement criteria are incorporated into a guidance document.⁷⁶ Nor must an agency explain its decision to decline prosecuting an individual violation because the Administrative Procedure Act (APA) exempts such decisions from judicial review.⁷⁷ Hence, enforcement policy is likely to be unknown and, even if known, not explained by the agency.

At first blush, the tort system might appear more transparent than agency regulation. Trials are open to the public and transcripts are generally public records. Evidence is admitted in open court so information from which liability stems is part of the open record. But few cases get to jury trial.⁷⁸ Attorneys settle cases on

73. See 5 U.S.C. § 552 (2006).

74. Stephen M. Johnson, *Good Guidance, Good Grief!*, 72 Mo. L. Rev. 695, 712–13 (2007).

75. Cf. Seidenfeld, *Why Agencies Act*, *supra* note 31, at 272, nn.69–70 (noting that agency enforcement and application of regulations is more readily subject to capture than rulemaking in part because of decreased monitoring of those activities by others in the agency).

76. An agency may incorporate criteria into a guidance document to inform its own staff of its enforcement policies. See Strauss, *Publication Rules*, *supra* note 12, at 804–05.

77. See *Heckler v. Chaney*, 470 U.S. 821, 837–38 (1985) (holding that decisions not to prosecute an alleged regulatory violation are excepted from judicial review by the APA because such decisions are committed to agency discretion by law).

78. John Fabian Witt, *Bureaucratic Legalism, American Style: Private Bureaucratic Legalism and the Governance of the Tort System*, 56 DEPAUL L. REV. 261, 267–68 (2007).

behalf of clients and part of getting the best settlement may include sealing or even destroying information.⁷⁹ Thus, the information needed to evaluate the efficacy of standard setting done via the tort system often is not public. Even for cases that go to trial, juries do not explain the reasoning underlying their verdicts. Hence, while the evidence admitted at trial may be available to the public, the evidence on which the jurors actually relied to reach their verdict remains uncertain.

E. Accountability

Although agency members are not directly elected, their relationship with the political branches provides significant democratic accountability.⁸⁰ The President has several mechanisms to assure that he retains significant influence over agency policy. First, and probably foremost, he appoints agency heads and their assistants.⁸¹ Second, for many agencies, the President has plenary power to remove political appointees.⁸² Third, agencies need the President as an ally if they are to succeed in the annual competition for appropriations for regulatory programs.⁸³ More formally, the President has issued several executive orders that have increased the authority

79. THOMAS O. MCGARITY & WENDY E. WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH* 121 (2008) (reporting that defendants offer bonuses for settlements in which plaintiffs agree not to disclose documents that may be damaging to the defendants).

80. Although judges are elected in many states, those who are generally get elected by those in the region where they sit. This has the potential to create geographical bias in those judges who are elected.

81. U.S. CONST. art. II, § 2.

82. Although Congress has significant leeway to restrict the President's removal power, *see Morrison v. Olson*, 487 U.S. 654, 694–96 (1988), it may not be able to restrict, and to date has not restricted, the President's power to remove the heads of executive departments. *See Elena Kagan, Presidential Administration*, 114 HARV. L. REV. 2245, 2251 (2001) (distinguishing between Congress's intent with respect to Presidential control over independent and executive agencies).

83. *See* Thomas H. Hammond & Jack H. Knott, *Who Controls the Bureaucracy?: Presidential Power, Congressional Dominance, Legal Constraints, and Bureaucratic Autonomy in a Model of Multi-Institutional Policy-Making*, 12 J.L. ECON. & ORG. 119, 124 (1996) (reporting that many studies support the theory that the President plays "an agenda-setting role for congressional deliberations on agency appropriations"); Terry M. Moe, *Control and Feedback in Economic Regulation: The Case of the NLRB*, 79 AM. POL. SCI. REV. 1094, 1101 (1985) (discussing the president's influence over agencies through the use of such mechanisms as the appointment process and the agency budget).

of the White House to monitor agency policies to ensure that they are consistent with the administration's priorities.⁸⁴

Despite the increase in presidential clout,⁸⁵ Congress still retains significant means of influencing agency policy. For instance, the Senate must approve appointments of principal officers of the United States.⁸⁶ Congress also controls funding and can influence agencies directly by limiting the use of funds for programs it dislikes and indirectly by threatening to cut the overall budget of an agency.⁸⁷ Congress can also engage in oversight hearings that can embarrass an agency head and in the process sway public opinion against practices that Congress can spin as being inconsistent with basic public expectations about the agency's mandate.⁸⁸

The courts too influence the administrative state by requiring agencies to reveal the data underlying most of their regulatory actions, and to explain those actions.⁸⁹ Additionally, the reasoned decision-making requirement of the current standard for arbitrary

84. See Michael Hissam, *The Impact Of Executive Order 13,422 on Presidential Oversight of Agency Administration*, 76 GEO. WASH. L. REV. 1292, 1293–1300 (2008). President Obama recently reversed this trend, at least temporarily, by rescinding President George W. Bush's Executive Orders 13,258 and 13,422, returning the formal channels for White House monitoring of agency rulemaking to those in place under President Clinton. See Exec. Order No. 13,497, 74 Fed. Reg. 6113 (Jan 30, 2009).

85. See Kagan, *supra* note 82, at 2281–82 (detailing increased presidential influence on agency regulation in the Clinton White House); Yaniv Heled, *On Presidents, Agencies, and the Stem Cells Between Them: A Legal Analysis of President Bush's and the Federal Government's Policy on the Funding of Research Involving Human Embryonic Stem Cells*, 60 ADMIN. L. REV. 65 (2008) (describing President George W. Bush's promotion of his personal agenda regarding stem cell research).

86. U.S. CONST. art. II, § 2.

87. See Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70, at 1980 (noting Congress's influence over agencies that derives from its appropriations power).

88. See David W. Case, *The EPA's Environmental Stewardship Initiative: Attempting to Revitalize a Floundering Regulatory Reform Agenda*, 50 EMORY L.J. 1, 22–23 (2001) (describing how congressional hearings undermined the perceived legitimacy of Reagan's EPA and forced him to appoint William Ruckelshaus to head the agency); Geoffrey P. Miller, *From Compromise to Confrontation: Separation of Powers in the Reagan Era*, 57 GEO. WASH. L. REV. 401, 413–14 & n.79 (1989) (reporting on congressional hearings of Secretary of the Interior James Watt and EPA head Anne Gorsuch as attempts to get these agencies to take specific actions); David Johnston & Neil A. Lewis, *Senate Democrats Plan a Resolution on Gonzales*, N.Y. TIMES, May 18, 2007, at A16 (discussing need for Attorney General Gonzales to resign in light of information revealed and pressure put on Gonzales in Senate hearings about firing of United States Attorneys).

89. *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 49 (1983); Seidenfeld, *Demystifying Deossification*, *supra* note 72, at 498–99.

and capricious review pragmatically forces agencies to include as members of their rulemaking teams individuals from diverse professions who incorporate those perspectives into the regulatory process.⁹⁰

Although, in the federal system, courts are often viewed as the least democratically accountable branch of government,⁹¹ there are reasons to believe that they may provide some accountability for standards of care set by tort suits. Juries provide input from the ordinary person and can therefore ensure basic consistency with community norms. Being drawn directly from the populace, they also avoid undue interest group influence that can plague representative government and potentially, to a greater extent, administrative agencies. But juries are not chosen to be representative either of the polity as a whole or of groups with interests at stake in the battle to set regulatory standards. Also, most states use some electoral process for selection or retention of judges, who therefore provide some political accountability.⁹² Usually, however, they are elected by those in the region where they sit,⁹³ which can induce a parochial bias, especially when a case involves a local individual plaintiff injured by the product of a distant corporation. By contrast, agencies answer most directly to the President, who is accountable to the entire national polity.⁹⁴

90. Some of the analysis required by statute and executive order for agency rulemaking also demands that agencies include varying perspectives in the rulemaking process.

91. See Richard J. Pierce, Jr., *The Role of Constitutional and Political Theory in Administrative Law*, 64 TEX. L. REV. 469, 506 (1985) (discussing the compelling logic of describing the judiciary as the least politically accountable branch).

92. Herbert M. Kritzer, *Law Is the Mere Continuation of Politics by Different Means: American Judicial Selection in The Twenty-First Century*, 56 DEPAUL L. REV. 423, 431 (2007).

93. Mark C. Weber, *Complex Litigation and the State Courts: Constitutional and Practical Advantages of the State Forum Over the Federal Forum in Mass Tort Cases*, 21 HASTINGS CONST. L.Q. 215, 227 (1994) (noting that state judges are elected from their local districts, appellate judges and even sometimes supreme court justices are usually elected from regions).

94. See Jerry L. Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J.L. ECON. & ORG. 81, 95 (1985) (arguing that the relationship between agencies and the President along with the President's accountability to the national polity justifies delegating political decisions to agencies). See generally Peter L. Strauss, *Overseer, or "The Decider"? The President in Administrative Law*, 75 GEO. WASH. L. REV. 696 (2007) (describing the debate about whether the President's authority allows him to substitute his decision for that of the agency to which Congress delegated authority). This does not mean that agencies are not capable of acting contrary to the preferences of the national polity, but it does mean that as a

The adversarial nature of the trial process also works to exclude the voice of many who have an interest in the regulatory standard established by the tort system. By pitting injured users of a product against the producer, the tort system fails to take into account others affected by the viability of the industry. These include, most notably, non-injured users as well as diverse groups such as employees and those who live near production facilities who may benefit from economic activity generated by production. In addition, the pragmatic financial need for plaintiffs' attorneys to aggregate mass tort suits, along with defendants' interest in resolving such suits once they mature sufficiently, creates a settlement system that favors lawyers over clients, and even some victims over others.⁹⁵

II. COMPARATIVE ADVANTAGES OF ALLOWING TORT SUITS

A. *Compensation for a Moral Wrong*

Although courts are not as knowledgeable as agencies about balancing costs and benefits—the grist for setting standards of care—tort claims have the advantage of providing compensation for victims of injuries caused by a product. The tort system, however, is not the only mechanism the state could use to provide compensation. For example, the state could provide a social insurance scheme to compensate victims, funded by a general tax. It could adopt New Zealand's system for accident compensation which couples an insurance scheme with contributions tied to the number and type of injuries a producer causes.⁹⁶ Such systems use a schedule of harms from injuries caused by covered conduct and, as such, may not accurately capture the costs and benefits of a particular course of conduct. More significantly, implementing such a system would require legislative action. These systems, however, do not placate the apparent desire of the public for a requirement that the state make a finding whether the causation of harm by a producer

matter of institutional structure, they are not beholden to a geographically distinct subset of the nation for their authority.

95. NAGAREDA, *supra* note 20, at 18–20.

96. See James C. Harris, Comment, *Why the September 11th Victim Compensation Fund Proves the Case for a New Zealand-Style Comprehensive Social Insurance Plan in the United States*, 100 NW. U. L. REV. 1367, 1373–76, 1389 n.161 (2006).

was wrong and, if so, to impose the costs created by that wrong on the producer.⁹⁷

B. Incentives for Producers to Determine the Optimal Level of Care

The tort system also creates an incentive for producers themselves to determine the appropriate level of care. The advantage of the system is its ability to induce producers to make the cost-benefit calculation, given that they will likely have better information than either regulators or the courts about the costs and benefits of the product. This is especially important because increased knowledge about product risks decreases costs of care. Hence, ex ante determinations of optimal care will be based on costs that are inflated above current costs of care, and the further out one moves from the date of approval, the less accurate the ex ante standard of care becomes.⁹⁸ As I already indicated, there are reasons to believe that the tort system imposes costs that are lower than the actual costs caused by use of products, and other reasons to believe that it imposes costs that are too high.⁹⁹ Even if the system is imperfect, however, it maintains an incentive for producers to continue learning about injuries caused by their product and how to decrease the costs of preventing those injuries—an incentive that would be eliminated were producers certain not to face liability for marketing in compliance with regulation.¹⁰⁰

By internalizing the cost of injuries to the producer, the tort system can make the producer a de facto insurer for these injuries: If the product remains viable, despite the prospect of tort damage awards, the producer can price the product to include the costs of

97. See Jules L. Coleman, *The Practice of Corrective Justice*, 37 ARIZ. L. REV. 15, 28–29 (1995); Benjamin C. Zipursky, *Rights, Wrongs, and Recourse in the Law of Torts*, 51 VAND. L. REV. 1, 56 (1998).

98. See Michael G. Faure, *Insurability of Damage Caused by Climate Change: A Commentary* 155 U. PA. L. REV. 1875, 1878 (2008) (noting that standards of care must be allowed to change to reflect new technology); Steven Shavell, *Liability and the Incentive to Obtain Information About Risk*, 21 J. LEGAL STUD. 259, 259–60 (1992) (contending that ex post liability for actions already taken give manufacturers an incentive to obtain information about product risks); cf. David Rosenberg, *Class Actions for Mass Torts: Doing Individual Justice by Collective Means*, 62 IND. L.J. 561, 575–79 (1987) (rebutting arguments that tort liability will deter investment in new technology).

99. See *supra* notes 35–39 and accompanying text. In addition to reasons why the tort system may impose liability that is greater or less than the actual cost of injuries, the system may impose costs in addition to direct liability to the extent it generates notoriety about a product that causes users to avoid buying the product.

100. See Mary L. Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137, 166–67 (1995).

harm, spreading the cost among all users. In addition, through the doctrine of comparative fault, the tort system can reduce moral hazard problems.¹⁰¹

In some instances, however, the insurance scheme set up by the tort system may not be ideal. Most obviously, requiring the filing of a tort suit to get compensation is administratively expensive. In addition, the class of individuals who pay for the insurance may not be that which society would prefer as a matter of social justice. The insurance scheme spreads the cost among all product users, thereby alleviating the burden on the unlucky losers who are injured by the product. But the product users may already be the unlucky members of society who, through no fault of their own, are forced to use the potentially injurious product. In such a situation, it may be most fair to have the public bear the cost of injuries from product use. For example, consider expensive drugs used to keep those with a serious illness alive. The users of the drug are most likely already burdened by their illness, and the costs of insuring against a bad reaction to the drug would just be a further weight imposed on those unfortunate to be ill. Finally, the tort system may spread risks among product users who prefer not to pay for insurance for some injuries.¹⁰²

C. *Information Production and Monitoring*

Use of a product provides information about problems with the product that facilitate development of improvements or substitutes. Agency regulation is structured to provide incentives to develop information about product safety prior to the decision setting a safety standard or approving sale of the product. The threat of a tough standard or refusal to approve a product provides a significant incentive for producers to cooperate with regulators to provide information relevant to the initial regulatory decision. Once the agency makes its initial decision, however, a producer's incentive to cooperate is decreased. Agencies have limited resources and usu-

101. See COOTER & ULEN, *supra* note 27, at 345–46 (noting that under assumptions of perfect compensation and standards set at optimal levels, all forms of negligence result in incentives to both injurer and victim for efficient precaution); John A. E. Pottow, *Private Liability for Reckless Consumer Lending*, 1 U. ILL. L. REV. 405, 458–59 (2007) (addressing comparative fault in the context of contract law, but illustrating how comparative fault may reduce the risks of moral fault); see also Tom Baker, *On the Genealogy of Moral Hazard*, 75 TEX. L. REV. 237, 273 (1996).

102. For example, as previously noted, people do not purchase insurance for pain and suffering from injuries. See *supra* note 45.

ally a significant backlog of other matters needing attention.¹⁰³ Staff members garner recognition for getting standards adopted or drugs approved, not for revisiting actions already taken.¹⁰⁴ Hence, an agency has little incentive either at the institutional or individual level to revisit an issue it has already resolved.¹⁰⁵ As a corollary, an agency therefore has little interest in continuing to develop or monitor information about product safety once it has taken its initial regulatory action. The prospect of large awards can motivate plaintiffs and their attorneys to discover information about the risks of harm posed by a product that an agency might not have the ability or incentive to uncover.¹⁰⁶ Regulatory preemption, however, threatens to cut off discovery as an avenue for development of information that might bear on the proper standard of care.

D. Public Awareness of a Potential Problem with a Product

Tort suits for significant damages tend to generate greater publicity than all but the most salient regulatory actions. Media reports on large awards can heighten public awareness of the benefits and harms created by a product.¹⁰⁷ Public interest entrepreneurs can use the media reports to help organize members of the public to weigh in on whether a producer has acted improperly by continuing to market a product that threatens injury to users.¹⁰⁸ Even if the jury or judge is not representative of the public, the process of soliciting public reaction to tort suits and popular support for hold-

103. Thomas O. Sargentich, *The Emphasis on the Presidency in U.S. Public Law: An Essay Critiquing Presidential Administration*, 59 ADMIN. L. REV. 1, 34 (2007).

104. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 270 (stating that “individuals who promote a policy are evaluated not on whether the policy turns out to be wise but rather on whether the policy is adopted by the agency”).

105. See Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 698–700 (2007) (describing reasons why agencies may not be motivated to monitor risks created by products they regulate); *cf.* Marjorie A. Silver, *The Uses and Abuses of Informal Procedures in Federal Civil Rights Enforcement*, 55 GEO. WASH. L. REV. 482, 574–75 (1987) (noting that the limited resources of the EEOC and OCR, and their desire to eliminate backlogs, induce these agencies to inadequately monitor resolved cases).

106. See Samuel Issacharoff, *Group Litigation of Consumer Claims: Lessons from the U.S. Experience*, 34 TEX. INT’L L.J. 135, 141 (1999); Wagner, *supra* note 105, at 700–01.

107. See Robert J. MacCoun, *Media Reporting of Jury Verdicts: Is the Tail (of the Distribution) Wagging the Dog?*, 55 DEPAUL L. REV. 539, 551 (2006) (addressing both strengths and weaknesses of this view).

108. See generally Timothy D. Lytton, *Clergy Sexual Abuse Litigation: The Policymaking Role of Tort Law*, 39 CONN. L. REV. 809 (2007) (addressing the media’s effect on public discourse in relation to church sex abuse scandals).

ing a product to a higher standard of care can increase accountability of the tort system.

The decentralized nature of tort suits may also facilitate the development of a public consensus about the appropriate standard of care. Under current law, a product's safety is likely to be challenged in multiple suits rather than a single class action.¹⁰⁹ This allows repeated opportunities for development of relevant information and consideration by independent juries of issues, such as causation of injury and the blameworthiness of marketing the product, that inform the calculation of an optimal level of care. If an agency fails to generate accurate information or for some other reason gets the standard of care wrong, and tort suits are not available, then the standard will not get corrected unless the agency recognizes its error. By contrast, if a single court misses some information and sets the standard of care incorrectly, other cases are available to fill the information gap and correct the balancing of a product's costs and benefits. Thus, at least in theory, the tort system can facilitate a continuing deliberative public discourse that may ultimately generate some accepted understanding of benefits and injuries that flow from marketing the product, and some consensus about whether a producer has failed to take appropriate care.¹¹⁰

Unfortunately, heightened media attention on tort suits for large awards can also undermine the responsible setting of standards. The media has an incentive to sensationalize injuries. In addition, a plaintiffs' attorney in a product liability suit has an incentive to encourage this sensationalism because it creates a threat to the defendant, independent of the merits of the suit that might induce a settlement favorable to the plaintiffs. It also creates publicity for the attorney that might aid his career. Thus, there are strong incentives to create a distorted public portrayal of the effects of the product. Rather than deliberative public discourse, exaggerated media attention can erode trust in the information being presented which in turn undermines deliberative decision-making.¹¹¹

109. See *supra* note 51 and accompanying text.

110. Lytton, *supra* note 108, at 879.

111. See MacCoun, *supra* note 107, at 545–48, 551–62.

III. INSTITUTIONAL COMPARISON OF WHO SHOULD DECIDE WHETHER REGULATION PREEMPTS

My analysis thus far indicates that both regulatory preemption and availability of tort suits are potentially beneficial although each can also have negative consequences. Moreover, there is no set of factors that can be specified a priori which might indicate whether preemption or the availability of tort liability is likely to provide greater net social benefits in the context of injury from a particular product. Hence, the more meaningful question is: Who should decide for any given case whether preemption is warranted? The institutions that potentially can make this decision include Congress, agencies and courts. The mechanism for determining whether a particular suit is preempted follows from which institution has primary responsibility for the preemption determination.

A. Congress

Proponents of allocating to Congress primary responsibility for determining when federal regulation will preempt state law contend that preemption involves political choices and that Congress—being more deliberative, transparent, and accountable than administrative agencies and courts—is best at making those choices.¹¹² Elsewhere, Brian Galle and I have rebutted the orthodox assumption that Congress is superior with respect to these attributes, and concluded that agencies are better suited for deciding preemption issues.¹¹³ With respect to preemption of tort law, other attributes of Congress, courts and agencies reinforce that conclusion.

The complexity and particularity of the determinations that bear on the efficacy of preemption are beyond that to which Congress can pragmatically attend, especially on a regular basis.¹¹⁴ When Congress enacts a regulatory statute, it sometimes includes an explicit preemption or saving clause, but such clauses often ap-

112. See Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2111–15 (1990).

113. Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70.

114. See Lisa Schultz Bressman, *Chevron's Mistake*, 58 DUKE L.J. 549, 567 (2009); David Epstein & Sharyn O'Halloran, *Administrative Procedures, Information, and Agency Discretion*, 38 AM. J. POL. SCI. 697, 699 (1994). The limits on Congress's ability to attend to the necessary details of regulatory programs has long been a pragmatic justification for allowing Congress broad authority to delegate law-making functions to agencies. See Andrew J. Ziaja, *Hot Oil and Hot Air: The Development of the Nondelegation Doctrine Through the New Deal, a History, 1813–1944*, 35 HASTINGS CONST. L.Q. 921, 940 (2008).

ply to the entire regulatory scheme or, at best, to broad provisions within the scheme.¹¹⁵ These clauses do not include guidance about preemption that takes into account the conduct that plaintiffs allege to be tortious in a particular case.¹¹⁶ For example, a new antibiotic to treat drug-resistant bacteria might promise enormous benefits by significantly reducing the risk of contagion. These benefits inure to the public, not just the purchasers of the antibiotic, so the price of the drug does not reflect its marginal social benefit. At the same time, because such a drug may be rushed to market, it might pose a foreseeable and significant, albeit uncertain, risk of harm when approved. For such a product, preemption to encourage its development and production would appear warranted.¹¹⁷ For other drugs subject to the same approval regime, such as a new painkiller that provides moderate benefits to a small percentage of potential users but poses uncertain but potentially significant risks, preemption would be much more difficult to justify. Different products subject to a particular statutory provision may also raise different questions regarding either the benefits of non-uniformity that state tort systems might impose or the different levels of uncertainty for the risk of future harm. For example, the ability of automobiles to protect passengers in front-end collisions would seem to affect residents of different states similarly while the design of automobiles to increase traction on icy roads would be of more value in northern states than in southern ones. Preemption would be easier to justify with respect to the first safety concern than the second. To be fair, on occasion, Congress has responded to an impending threat to the public health or safety by providing guidance about potential tort liability for products developed to alleviate the threat.¹¹⁸ But in general, Congress lacks the time and

115. See e.g., Sharkey, *Products Liability Preemption*, *supra* note 3, at 461–62 (discussing the explicit preemption and savings clauses in the Motor Vehicle Safety Act of 1966).

116. See Sharkey, *Federalism Accountability*, *supra* note 2, at 2148 (saying Congress generally addresses preemption with “all-or-nothing” statutory provisions).

117. Such a drug would provide a public good, and therefore will be underproduced by the market unless subsidized by the government. MARK SEIDENFELD, *MICROECONOMIC PREDICATES TO LAW AND ECONOMICS* 65–66 (1996).

118. For example, in response to a pharmaceutical company’s unwillingness to produce vaccines against childhood diseases because of liability concerns, Congress enacted the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, 100 Stat. 3756 (codified as amended 42 U.S.C. §§ 300aa-1 to -34 (2006)). The goal of the Act was “to provide an expeditious method of compensating children who are injured because of vaccines and to make liability for vaccine manufacturers more predictable so that the supply of vaccines in the United States will be adequate.” Victor E. Schwartz & Liberty Mahshigian, *National Childhood Vaccine Injury*

incentive to focus on the differences in products at a level of detail that is needed to optimize the use of the tort system as a regulatory backdrop.

The breadth of matters Congress considers, coupled with the inertia built into the legislative process, decreases the attractiveness of Congress as the primary institution to set the bounds of regulatory preemption. These attributes preclude Congress from acting other than episodically,¹¹⁹ thus impeding its ability to react to new information about the need for tort liability. For many products, however, safety information bearing on the value of allowing tort suits is only developed or revealed after the product has reached the market.¹²⁰ If one had to wait for Congress to amend a regulatory statute to take such new information into account, the country likely would be stuck with Congress's initial determination regarding preemption, which could be far from efficient. In addition, post-marketing information can change the public's attitude about a particular product or the workings of an entire regulatory scheme. For example, the public's trust in both the medical profession—whose responsibilities include prescribing the most beneficial drugs on the market—and FDA regulators—whose job it is to keep drugs that are not safe and effective off the market—has declined markedly between the 1960s and 1990s.¹²¹ Yet Congress has not reacted by significantly amending preemption provisions that govern either medical devices or FDA approval of drugs.¹²²

Act of 1986: An Ad Hoc Remedy or a Window for the Future?, 48 OHIO ST. L.J. 387, 394 (1987).

119. See Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70, at 1980.

120. See Lyndon, *supra* note 100, at 148–50.

121. See Jonathan Todres, *Toward Healing and Restoration for All: Reframing Medical Malpractice Reform*, 39 CONN. L. REV. 667, 689 (2006); cf. Oliver Quick, *Outing Medical Errors: Questions of Trust and Responsibility*, 14 MED. L. REV. 22, 37–38 (2006) (characterizing changes in trust of the doctors as moving from “unconditional to conditional trust”).

122. With respect to medical devices, the Food, Drug, and Cosmetic Act (FDCA) includes both a clause seeming to permit state suits for liability despite compliance with an order approving a device, *see* 21 U.S.C. § 360h(d), and a clause preempting state health or effectiveness based requirements different from those imposed by the FDA, *see id.* § 360k. According to the United States Code Annotated, neither clause has been substantively amended since it was enacted as part of the Medical Device Act in 1976. With respect to approved drugs, the United States Code Annotated indicates that The FDCA has never contained any clause giving guidance on state law preemption or the availability of state tort suits for injuries caused by such drugs. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008) (noting that Congress could have, but did not, apply the preemption clause of the Medical Device Act to the entire FDCA).

My conclusion that in most instances Congress will not be well suited to determining whether a regulatory scheme should preempt tort law in the context of a particular case does not mean that Congress should never provide for preemption or, alternatively, for savings clauses allowing tort suits. Congress plays an important role in constraining agency action when the agency might otherwise pursue idiosyncratic preferences that deviate significantly from those of the polity generally.¹²³ In those instances, Congress can use the myriad means it has to influence the agency to “do the right thing.”¹²⁴ Ultimately, it may be necessary for Congress to override the agency by passing a statute explicitly mandating or prohibiting preemption. But my conclusion does imply that statutory preemption or savings clauses should be used sparingly by Congress—perhaps only when Congress believes that there are unusual circumstances indicating that the regulators cannot be trusted to decide the preemption issue to best serve the overall national interest.¹²⁵ Congress’s relatively weak competence to evaluate the wisdom of preemption in particular circumstances also suggests that courts should not read legislative intent to deny agency authority with respect to preemption of state tort law from anything less than clear statutory language.

B. Agencies

1. Agencies’ Superior Institutional Capacity to Evaluate the Need for the Availability of Tort Suits

The decision whether a particular regulatory action should preempt tort suits hinges on balancing the benefits of allowing tort suits against the detrimental impact such suits threaten. Agencies are uniquely suited among government institutions to perform such balancing. They develop knowledge about the cost structure and likely impact of potential liability on the industries that they

123. See Mark Seidenfeld, *Bending The Rules: Flexible Regulation and Constraints on Agency Discretion*, 51 ADMIN. L. REV. 429, 481 (1999).

124. See Jacob E. Gersen & Eric A. Posner, *Soft Law: Lessons from Congressional Practice*, 61 STAN. L. REV. 573, 606 (2008) (“Congress uses a range of instruments to influence administrative agencies, including restrictions on the appointment and removal of personnel, specification of substantive or procedural restrictions, appropriations, oversight hearings, and deadlines.”).

125. Such circumstances might result from an agency abdicating its regulatory responsibility, such as occurred in the EPA under President Reagan. See David W. Case, *The EPA’s Environmental Stewardship Initiative: Attempting to Revitalize a Floundering Regulatory Reform Agenda*, 50 EMORY L.J. 1, 22–23 (2001) (describing “the political embarrassment of mismanagement and scandal at the EPA under the watch of Reagan’s first EPA administrator, Anne Gorsuch”).

regulate.¹²⁶ Agencies that monitor product safety and approve products for market also often have the power to require producers to disclose potential injuries threatened by their products,¹²⁷ and may have independent knowledge about the likelihood of such injuries. Most significantly, during a rulemaking or approval process, an agency will directly face the uncertainties in the information available and will have to estimate the likely importance of such information in predicting product safety. Deliberating about the value of known information may provide the agency with some idea of the extent and importance of missing information, as well as whether experience with the product after it is marketed is likely to provide such information.

Preemption determinations may also involve a value judgment about whether and how to compensate those injured by a product. As noted above, agency rulemaking may be superior to the legislative process even with respect to deliberation, transparency and accountability. Agencies are subject to oversight by Congress and the President.¹²⁸ Simultaneously, unlike the legislature, agencies are not subject to vetogates or pragmatically limited to episodic behavior.¹²⁹ Moreover, unlike courts, agencies can be proactive and decide issues not yet presented by a dispute between particular parties. As such, agencies seem to be well suited to decide whether tort suits should be preempted.

126. Cf. Simonetti Samuels, *Interpreting Health Care Cost Containment Legislation: Good Samaritan Hospital v. Shalala and Relative Institutional Competence*, 4 SUP. CT. ECON. REV. 141, 142 (1995) (reporting how the Department of Health and Human Services developed knowledge of the health care industry as it gained experience setting limits on payments to Medicare providers).

127. Although agencies generally have such power, they may not have sufficient motivation to gather all the information they need to set an optimal standard. See Wagner, *supra* note 105, at 698–700 (describing reasons why agencies may fail to demand sufficient information on product risks from industry).

128. See generally Sidney A. Shapiro, *Political Oversight and the Deterioration of Regulatory Policy*, 46 ADMIN. L. REV. 1, 1 (1994) (describing how Congress and the President compete to control agencies).

129. Vetogates are structural requirements in the legislative process that can prevent legislation from being passed even if it is popularly supported. They include the constitutional requirements of bicameralism and presentment, and congressionally adopted structures such as the committee system, which gives committee chairs significant power to kill legislation, and the filibuster in the Senate. See Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70 at 1962. The episodic behavior of Congress refers to the inertia that plagues the legislative process and the resulting phenomenon that Congress does not regularly update statutes to reflect new information or political preferences. See *id.* at 1967. Agencies' procedures for adopting regulations are more flexible, allowing them to amend regulations on a more regular basis. *Id.* at 1983.

2. Imperfections in the Administrative Process

The institutional superiority of agencies suggests that they should play a more central role in determining when their actions preempt tort law. But the administrative state suffers from its own imperfections. Most notably, an agency may act to further its own interests, which may deviate from those of the polity as a whole or from the balance of goals that Congress might have meant the agency to implement when it authorized agency action.¹³⁰

Folklore about the administrative state has led to the belief that agencies are motivated to maximize their power, measured either by their budget¹³¹ or the reach of their jurisdiction.¹³² Studies of agency motivation, however, demonstrate that this concept is not particularly coherent.¹³³ Agencies regulate through actions of their staff members and ultimately their agency head. Rarely is either interested in simply maximizing the agency budget or jurisdiction.¹³⁴

Agency staff members tend to see their role as performing the prescribed functions of their jobs which they view as allowing the

130. See Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1570–74 (1992) [hereinafter Seidenfeld, *A Civic Republican Justification*] (describing the potential for agencies to pursue idiosyncratic values).

131. WILLIAM A. NISKANEN, JR., *BUREAUCRACY AND REPRESENTATIVE GOVERNMENT* 114 (1971) (arguing that “the coterminous relation of a bureaucrat’s rewards and his position implies that a bureaucrat will maximize the total budget of his bureau”).

132. See Jonathan R. Macey, *Positive Political Theory and Federal Usurpation of the Regulation of Corporate Governance: The Coming Preemption of the Martin Act*, 80 NOTRE DAME L. REV. 951, 956 (2005) (positing that agencies care about their budget and jurisdictional turf); Mendelson, *supra* note 3, at 794–95 (asserting that agencies have incentives to maximize their jurisdiction to increase their ability to work out deals with interest groups).

133. Thus, one recent study undermined the notion that the agency can act with a single motivation because agency managers cannot easily get staff members to follow their bidding. JOHN BREHM & SCOTT GATES, *WORKING, SHIRKING, AND SABOTAGE: BUREAUCRATIC RESPONSE TO A DEMOCRATIC PUBLIC* 79, 101–08 (2000).

134. See Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 235 (labeling assumptions that agencies seek to maximize their jurisdictions as “unproven background assumptions”); Daryl J. Levinson, *Empire-Building Government in Constitutional Law*, 118 HARV. L. REV. 915, 932 (2005) (noting that “the relationship between a larger agency budget and higher salaries or cushier working conditions is empirically tenuous”); see also Seidenfeld, *Why Agencies Act*, *supra* note 31, at 268–86 (2009) (describing motives for action by agency staff and agency heads).

agency to achieve its mission.¹³⁵ Staff members, however, may harbor an idiosyncratic understanding of that mission. Agency staff members may be zealots for the stated regulatory protections of the programs within which they work.¹³⁶ If so, they may view tort suits favorably as a means of encouraging implementation of the agency mission regardless of the cost suits imposed on regulated entities. Some staff members, however, may see potential tort liability as going farther than the balance they deem appropriate between public protection and encouragement of beneficial production by the industry the agency regulates. These members would be predisposed to advocate preemption of tort claims stemming from products they regulate.

The motivation of an agency head will depend on his career goals.¹³⁷ The heads of regulatory agencies tend to come from political or professional backgrounds, rather than a career within the agency.¹³⁸ They also tend not to be interested simply in maximizing agency budgets, especially because their tenure is short and their ultimate future lies outside of their agency. Like staff, they too seek credit for getting things done at the agency. Agency heads, however, may be appointed because of their relationship with the current administration and their future careers may depend on the political support of those in the White House when their tenure ends.¹³⁹ Hence, they may be prone to an agenda that

135. See BREHM & GATES, *supra* note 133, at 79 (reporting that the two most popular aspects of public bureaucrats jobs were “a feeling of accomplishment,” and “chances. . .to accomplish something worthwhile”); cf. MARISSA MARTINO GOLDEN, *WHAT MOTIVATES BUREAUCRATS: POLITICS AND ADMINISTRATION DURING THE REAGAN YEARS 1981-89* (2000) (reporting that upper level career civil servants are guided by “role perception” to provide analyses and information to allow their superiors to set agency policy).

136. That “single mission agencies” may have “dedicated but zealous” staff, which needs to be checked by political oversight outside the agency is a commonly cited excerpt from an administrative law opinion. *Sierra Club v. Costle*, 657 F.2d 298, 406 (D.C. Cir. 1981).

137. For an extended discussion of the motivations of agency staff members and heads, see Seidenfeld, *Why Agencies Act*, *supra* note 31, at 267-86.

138. *Id.*, at 282, n.101; see also JAMES Q. WILSON, *BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT 200-01* (1989) (careerist as opposed to political agency heads generally run agencies presented with the same sorts of decisions every day and not with policy choices).

139. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 282; see also *id.* at 284-84 (explaining that political agency heads may be loyal to their administration for social reasons as well).

the White House sees as politically expedient, which may deviate from what is best for the country.¹⁴⁰

As opposed to maximizing budgets or jurisdiction, it is more likely that both agency staff and heads prefer autonomy.¹⁴¹ Autonomy is created by an agency having a unique mission and therefore not having to compete with rivals to ensure its continued existence. Whether one is fanatical about protecting the putative beneficiaries of regulation or hell-bent on freeing industry from regulatory constraints, achievement of one's goals is easier without competition for resources and support of a constituency. It is possible that those in agencies may see tort suits as interfering with agency autonomy to the extent that the tort system is a regulatory rival that can increase the work load on an agency. This could occur if tort suits forced the agency to reconsider a prior regulatory decision when it is anxious to address the next problem or product.

Another concern raised by critics is capture of the agency by the regulated industry.¹⁴² Capture is not a precisely defined concept.¹⁴³ In the broadest sense it occurs when an agency acts on behalf of the entities it regulates rather than in the public interest.¹⁴⁴ But, the public interest usually requires a balance between zealous regulation and industry flexibility that permits production of beneficial goods and services at the lowest cost. Hence, it is not easy to determine when any agency decision reflects capture rather than a proper balance, especially when viewed by a group representing those potentially injured by a product. Moreover, an agency's political overseers may strike their own balance in favor of regulation. If the President and Congress favor a pro-industry outcome of a regulatory matter, an agency that implements their pref-

140. See John McKay, *Train Wreck at the Justice Department: An Eyewitness Account*, 31 SEATTLE U. L. REV. 265, 283–84 (2008) (describing Attorney General Gonzales' problematic and perhaps unlawful firing of United States Attorney David Iglesias seemingly to support the administration's political preferences); David Scheffer, *For Love of Country and International Criminal Law, Further Reflections*, 24 AM. U. INT'L L. REV. 665, 667–68 (2009) (describing how Justice Department lawyers who wrote memos justifying torture "did exactly what was required of them to fulfill the expedient objectives of their political masters").

141. See WILSON, *supra* note 138, at 180–82, 188–92 (1989).

142. See generally Thomas W. Merrill, *Capture Theory and the Courts: 1967–1984*, 72 CHI.-KENT L. REV. 1039 (1997) (describing the history of capture theory and its influence on judicial doctrines of administrative law).

143. See *id.* at 1059–62 (describing several different understandings of agency capture).

144. See Thomas W. Merrill, *Rethinking Article I, Section 1: From Nondelegation to Exclusive Delegation*, 104 COLUM. L. REV. 2097, 2143–45 (describing capture as a form of agency drift from the preferences of the polity).

erence for a regulatory scheme can be characterized as responsive to political influence rather than captured.¹⁴⁵

Nonetheless, regardless of whether through the influence of Congress or the President, or through incentives the regulated industry provides to agency staff members, agencies can be induced to further the interests of producers at the expense of the public.¹⁴⁶ Therefore, were courts to grant an agency primary responsibility to determine tort preemption, they would have to structure how the agency makes that determination to minimize the potential for capture.

3. Notice-and-Comment Procedures and Hard Look Review as Cures for Agency Imperfections

The two threats of the administrative state just described—officials' desire for autonomy to institute their conception of the regulatory scheme and industry capture—can be ameliorated to a great extent by requiring agencies to use notice-and-comment rulemaking to preempt tort law and by courts applying the exacting “hard look” standard of review to such preemptive rules.¹⁴⁷

However one defines capture, agency rulemaking is less likely to reflect an inappropriate balance of interests than agency enforcement or permitting actions.¹⁴⁸ Enforcement requires investigation in a particular instance to see if conduct violates rules or policies of the agency. As such, it necessarily involves “street level” officials who retain much discretion about whether to report a violation.¹⁴⁹ Hence, a regulated entity can provide “benefits”¹⁵⁰ to the

145. For example, the Interstate Commerce Commission (ICC) under President Reagan pursued a strong deregulatory agenda, which was the hallmark of Reagan's domestic policy against big government. But ICC actions were not so much a product of the agency being controlled by the trucking industry as it was the agency implementing the agenda of a free market-oriented President and, to a lesser extent, Congress. See Paul Stephen Dempsey, *The Interstate Commerce Commission—Disintegration of an American Legal Institution*, 34 AM. U. L. REV. 1, 49 (1984) (criticizing ICC deregulation of trucking and opining that “[t]he Commission has lost the autonomy that traditionally shielded its decisionmaking from the political winds that blow down Pennsylvania Avenue”).

146. Note, *The Mysteries of the Congressional Review Act*, 122 HARV. L. REV. 2162, 2178–79 (2009) (describing various posited mechanisms for agency capture and asserting that capture in the broad sense of an agency acting against the public interest does occur).

147. See *infra* notes 160–66 and accompanying text.

148. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 271–73 (2009).

149. See Keith Hawkins & John M. Thomas, *The Enforcement Process in Regulatory Bureaucracies*, in ENFORCING REGULATION 3, 9 (Keith Hawkins & John M. Thomas, eds., 1984) (describing how discretion of meat packing plant inspectors

official responsible for enforcement more easily and more secretly than it can to those responsible for rulemaking.¹⁵¹ The susceptibility of licensing to capture, which under the APA includes such actions as FDA approval to market a drug,¹⁵² falls somewhere in between that of enforcement and rulemaking.¹⁵³ Ostensibly, approval is a matter between the agency and the entity seeking approval, and public participation in a particular product approval may be limited by concerns for proprietary information and trade secrets.¹⁵⁴ Nonetheless, there may be some opportunity for public participation in setting standards for product approvals.¹⁵⁵ Public interest groups, however, will be limited in the extent they can introduce information into the record or challenge an agency decision to approve the marketing of a product. In addition, issuance

led to a norm of inspectors accepting gratuities from the plants they inspected); *id.* at 11 (stating that “field-level officials . . . have the power to commit the agency to the investigation and prosecution of specific violations”).

150. Benefits may be promises of future jobs or outright bribes, but may also be as simple as cooperating in providing information that allows an official expend less effort and time to perform his job. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 271–74 (discussing capture of staff involved in the rulemaking process).

151. For a recent example of apparent capture in the enforcement context, see Matthew L. Wald, *Inspectors Say FAA Ignored Southwest Violations*, N.Y. TIMES, Apr. 4, 2008, at C3 (reporting that a manager in an FAA (Federal Aviation Administration) regional office had allowed Southwest to continue flying planes that had not been inspected as required by FAA regulations).

152. The APA defines a “license” to include “the whole or part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission.” 5 U.S.C. § 551(8) (2006). Licensing is “adjudication” under the APA, 5 U.S.C. § 551(6)–(7) (2006), and hence the public may be limited in its ability to participate in the proceeding. See 5 U.S.C. § 555(b) (2006) (specifying that, unlike a party, an interested person may appear before an agency only “[s]o far as the orderly conduct of public business permits”).

153. As an example of what might be undue industry influence, the FDA has been criticized for pressuring drug reviewers to approve new drugs even when they had questions about the drugs’ safety or effectiveness. Christine D. Galbraith, *Dying To Know: A Demand For Genuine Public Access To Clinical Trial Results Data*, 78 MISS. L.J. 705, 769–70 (2009).

154. See James T. O’Reilly, *Knowledge Is Power: Legislative Control of Drug Industry Trade Secrets*, 54 U. CIN. L. REV. 1, 8 (1985) (reporting that from 1967 through the writing of the article, “the FDA uniformly has withheld, as confidential business information or trade secrets, business data it has received in the course of drug product approvals”).

155. See Lewis Rosman, *Public Participation in International Pesticide Regulation: When the Codex Commission Decides, Who Will Listen?*, 12 VA. ENVTL. L.J. 329, 355 (1993) (describing opportunities for participation and judicial challenges to EPA approval of pesticides).

of approvals may involve a single office in an agency,¹⁵⁶ which in turn may discourage deliberation between staff members with different professional backgrounds. Rulemaking, in contrast, allows all those with an interest in a rule to provide input into the ultimate decision in a transparent forum. Development and adoption of rules usually involves a team of agency officials from several offices within the agency.¹⁵⁷ It would be extremely difficult for an industry to provide incentives for all team members to unjustifiably support the industry's preferences.¹⁵⁸ If capture happens, it often occurs when the industry convinces Congress and the White House—the political overseers of the agency—to demand a pro-industry outcome.¹⁵⁹

The potential for an agency inappropriately to preempt tort law can be ameliorated by requiring agencies to proceed by notice-and-comment rulemaking subject to hard look review.¹⁶⁰ Rulemaking proceedings inform interest groups of the agency's plans before it formulates a final rule and allows these groups to alert Congress if they believe the proceedings are contrary to their interests. Use of rulemaking subject to exacting judicial review encourages the agency to collect input from its staff, usually comprised of individuals with varied professional backgrounds and different private con-

156. For example, at the FDA, new drugs are approved by “drug reviewers” in the agency's Center for Drug Evaluation and Research. Galbraith, *supra* note 153, at 769.

157. Mark Seidenfeld, *Cognitive Loafing, Social Conformity, and Judicial Review of Agency Rulemaking*, 87 CORNELL L. REV. 486, 527–28 (2002) [hereinafter Seidenfeld, *Cognitive Loafing*]; Thomas O. McGarity, *The Internal Structure of EPA Rulemaking*, 54 LAW & CONTEMP. PROBS. 57, 90 (1991).

158. The evidence that agencies as a body are improperly influenced by special interest groups is slim. See PAUL J. QUIRK, *INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES* 4–21 (1981); Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 52–56 (1998); Mark Kelman, *On Democracy-Bashing: A Skeptical Look at the Theoretical and “Empirical” Practice of the Public Choice Movement*, 74 VA. L. REV. 199, 238–68 (1988).

159. One example is the FCC giveaway of billions of dollars of electromagnetic spectrum to existing television stations, which was essentially mandated by Congress. See Thomas W. Hazlett, *Physical Scarcity, Rent Seeking, and The First Amendment*, 97 COLUM. L. REV. 905, 938–42 (1997) (describing how broadcasters influenced Congress to give away spectrum for HDTV licenses to existing television stations). See generally Ellen P. Goodman, *Digital Televisions and the Allure of Auctions: The Birth and Stillbirth of DTV Legislation*, 49 FED. COMM. L.J. 517 (1997) (giving a detailed account of congressional consideration of the auction of HDTV spectrum).

160. Seidenfeld, *Demystifying Deossification*, *supra* note 72, at 490–92 (describing “hard look” review).

tacts and constituents.¹⁶¹ Thus, interest groups can more effectively influence agency deliberation while the agency is formulating a proposed rule, rather than after a rule is proposed. Once the agency has formulated its position, it is less open to change. Nonetheless, even after an agency proposes a rule, interest groups can place comments in the record which often include data that can undermine the agency's explanation if it is later forced to defend its decision in court. Hence, subject to standing limitations, an interest group can use the data it submits to challenge an agency rule as arbitrary and capricious.

Hard look judicial review also provides a check against unjustified political influence. Courts require that agencies explain their actions in terms of factors "relevant" to their actions.¹⁶² Generally, such factors include those identified in the agency's authorizing statute,¹⁶³ and other fairly universally accepted values, such as the desire to avoid spending money unnecessarily. Thus, even when the political branches pressure an agency to preempt tort law, in at least some situations, the agency will simply not have sufficient data regarding the impact of future liability on a producer or its product to convince a reviewing court that preemption is warranted. Undoubtedly, mandated decision-making procedures and exacting judicial review on their own will not always prevent an agency from acting contrary to perceptions of the nation's interest. If Congress and the President support an agency's particular course of action, judicial review will not prevent the agency from ultimate implementation.¹⁶⁴ But even when Congress and the President strongly support a course of action, the public may be more hesitant about pursuing it, in which case procedures and review can slow the administrative process enough for politics to catch up with the agency

161. *Id.* at 493–94.

162. Jessica Mantel, *Procedural Safeguards For Agency Guidance: A Source Of Legitimacy For The Administrative State*, 61 ADMIN. L. REV. 343, 387 (2009); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1442 (1992).

163. See Richard J. Pierce & Sidney A. Shapiro, *Political and Judicial Review of Agency Action*, 59 TEX. L. REV. 1175, 1190–91 (1981) (noting that judges can pick and choose which of scores or even hundreds of statutory factors were relevant).

164. See Seidenfeld, *A Civic Republican Justification*, *supra* note 130, at 1547–48; see also William S. Jordan, III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere With Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393, 440 (2000) (finding that in almost every instance over a decade long period, agencies were able to reinstate the substance of rules remanded by the D.C. Circuit as arbitrary and capricious when the agency did not agree with the court's conclusion about the rule).

agenda.¹⁶⁵ In some cases this can facilitate political mobilization of less focused interest groups to protect the public interest.¹⁶⁶

4. Agencies' Potential Disdain for State Interests in Maintaining Tort Suits

Thus far, I have presented arguments for why notice-and-comment rulemaking along with hard look review can be expected to alleviate some of the pathologies of granting agencies wide discretion to set policy. Some scholars, however, cite evidence of an apparent trend among several agencies to support preemption generally and an accompanying willingness to shortchange state interests even in the rulemaking process.¹⁶⁷ In particular, these naysayers report that these agencies have virtually ignored their obligations under Executive Order 13,132¹⁶⁸ to consult with state and local government officials and prepare an analysis of significant impacts on these governmental entities.¹⁶⁹ In addition, scholars have reported that in several instances, agencies have abused the notice-and-comment process by sneaking preemption provisions into the preamble to rules thereby avoiding the notice-and-comment process altogether.¹⁷⁰ In other instances, agencies did accept comments on preemption, but entirely ignored them in their final determination to preempt state tort law.¹⁷¹ I believe that these scholars infer more about agency hostility to federalism than the

165. See Seidenfeld, *Why Agencies Act*, *supra* note 31, at 320 (describing how judicial review of the National Highway Traffic Safety Administration's (NHTSA) passive restraint rule allowed politics to catch up with the agency and derail its aggressive safety standard program).

166. See Mathew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Administrative Procedures as Instruments of Political Control*, 3 J.L. ECON. & ORG. 243, 257–58 (1987) (arguing that rulemaking procedures give Congress and the President early warning of agency moves potentially requiring oversight); Metzger, *supra* note 3, at 2087 (noting that “by forcing an agency to provide notice of actions it plans to take, procedural requirements empower congressional oversight and thus reinforce such political safeguards as Congress has to offer”).

167. See, e.g., Ronald K. Chen, *State Incarceration of Federal Prisoners After September 11: Whose Jail is it Anyway?*, 69 BROOK. L. REV. 1335, 1344–45 (2004); Thomas O. McGarity, *The Perils of Preemption*, 44 TRIAL 20, 20–24 (2008); Mendelson, *supra* note 3, at 783–86.

168. Exec. Order No. 13,132, 64 Fed. Reg. 43,257 (Aug. 10, 1999).

169. See Chen, *supra* note 167, at 1344–45; McGarity, *infra* note 174, at 24; Mendelson, *supra* note 3, at 783–86; see also Sharkey, *What Riegel Portends*, *supra* note 8, at 457 (taking the FDA to task for failing to prepare federalism impact statements, but adopting a more nuanced position on agency preemption generally).

170. See, e.g., Sharkey, *Federalism Accountability*, *supra* note 2, at 2131–34.

171. See, e.g., *id.* at 2137.

evidence supports. Rather than manifesting insensitivity to tort victims and federalism, recent agency decisions preempting tort suits reflect shortcomings in institutional incentives to consider such matters. Moreover, were judges to view the choice of preemption as a policy decision for which agencies have primary responsibility by way of the rulemaking process, judicial review would realign these institutional incentives so that administrative law would alleviate the supposedly antagonistic attitude of agencies towards tort suits.

To understand the significance of agency ignorance regarding Executive Order 13,132,¹⁷² one must recognize that this Order is one of many that purport to require consultation and analysis.¹⁷³ From an agency's perspective, these required analyses are "paperwork," rather than documents that inform their rulemaking decisions.¹⁷⁴ The requirement that agencies perform them is enforced by the Office of Management and Budget (OMB),¹⁷⁵ and is not backed up by judicial review.¹⁷⁶ From the White House's perspective these executive orders provide mechanisms for the President to force agencies to consider issues that the President deems important and generally to exert more influence on agency rulemaking.¹⁷⁷ Thus, that the Office of Information and Regulatory Affairs (OIRA)¹⁷⁸ did not rigorously police agency preparation of federalism impact analyses when the underlying rules were favored by the President says little about agency attitudes toward federalism.

172. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999).

173. See Mark Seidenfeld, *A Table of Requirements for Federal Administrative Rulemaking*, 27 FLA. ST. U. L. REV. 533, 536–37 (2000) (detailing all of the procedures with which an agency had to comply, in 2000, to adopt a legislative rule).

174. See THOMAS O. MCGARITY, *REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY* 43 (1991) (opining that the EPA did not devote much attention to an initial regulatory flexibility analysis in its lead phase down rule because it regarded the analysis "merely as a paperwork hurdle").

175. Exec. Order No. 13,132, 64 Fed. Reg. 43,258 (Aug. 10, 1999).

176. *Id.* at 43,259.

177. See Kagan, *supra* note 82, at 2288 (noting how President Clinton's executive order on regulatory review was worded to expand his ability to control agency rulemaking); Shapiro, *supra* note 128, at 8–10 (describing executive orders requiring regulatory impact analyses as one means for the President to engage in an oversight game with Congress).

178. OIRA is the group within OMB that is responsible for regulatory oversight. See Exec. Order No. 12,866 § 6(b), 58 Fed. Reg. 51,735 (Sept. 30, 1993) (directing OIRA to "provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order").

Even when analyses are required by statute, agencies tend to avoid preparing meaningful statements, or even preparing statements at all. For example, the Regulatory Flexibility Act requires an agency to determine whether a rule will have a “significant economic impact on a substantial number of small entities,” and to prepare a Regulatory Flexibility Analysis (RFA) if it will.¹⁷⁹ The Act originally precluded judicial review of its requirements,¹⁸⁰ which led to complaints of lagging compliance, including agency failures to consult with small businesses about the effect of rules and failures to prepare RFAs when the impact would be significant.¹⁸¹ Congress has since amended the Act to allow judicial review of its requirements,¹⁸² and to make regulatory flexibility analyses prepared by agencies part of the rulemaking record.¹⁸³ This seems to have induced agencies to prepare RFAs, although it is not clear whether judicial review has prompted more consistent consideration of small business interests. Agencies are apt to continue to consider these analyses as “paperwork” unless courts consider the impact on small businesses a relevant factor in assessing whether a rule is arbitrary or capricious.

Given that Executive Order 13,132 is not judicially enforceable¹⁸⁴ and that the George W. Bush administration strongly pushed for preemption of state tort law, it is no surprise that agencies did not comply with the Order prior to issuing their stealth preemption statements. As such, if that executive order is to empower states in the regulatory process, at a minimum, Congress will have to make its requirements judicially enforceable. Such action, at least for now, would be unwarranted because one can give agencies better incentives to seriously consider state interests in allowing tort suits while still allowing more flexibility in the preemption decision. This can be done by requiring agencies to explicitly include their preemption determinations in rules. This, in turn, will trigger the reasoned decision-making requirements of arbitrary and capricious review under the APA.

179. 5 U.S.C. §§ 603, 604, 605(b) (2006).

180. Regulatory Flexibility Act, Pub. L. No. 96-354, § 3(a), 95 Stat. 1164, 1169–70 (1980).

181. See Jennifer McCoid, *EPA Rulemaking under the Regulatory Flexibility Act: The Need for Reform*, 23 B.C. ENVTL. AFF. L. REV. 203, 204, 231 (1995) (noting agencies’ propensity not to comply with the Act and suggesting judicial review as a cure).

182. Small Business Regulatory Enforcement Fairness Act (SBREFA), 5 U.S.C. § 611(a)(1) (2006).

183. *Id.* § 611(b).

184. Exec. Order No. 13,132, 64 Fed. Reg. 43,259 (Aug. 10, 1999).

Abuse of the notice-and-comment process is somewhat more troubling because a state tort system does not necessarily involve any particular state regulatory office that can effectively represent a state's interests early in the rulemaking process. By the time a rule is proposed, an agency has usually invested significant time and effort in the matter and may remain wedded to the position it has taken. Therefore, the key for interest groups to influence a rulemaking is for them to get involved in pre-NOPR rule development, usually through interactions with agency staff members from the same profession or with similar views of the regulatory scheme.¹⁸⁵ If the subject of a rulemaking happens to fall within the ambit of a state regulatory office, staff members from that office will be aware of the pre-NOPR developments in the federal agency as state agency staff members will often have professional acquaintances on the federal agency staff,¹⁸⁶ and can get their viewpoints heard early in the process. Unfortunately, when the subject of preemption is tort law, there may be no state office to play the role of the informed and involved representative of the state's interest.¹⁸⁷ And although one might look to state attorneys general to represent state interests in the federal agency proceeding, these attorneys general do not have the focused mandate on particular regulatory matters to generate either the incentive or the agency contacts to keep abreast of rulemaking developments in the various industries regulated at the federal level.

185. See CORNELIUS M. KERWIN, *RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY* 79–80 (3d ed. 2003) (describing the importance of rule development before a rule is proposed); Scott R. Furlong, *Interest Group Influence on Rule Making*, 29 *ADMIN. & SOC'Y* 325, 334–35 (1997) (reporting that interest groups believe that informal contacts prior to a rule being proposed is one of the most effective ways to influence rulemaking).

186. See Mark Seidenfeld, *The Psychology of Accountability and Political Review of Agency Rules*, 51 *DUKE L.J.* 1059, 1078 (2001) (stating that “[o]ne suspects that agency staff also maintains contacts with representatives from affected interest groups and tries to keep such groups sufficiently placated to dissuade them from sounding the alarm to the [congressional] oversight committee”); James A. Thurber, *Dynamics of Policy Subsystems*, in *INTEREST GROUP POLITICS* 319, 325–26 (Allan J. Cigler & Burdett A. Loomis eds., 3d ed. 1991) (describing the role of participants in “policy subsystems,” including interest groups, agencies, policy specialists, and the media, among others); see also *id.* at 332 (noting that, even when policy subsystems are competitive, they often involve repeat players who “try to keep final decisions out of the view of the public”).

187. Cf. Sharkey, *Federalism Accountability*, *supra* note 2, at 2158–63 (discussing the problem of who represents the state regulatory interests in tort preemption questions); *id.* at 2160 (noting that few states have agencies focused on food and drug safety that could represent state interests in tort preemption issues before the FDA).

Perhaps the best representative of state interests in maintaining tort suits against firms in a federally regulated industry would be trial lawyers who represent potential victims, as they have a significant financial incentive in the continued availability of tort suits. Trial lawyers who sue firms in a particular industry will be aware of the developing federal regulations affecting that industry and are likely to have contacts on the staff of the federal agency. One might object that private plaintiffs' lawyers are not the state and cannot be trusted to represent the states' interests. The extent to which this is troubling may reflect one's attitude toward federalism. If one believes that preemption threatens "abstract federalism" interests—state sovereignty interests that can keep the federal government in check—then this objection has bite.¹⁸⁸ But if one believes in federalism for its instrumental potential—to create a system of government that in a particular context leads to better substantive outcomes—then it may be that those who have an interest in the substantive outcome are better suited to represent state interests before the federal agency than state officials.¹⁸⁹

The final concern with my proposal to have agencies preempt by legislative rule stems from the standing and ripeness restrictions courts have imposed in suits directly challenging agency preemption.¹⁹⁰ If courts do not allow those opposing preemption to seek judicial review, then reliance on judicial review's ability to force agencies to deliberate about preemption rings hollow. This concern warrants more extended treatment than I can give it in this

188. See Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70, at 1941–42, 1978–79 (distinguishing abstract from instrumental federalist interests and explaining why they do not put much weight on abstract federalism interests).

189. The response of the National Conference of State Legislatures (NCSL) to a proposed preemption provision in a NHTSA rulemaking is illustrative of the problems of having state officials represent state interests in rulemakings addressing preemption of tort law. NHTSA proposed a rule governing automobile roofs' resistance to being crushed in rollover accidents. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223 (proposed August 23, 2005). NCSL comments simply asserted that NHTSA was usurping state authority to set tort standards and argued that NHTSA did not have authority to preempt state law on its own. Comment, Federal Motor Vehicle Safety Standards; Roof Crush Resistance, Docket No. NHTSA 2005-21243 (filed Dec. 14, 2005). The comments did not address whether the NHTSA rule was justified by the need for uniformity, the uncertainty that the rule would reasonably protect against unforeseen types of injury in case of rollovers, or any other factor that bears on the wisdom of the preemption provision.

190. See *Time Warner Entm't Co. v. FCC*, 56 F.3d 151, 194–96 (D.C. Cir. 1995) (holding that a statement of FCC regarding preemption of inconsistent law not ripe for review because the FCC statement did not resolve whether a state regulation would be preempted in any particular factual setting).

Article, but let me suggest several reasons to believe that these issues may not be insurmountable for my approach.

Most significantly, until recently, the issue of preemption was treated as one of statutory interpretation, not agency policy.¹⁹¹ As such, agency statements about preemption represented, at best, the informed interpretations of the agency. Such interpretations warrant some deference from courts but are not pronouncements with independent force of law.¹⁹² To put this in more concrete terms, under current preemption doctrine, when a victim of an injury from a product sues in state court, there is no guaranty that that court will find the suit preempted by the statute just because the agency opined that it is.¹⁹³ Under the proposed approach, an agency could preempt only by issuing a legislative rule which by definition has independent force of law. Hence, a state court would be obligated to follow the determination of the agency so long as the case fell within the bounds of the preemption specified in the agency rule.

This goes a long way toward curing any uncertainties regarding standing and ripeness. For instance, if the agency rule preempted tort suits already filed in state court, any plaintiff in such a suit would be directly and immediately affected by the rule and could seek a direct review. Conversely, if the rule only preempted suits not yet filed, then plaintiffs who suffered injury and could show that they were preparing to file a suit in state court would probably be able to meet standing and ripeness requirements because they could show that they were precluded by the rule from conduct in which they would have engaged: filing the suit. Finally, even if plaintiffs could not directly seek review of a preemption rule, state attorneys general would most likely be able to do so.¹⁹⁴ Espe-

191. See Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 Nw. U. L. REV. 695, 697–98 (2008) (noting that recently agencies have asserted the authority to preempt state law without explicit statutory authority, which has changed preemption analysis from one of statutory interpretation to one of legitimacy).

192. See *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (denying *Chevron* deference to agency interpretative rule); *United States v. Mead Corp.*, 533 U.S. 218, 219 (2001) (stating that an interpretation gets *Chevron* deference only when “Congress would expect the agency to be able to speak with the force of law”).

193. Cf. *NRDC v. EPA*, 559 F.3d 561, 564–65 (D.C. Cir. 2009) (generally a preamble to a rule is not ripe for review because it does not constitute binding agency action).

194. The fact that state attorneys general may not be the best entities to represent states’ interests early in a federal rulemaking proceeding involving tort preemption, cf. *supra* notes 116–18, 186–87 and accompanying text, does not imply

cially in light of *Massachusetts v. EPA*'s "special solicitude" for allowing states to sue federal regulators to protect the interests of their citizens,¹⁹⁵ it is difficult to argue that a state official responsible for the enforcement of state legal standards would not have an interest in a rule that would prevent courts in her state from addressing the appropriate standard of care.

C. Courts

Courts can play several roles in tort preemption depending on which institution is primarily responsible for deciding when preemption is appropriate. If one sees Congress as the primary body responsible for preemption, the courts' role essentially consists of interpreting statutes to determine when they call for preemption.¹⁹⁶ If instead one views the judiciary as the body best suited to determine when tort preemption is warranted, courts would have to evaluate whether a particular suit interferes with the object of federal regulation to an extent that it is counterproductive.¹⁹⁷

Courts are not well suited, either theoretically or pragmatically, to evaluate whether allowing tort suits will pose sufficient hurdles to federal regulation to justify preemption. Such an evaluation will not follow from precedent, or some definitive legal text on which

that they would not be good representatives of the state's interests to challenge a preemption rule. By the time the challenge occurs, the agency will have issued a final rule. At that point, the attorney general will be aware of the preemption rule and the challenges raised before the agency about the propriety of preemption, and the state will not be shortchanged because the attorney general will have entered the fray late.

195. *Massachusetts v. EPA*, 549 U.S. 497, 520 (2007).

196. Under this view, preemption can occur because of actual conflict between state and federal law—when conduct necessary to comply with state law would violate federal law—and where a statute manifests intent to displace state law within an area. Displacement can occur either implicitly, for example when a court determines that Congress intended a statute to occupy the entire regulatory field, or explicitly, when the statutory text states that it preempts state law. See Merrill, *Preemption*, *supra* note 3, at 730–32 (distinguishing preemption by "displacement" from that by "trumping"). Strictly speaking, tort law simply mandates that a producer pay for the harm its product causes. In theory, therefore, state tort law that imposes liability for complying with federal regulations does not render compliance with both state law and federal regulation impossible. Pragmatically however, tort law that imposed such liability could dissuade producers from conduct that the federal government has determined to be beneficial.

197. See Sharkey, *What Riegel Portends*, *supra* note 8, at 438. Courts currently do this under the rubric that state law is an obstacle to the objectives of a federal regulatory scheme. See *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); see also Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 228–29 & n.14 (2000) (describing obstacle preemption as a version of conflict preemption and collecting case cites).

the court can rely. Instead, courts will have to make value judgments of the kind better left to the politically accountable branches. Moreover, any judicial evaluation will not depend on skills that judges hone, such as parsing statutes or evaluating evidence to determine whether an event occurred or not. Rather, they will depend on understanding the significance of data about costs to producers and benefits to society that might flow from allowing tort suits. Courts will have to resolve questions about how well markets are likely to work to ensure that beneficial products are not forced out and detrimental ones not allowed to succeed. This in turn will depend on an evaluation of the value the public places on avoiding risks both posed by the product and by its absence from the market. It also requires an understanding of how producers are likely to react to post-market uncertainty posed by potential tort suits, how much remains unknown about future risks from the product, and a host of other fairly complex questions that fall into the realm of policy analysis.¹⁹⁸ If one adopts my suggestion that agencies be primarily responsible for preemption determinations, one must reject both Congress and the courts as primary arbiters of preemption. That rejection, however, still leaves some important roles for Congress and the courts. Congress still retains its role of agency oversight. As with any other agency regulation, Congress can statutorily override agency preemption if it can muster the political will to do so.

As for courts, federal courts will be responsible for direct review of preemption rules.¹⁹⁹ Aggressive review of an agency's reasoning is an important constraint against the pathologies that might otherwise afflict agency policy making and an important incentive to encourage more deliberative decision-making.²⁰⁰ Judicial review can slow down politically driven decisions that reflect fleeting public preferences or imperfections that cause the politically accountable branches to drift from goals that best serve the

198. I concede that courts may have an advantage with respect to one determination—the abstract value of maintaining a federal system. But this value is not likely to be of great significance given the current state of the world in which states remain viable political competitors to the federal government, thereby providing some potential protection against the threat of a future tyrannical federal government. Galle & Seidenfeld, *Administrative Law's Federalism*, *supra* note 70, at 1971–72, 1978.

199. The APA provides for any person adversely affected by final agency action to seek judicial review. 5 U.S.C. § 704 (2006).

200. Seidenfeld, *Cognitive Loafing*, *supra* note 157, at 512–22; *see also* Buzbee, *supra* note 2, at 1576–77 (arguing that hard look review of agency preemption decisions will foster transparency, accountability and deliberation).

national polity.²⁰¹ Judicial review is also crucial for encouraging agencies to incorporate staff members with expertise in the tort system into their preemption decision-making process.

Of particular significance, judicial review can force agencies to confront not only whether to preempt, but also the bounds of that preemption. For example, cost advantages of uniformity, and the potential perversities of having to comply with the strictest state standard may justify preemption of torts based on defective product design. Presumably an agency would have to have additional reasons, such as a market imperfection necessitating a subsidy for the product, in order to justify a blanket preemption of torts relating to the product. Hence, in this example, review would encourage the agency to allow torts based on faulty manufacturing. More generally, judicial review will prompt agencies to limit preemption to precise situations where it would not eliminate a producer's incentives to continue improving the safety of their products and where elimination of tort suits would provide a demonstrable social benefit.

In addition, courts (or more broadly state tort systems) will provide an avenue for continued deliberation about an agency preemption decision. Even after regulating, agencies retain authority to continue monitoring and revising their rules.²⁰² Post-regulatory marketing and use may reveal the extent to which a product creates a public benefit or poses a threat of injury and may allow a producer to develop data about the costs of taking further care to avoid injuries. Although agencies can amend their preemption rules more easily than Congress can amend statutes,²⁰³ agencies, unfortunately, do not have much incentive to continue monitoring injuries from a product once it has adopted a preemption rule. Tort plaintiffs' lawyers, however, do. State courts thus can play a role in keep-

201. Seidenfeld, *Why Agencies Act*, *supra* note 31, at 320 (concluding that reversal of NHTSA's passive restraint rule in 1972 allowed interested parties and the public to organize to stop the agency from imposing this and other aggressive auto safety regulations).

202. Agency authority to issue rules includes the authority to amend them once issued. 5 U.S.C. § 551(5) (2006) (defining "rule making" to include the process for amending a rule). One impediment, however, to agency rule revision with respect to particular products may be an absence of agency authority to require manufacturers to provide data on the safety of products after they are approved. See Peter Chang, *Reauthorization of PDUFA: An Exercise in Post-Market Drug Safety Reform*, 36 J.L. MED. & ETHICS 196, 196 (concluding that the latest iteration of the Prescription Drug User Fee Act "augments a [previously] feeble post-marketing drug safety regime").

203. Recall that the ability to act on a more continuous basis was one of the advantages of granting primacy on preemption to agencies rather than Congress. See *supra* notes 119-22 and accompanying text.

ing plaintiffs' attorneys active in monitoring producers even after an agency adopts a preemption rule. The question is how the plaintiffs' bar can play that role if the agency has preempted tort suits. The answer is the flexibility state courts have in determining the scope of preemption rules.

Because agencies will be discouraged from adopting blanket preemption rules, a state court will have the opportunity to determine the bounds of preemption in many cases before it. For example, consider the National Highway Traffic Safety Administration (NHTSA) notice of proposed rulemaking on the ability of automobile roofs to withstand rollover collisions, which includes the following provision:

[T]he agency believes that either a broad State performance requirement for greater levels of roof crush resistance or a narrower requirement mandating that increased roof strength be achieved by a particular specified means, would frustrate the agency's objectives by upsetting the balance between efforts to increase roof strength and reduce rollover propensity. . . . [I]f the proposal were adopted as a final rule, it would preempt all conflicting State common law requirements, including rules of tort law.²⁰⁴

Assume that NHTSA adopts the rule. Suppose further that a plaintiff injured in a rollover collision in which the roof fails to protect him discovers that the automobile he was driving was three times more likely than the average car to rollover in a crash. The plaintiff then sues claiming that the car design was defective because of this tendency to rollover rather than any problem with the roof.

Presumably, the defendant will move for dismissal, and the trial court will have to decide whether this suit is preempted by NHTSA's rule. The trial court could delay the determination of preemption until discovery occurs, allowing the parties to develop information relevant to whether the injury could be attributed to something other than a faulty roof. In this way, suits that might generate information relevant to the agency's preemption decision will not be entirely barred by the preemption rule.²⁰⁵ Moreover,

204. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,245–46 (proposed Aug. 23, 2005).

205. Courts would have the best information if they could delay any preemption determination until after plaintiffs have discovered information the producer has amassed about a product that has already gone to market. There is a catch-22, however, to a court waiting until after discovery to decide a preemption motion. Allowing a case to proceed to the discovery phase will encourage producers to

this information can be shared with the agency either informally in communications with agency staff, or more formally by a petition asking the agency to amend its preemption rule.²⁰⁶ Finally, if an agency that has already adopted a preemption rule is truly unresponsive to persuasive arguments that determinations should be revisited, those seeking to allow suits could go to Congress or the White House to pressure the agency to reconsider its position.

CONCLUSION

In many contexts, there are benefits that derive from maintaining state tort suits as a backup to federal regulation of nationally marketed goods or services. In other contexts, however, there are benefits to prohibiting such tort actions. Thus, the more interesting question than whether regulation or torts are best at setting standards of care is: Who should decide whether the standard should be set by regulation or tort? With respect to that question, the institutional advantages of agencies suggests that they are best suited to exercise primary responsibility to answer the question of whether tort suits should be preempted in specific contexts.

In order for society to reap the rewards of agencies' institutional advantages, however, courts should require that agencies use notice-and-comment rulemaking subject to hard look judicial review when making preemption determinations. Congress and the state courts also retain roles in determining preemption. Congress remains an overseer of the agency and can reverse an agency regarding preemption. State courts still have to decide particular tort cases, and therefore must rule on the bounds of regulatory preemption. Because state courts may have more recent and complete information about product risks than the agency did when it issued its preemption rule, state judges should use their decisions about the bounds of preemption to update agencies about such risks.

settle on terms that allow them to keep trade secrets or embarrassing information secret. This in turn could keep hidden the very information the court hoped to obtain by delaying the preemption determination until after discovery. *See* McGARITY & WAGNER, *supra* note 79.

206. 5 U.S.C. § 553(e) (2006).

THOUGHTS ON THE RISE AND DECLINE OF THE IMPLIED PREEMPTION THEORY FOR STATE LAW DAMAGES CLAIMS

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Over the past decade, and particularly over the past few years, implied preemption of state law damages claims has become a topic of significant interest to practicing lawyers and academics. Yet both damages claims and preemption doctrine—which has its roots in the Supremacy Clause of the United States Constitution¹—have long been part of the legal landscape. This Article outlines how and why the topic has become such an important one and offers a consumer advocate’s perspective on the issue.

I. IN THE BEGINNING

Traditional tort law principles recognize that federal approval of a product for marketing and compliance with federal requirements for product safety have a role to play, and a potentially very powerful role to play, in product liability cases. Consistent with this tradition, the current law in most states allows a manufacturer that is alleged to have sold a defective product to use compliance with federal standards or regulations as non-dispositive evidence that the product was not defective or that the manufacturer acted non-negligently.² A typical jury instruction might say, for example, that

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1. U.S. CONST. art. VI., para. 2.

2. RESTATEMENT (THIRD) OF TORTS § 4(b) (1998); accord 63B AM. JUR. 2d *Products Liability* § 2022 (2008) (“As a general rule, compliance with applicable federal standards is relevant but not conclusive evidence in a products liability case.”); see, e.g., IND. CODE § 34-20-5-1 (LexisNexis 2008); KAN. CIV. PROC. CODE ANN. § 60-

“Food and Drug Administration (FDA) approval, though not dispositive, may be considered to show whether a product is safe or not safe.”³ Sometimes evidence of approval is given even greater weight, as in this pattern jury instruction from Kansas:

If a product was at the time of manufacture in compliance with administrative regulatory safety standards relating to design or performance, the product is not defective by reason of design or performance, unless the plaintiff proves that a reasonably prudent manufacturer could and would have taken additional precautions to design the product so as to be reasonably safe for the ordinary consumer who possesses knowledge common to the community as to the product’s characteristics.⁴

Over the past twenty years or so, manufacturers have argued with increasing success that regulatory approval or compliance is not only a defense on the merits—not only evidence that the product was not defective or that the label was adequate—but a defense that operates regardless of the merits of the underlying claim. In terminology that has become all too familiar to lawyers, academics, and consumer advocates interested in tort law, the manufacturers argue that federal approval *preempts* state law damages claims as a threshold matter, creating a bar to product liability suits. The argument for preemption is unrelated to whether a product has caused injury; it applies regardless of causation. The argument is not about whether the company or the consumer was at fault—it applies even if the company acted purposefully or negligently. The argument does not care about the nature of the injury or the extent

3304 (West 2008); TENN. CODE ANN. § 29-28-104 (2008); UTAH CODE ANN. § 78B-6-703(2) (2008); Howard v. McCrory Corp., 601 F.2d 133, 138 & n.9 (4th Cir. 1979) (Maryland law); Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1362 (4th Cir. 1975) (North Carolina law); Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1030 (D.N.J. 1988) (New Jersey law); Shell Oil Co. v. Gutierrez, 581 P.2d 271, 279–80 (Ariz. Ct. App. 1978); Hernandez v. Badger Constr. Equip. Co., 34 Cal. Rptr. 2d 732, 756 (Cal. Ct. App. 1994); Wagner v. Clark Equip. Co., 700 A.2d 38, 50 (Conn. 1997); Banks v. ICI Americas, Inc., 450 S.E.2d 671, 675 n.6 (Ga. 1994); Toner v. Lederle Labs., 732 P.2d 297, 311 n.12 (Idaho 1987); Malek v. Lederle Labs., 466 N.E.2d 1038, 1039–40 (Ill. App. Ct. 1984); Asbestos v. Bordelon, Inc., 726 So. 2d 926, 958 (La. Ct. App. 1998); MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 70–71 (Mass. 1985); Bennett v. Mallinckrodt, Inc., 698 S.W.2d 854, 859 (Mo. Ct. App. 1985); Brooks v. Beech Aircraft Corp., 902 P.2d 54, 63 (N.M. 1995); Sherman v. M. Lowenstein & Sons, Inc., 282 N.Y.S.2d 142, 143–44 (N.Y. App. Div. 1967); Gable v. Village of Gates Mills, 784 N.E.2d 739, 747–48 (Ohio Ct. App. 2003); Zacher v. Budd Co., 396 N.W.2d 122, 133–34 (S.D. 1986).

3. See, e.g., O’Neill v. Novartis Consumer Health, Inc., 55 Cal. Rptr. 3d 551, 556 (Cal. Ct. App. 2007).

4. PATTERN INSTRUCTIONS KANSAS 4TH CIVIL § 128.02 (2008).

of damages. The argument for preemption is that because the product is in compliance with federal regulations (or sometimes simply because the product is subject to federal regulation), the company cannot be held liable, no matter the facts of the case.

Over the past few years, defendant companies' preemption arguments have focused on conflict preemption theories, in particular the notion that state product liability claims pose an obstacle to federal regulation.⁵ That focus, however, is a fairly recent development in product liability and unfair and deceptive trade practices cases. The argument was raised only rarely prior to 2002, and it did not become popular until 2006.⁶ In the 1990s, express preemption became the favored defense of medical device, pesticide, and automobile companies.⁷ The common thread in the express preemption cases was a consumer protection statute that established federal regulation of a category of products—cigarette labels, medical devices, pesticides, motor vehicles—that directly addressed preemption of state law.⁸ The question in these cases was whether damages claims were preempted by statutory language explicitly stating that certain state “requirements” or “standards” are preempted. The argument that the preemption provisions barred damages claims seems to have been devised by lawyers for tobacco companies, who in the mid-1980s developed the argument that the express preemption provision of the Cigarette Labeling Act preempted failure-to-warn claims. The earliest reported decision discussing the tobacco companies' argument came in 1984.⁹ The earliest reported decision involving the express preemption provision in the Medical Device Amendments came in 1987.¹⁰

5. See *infra* Part II.

6. For examples of earlier cases in which the argument was made, see *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at *1 n.2 (S.D. Ind. Jan. 28, 2002) and *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1031–32 (S.D. Ill. 2001).

7. See, e.g., *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867 (2000) (automobiles); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481 (1996) (medical devices); *Grenier v. Vermont Log Buildings, Inc.*, 96 F.3d 559, 562 (1st Cir. 1996) (pesticides).

8. See, e.g., Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136v(b) (2006); Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334 (2006); Medical Device Safety Act, 21 U.S.C. § 360k(a) (2006).

9. *Cipollone v. Liggett Group, Inc.*, 593 F. Supp. 1146, 1148–49, 1154, 1157, 1159 (D.N.J. 1984), *rev'd*, 789 F.2d 181 (3d Cir. 1986); *Roysdon v. R.J. Reynolds Tobacco Co.*, 623 F. Supp. 1189, 1190 (E.D. Tenn. 1985), *aff'd*, 849 F.2d 230 (6th Cir. 1988).

10. See *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1232–33 (Kan. 1987). *Tetuan* was a suit for damages arising from use of the Dalkon Shield, the intrauterine device that caused thousands of injuries and helped to motivate Congress to enact

In 1992, the Supreme Court decided *Cipollone v. Liggett Group, Inc.*,¹¹ a product liability case against a tobacco company, in which the question was whether a provision in the Public Health Cigarette Smoking Act of 1969 that preempted certain state “requirements” encompassed damages claims. The Court held that, as used in that Act, “requirements” could include damages claims and that certain damages claims were preempted by the provision.¹² After that, express preemption took off as a popular defense. Yet in the end, the plaintiffs did not fare too badly in the express preemption cases. With regard to vehicles and motor boats, the Supreme Court held that the relevant statutes do not expressly preempt damages claims;¹³ with regard to medical devices and pesticides, the Supreme Court held that some but not all damages claims are expressly preempted.¹⁴

II.

THE RISE OF “OBSTACLE” PREEMPTION

After a decade of watching litigation over the scope of express preemption provisions, and having failed to push any bills through Congress to eliminate product liability suits, manufacturers started pressing an implied preemption theory. In the context of product liability law, the implied preemption doctrine asks whether the obligations imposed on manufacturers of federally regulated products are inconsistent with duties imposed by state common law. The implied preemption theory essentially is that the applicable federal regulation—whether a performance standard for an automobile or FDA marketing approval and labeling regulations for a device—es-

the MDA. The court in *Tetuan* rejected the preemption argument. *Id.* Many of the early cases involving preemption under the MDA involved injuries caused by tampons, for which FDA regulations set forth specific required warning and testing requirements. *See* *Edmondson v. Int'l Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987); *Ignace v. Int'l Playtex, Inc.*, No. 86-C-480-C, 1987 WL 93996, at *5 (W.D. Wis. Aug. 14, 1987). As litigation over the subsequent two decades illustrates, the device companies later expanded their preemption theory to include all devices, no matter the extent of applicable regulation.

11. 505 U.S. 504 (1992).

12. *Id.* at 520–24 (plurality opinion); *id.* at 548–49 (Scalia, J., concurring in the judgment in part and dissenting in part).

13. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69–70 (2002) (holding Boat Safety Act does not expressly preempt tort claims against motor boat manufacturers); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 868 (2000) (holding Motor Vehicle Safety Act does not expressly preempt tort claims against automakers).

14. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (medical devices); *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 452 (2005) (pesticides); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996) (medical devices).

establishes both a floor and a ceiling for regulated products.¹⁵ Accordingly, the argument goes, the regulatory scheme would be frustrated if manufacturers went beyond the federal requirements to provide better equipment than the relevant automobile safety standard or stronger warnings that the specific labeling approved for a medical device.

Automakers tried this approach concurrently with arguing about express preemption,¹⁶ and occasionally medical device companies made the argument.¹⁷ Before 2002, however, drug companies seldom made this argument. Soon after President George W. Bush took office, drug companies began to push an implied preemption theory, mostly in cases involving suicides allegedly associated with use of a type of antidepressants known as selective serotonin reuptake inhibitors, or SSRIs.¹⁸ Most product liability cases about injuries from drugs are failure-to-warn cases based on inadequacies in the labeling, and the SSRI manufacturers focused their preemption arguments on the history of FDA review of the labeling of those drugs.¹⁹ Their theory was that holding them liable for failing to comply with a state law duty to warn would be inconsistent with the FDA's careful review and approval of the labeling of SSRIs, and the agency's decision not to require the drug's label to warn about an increased risk of suicidality.²⁰

After SSRI manufacturer Pfizer was successful in getting the FDA to file an amicus brief on its behalf in a product liability case,²¹ the preemption argument quickly spread beyond antidepressants. Then in January 2006, the FDA restated the pro-preemption position taken in its amicus brief in a preamble to a new regulation about drug labeling that not only addressed antidepressants, but

15. See generally William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547 (2007).

16. See, e.g., *Geier*, 529 U.S. 861. In the context of suits against automakers, defendants continue to make implied preemption arguments. See, e.g., *O'Hara v. General Motors Corp.*, 508 F.3d 753, 755 (5th Cir. 2007).

17. See, e.g., *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998).

18. See, e.g., *Dusek v. Pfizer Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004); *Motus v. Pfizer Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), *aff'd*, 358 F.3d 659 (9th Cir. 2004).

19. See, e.g., Brief of Defendant-Appellee and Cross-Appellant Pfizer Inc. at 19, *Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372 & 02-55498), 2002 WL 32303085.

20. See *id.*

21. Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court's Order Denying Partial Summary Judgment to Defendant-Appellee and Cross-Appellant, *Motus*, 358 F.3d 659 (Nos. 02-55372 & 02-55498), 2002 WL 32303084.

also advocated for broad preemption of labeling claims with regard to any FDA-approved drug.²² Not surprisingly, after the FDA issued this preamble, preemption became a standard theory for drug company defendants in product liability cases.²³ And just as the companies' arguments expanded, so did the FDA's theory. Whereas in 2006 the agency filed an amicus brief stating that, in its view, there would be no preemption in situations where the agency had not specifically considered the risk or labeling issue involved in a particular lawsuit,²⁴ a 2008 FDA amicus brief described a theory of preemption so broad as to bar most if not all labeling claims.²⁵

The courts had mixed reactions to the FDA's position. Some stated that it warranted no deference and that FDA regulation does not preempt tort claims.²⁶ Others gave the FDA's views some level of deference—some a lot and some less—and held that a plaintiff's claims were preempted.²⁷

22. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

23. See, e.g., *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699, 2006 WL 2374742, at *2 (N.D. Cal. Aug. 16, 2006); *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 680 (E.D. Pa. 2006); *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 967–68 (D. Neb. 2006).

24. Letter from U.S. Dept. of Justice to Judge Stewart Dalzell, Eastern District of Pennsylvania (Sept. 21, 2006), available at <http://druganddevicelaw.net/FDA%20Amicus%20Briefs/Perry%20FDA%20amicus%20brief.pdf>.

25. Brief for the United States as Amicus Curiae Supporting Petitioner at 8–9, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 2308908.

26. See, e.g., *Jackson*, 432 F. Supp. 2d at 968 (D. Neb. 2006) (“The recent notice issued by the FDA claiming preemption is not persuasive.”).

27. *Colacicco v. Apotex Inc.*, 521 F.3d 253, 274–75 (3d Cir. 2008), vacated, 129 S. Ct. 1578 (2009) (concluding “(1) that an agency’s position concerning preemption need not be contained in a formal regulation in order to be considered, and (2) that such a position is subject to a level of deference approximating that set forth in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944),” and holding all claims preempted); *In re Bextra*, 2006 WL 2374742, at *6 (stating that “[t]he FDA’s interpretation of the preemptive effect of its regulations is entitled to deference” and holding some claims preempted); *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 674 (E.D. Ky. 2006) (“FDA’s position has not been consistent and is therefore entitled only to *Skidmore* deference In particular, FDA’s position is persuasive insofar as it rejects failure-to-warn claims (1) based on conduct that allegedly occurred prior to and during the labeling approval process and (2) based on proposed warnings that FDA has specifically considered and rejected as scientifically unsubstantiated.”); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 525 (E.D. Pa. 2006), *aff’d*, 521 F.3d 253 (3d Cir. 2008), vacated, 129 S. Ct. 1578 (2009) (stating that “[t]he FDA’s view is critical to this Court’s analysis because Supreme Court precedent dictates that an agency’s interpretation of the statute and regulations it administers is entitled to deference” and holding all claims preempted).

III. BROADENING INDUSTRY EFFORTS

The FDA's proactive approach to preemption with respect to drugs illustrates the George W. Bush Administration's effort to use the preemption doctrine to effect "tort reform," which companies and their advocates have had so little success achieving in Congress.²⁸ Not only the FDA, but also the National Highway Traffic Safety Administration (NHTSA), the Consumer Product Safety Commission (CPSC), and the Federal Railroad Administration (FRA) made pro-preemption statements during 2005–2008 in the commentary that accompanied the issuance of proposed and final rules in the Federal Register.²⁹ These preambles were not part of

28. *See, e.g.*, Product Liability Reform Act of 1998, S. 2236, 105th Cong. (2d Sess. 1998); Product Liability Reform Act of 1997, S. 648, 105th Cong. (1st Sess. 1997); Common Sense Legal Standards Reform Act of 1995, H.R. 956 (1st Sess. 1995).

29. *See, e.g.*, Flammability (Open Flame) of Mattress Sets, 71 Fed. Reg. 13,472, 13,496–97 (Mar. 15, 2006) (to be codified at 16 C.F.R. pt. 1633) ("The Commission intends and expects that the new mattress flammability standards will preempt inconsistent state standards and requirements, whether in the form of positive enactments or court created requirements."); Reflectorization of Rail Freight Rolling Stock, 70 Fed. Reg. 144, 152 (Jan. 5, 2005) (to be codified at 49 C.F.R. pt. 224) ("With the exception of a provision directed at an essentially local safety hazard that is not inconsistent with a Federal law, regulation, or order, and that does not unreasonably burden interstate commerce, section 20106 will preempt any State or local law or regulatory agency rule covering the same subject matter as this final rule."); Federal Motor Vehicle Safety Standards; Door Locks and Door Retention Components, 72 Fed. Reg. 5385, 5397 (Feb. 6, 2007) (to be codified at 49 C.F.R. pt. 571) (claiming the newly enacted standard preempts state law under the National Traffic and Motor Vehicle Safety Act's express preemptive provision); Railroad Operating Practices: Handling Equipment, Switches and Derails, 71 Fed. Reg. 60,372, 60,404 (proposed Oct. 12, 2006) (to be codified at 49 C.F.R. pts. 217 & 218) ("This is a rule with preemptive effect. Subject to a limited exception for essentially local safety hazards, its requirements will establish a uniform Federal safety standard that must be met, and State requirements covering the same subject are displaced, whether those standards are in the form of State statutes, regulations, local ordinances, or other forms of State law, including State common law."); Passenger Equipment Safety Standards; Front-End Strength of Cab Cars and Multiple-Unit [MU] Locomotives, 72 Fed. Reg. 42,016, 42,028 (proposed Aug. 1, 2007) (to be codified at 49 C.F.R. pt. 238) ("FRA believes that it has preempted any State law, regulation, or order, including State common law, concerning the operation of a cab car or MU locomotive as the leading unit of a passenger train"); Railroad Operating Rules: Program of Operational Tests and Inspections; Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49,223, 49,245–46 (proposed Aug. 23, 2005) (to be codified at 49 C.F.R. pt. 571) (noting that 49 U.S.C. § 30103(b) provides for preemption of state law, and "[t]hus, all differing state statutes and regulations would be preempted" and that "any effort to impose either more stringent requirements or specific methods of compliance

the regulations, and they do not have the force of law.³⁰ That is, damages claims are not preempted just because an agency says in a Federal Register notice that it thinks that claims are preempted. Nonetheless, this development—agencies offering broad and often unsolicited statements about preemption—was troubling because companies’ preemption arguments would have far less success in the courts if they were not supported by the agencies. The debate about whether to hold companies liable for injuries caused by their products really is one that belongs in Congress, the branch of government structured to be sensitive to state interests. But by inserting statements about preemption into Federal Register notices, unelected officials at the regulatory agencies and the Office of Management and Budget were attempting to effect broad “product liability reform,” while side-stepping both the legislative branch and open debate on the issue.

Encouraged by the government’s support of the conflict preemption theory, defendant manufacturers during the past eight years were increasingly creative in finding some regulatory hook on which to hang a preemption argument. Describing a few examples is perhaps the best way to show how far companies sought to extend preemption doctrine. I do not cite these cases to make any comment on their merits or who should ultimately prevail, but only as illustrations of the extent to which preemption theory was being stretched in recent years.

In one case, *Fellner v. Tri-Union Seafoods, L.L.C.*, a tuna company argued that it could not be held liable for failing to warn about the risk of mercury poisoning from eating too much tuna because several years earlier the FDA issued what it called a “consumer advisory” and “backgrounder” telling people that eating too much of some types of fish could be bad for pregnant women and children, but also saying that having some fish in your diet was

would frustrate our balanced approach”); Federal Motor Vehicle Safety Standards; Designated Seating Positions and Seat Belt Assembly Anchorages, 70 Fed. Reg. 36,094, 36,101 (proposed June 22, 2005) (to be codified at 49 C.F.R. pt. 571) (“The proposed rule is not intended to preempt state tort civil actions, except that the determination in those actions of what is a ‘designated seating position’ would be governed by the definition and procedure contained in the Federal motor vehicle safety standards.”).

30. See *Nat’l Res. Def. Council v. Env’t Prot. Agency*, 559 F.3d 561, 564–65 (D.C. Cir. 2009) (“While preamble statements may in some unique cases constitute binding, final agency action susceptible to judicial review, *Kennecott Utah Copper Corp. v. Dep’t of Interior*, 88 F.3d 1191, 1222–23 (D.C. Cir. 1996), this is not the norm.”).

healthy.³¹ The FDA advisory is available on the FDA's website and apparently was sent to some physicians' offices and clinics.³² The company argued that allowing a suit for damages for failure to warn would conflict with the FDA's "approach" to the problem of mercury in tuna.³³ Notwithstanding the agency's very limited and informal "approach," the trial court held that the case was preempted.³⁴ However, the Third Circuit reversed,³⁵ and the Supreme Court denied the company's petition for certiorari.³⁶

Another example of industry efforts to broaden preemption doctrine is a recent series of cases in which plaintiffs have brought claims under state unfair and deceptive trade practices laws against food and beverage manufacturers that label and promote their products as "all natural," when those products contain high fructose corn syrup, a highly processed sweetener.³⁷ The defendants have argued that these cases are preempted by federal regulations that address some aspects of statements on food or beverage labels and an FDA policy, pursuant to which the agency has said that it will not restrict use of the term "natural" and that it construes the word to mean "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food."³⁸ These arguments were made notwithstanding a provision of the federal food labeling law that "explicitly forecloses the possibility that state law would be impliedly preempted"³⁹ by stating that

31. 539 F.3d 237, 241–42 (3d Cir. 2008).

32. U.S. ENVTL. PROT. AGENCY & U.S. FOOD AND DRUG ADMIN., WHAT YOU NEED TO KNOW ABOUT MERCURY IN FISH AND SHELLFISH, ADVICE FOR WOMEN WHO MIGHT BECOME PREGNANT, WOMEN WHO ARE PREGNANT, NURSING MOTHERS, AND YOUNG CHILDREN (2004), <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm110591.htm>.

33. See *Fellner*, 539 F.3d at 242.

34. *Fellner v. Tri-Union Seafoods, L.L.C.*, No. 06-CV-0688 (DMC), 2007 WL 87633, at *6–7 (D.N.J. Jan. 29, 2007), *rev'd*, 539 F.3d 237 (3d Cir. 2008).

35. *Fellner*, 539 F.3d 237.

36. *Tri-Union Seafoods, L.L.C. v. Fellner*, 129 S. Ct. 1987 (2009).

37. See *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1030–34 (N.D. Cal. 2009) (rejecting express and implied preemption arguments in connection with challenge to "all natural" marketing practices); *Hitt v. AriZona Beverage Co.*, No. 08-809 WQH (POR), 2009 WL 449190, at *4–6 (S.D. Cal. Feb. 4, 2009) (same).

38. Food Labeling: Nutrition Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

39. *New York State Rest. Ass'n v. New York City Bd. of Health*, 509 F. Supp. 2d 351, 355 (S.D.N.Y. 2007) (discussing the Nutrition Labeling and Education Act of 1990).

the statute “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted” by the statute.⁴⁰ Moreover, the FDA acknowledged as long ago as 1991, when setting forth the policy on the use of “natural,” that the term is used in ways that confuse and mislead consumers.⁴¹ The FDA has acknowledged that a definition would abate that problem, but has declined to issue a regulation defining the term “natural” “[b]ecause of resource limitations and other agency priorities.”⁴² As the Third Circuit recently explained, there can be no preemption without federal law to do the preempting.⁴³ Accordingly, three of the four district courts that have ruled in these “natural” cases have rejected the preemption argument.⁴⁴ The only district court to find preemption (the first of the cases decided) was reversed on appeal.⁴⁵

My last example is a case decided by the Texas Supreme Court. The question in the case was whether CPSC regulations about child-resistant lighters preempted damages claims brought on behalf of a six-year-old child who was severely burned when her five-year-old brother lit her dress with a disposable Bic lighter.⁴⁶ According to the CPSC, if a lighter cannot be lit by eighty-five percent of the children who try, the lighter can be marketed as “child-resistant.”⁴⁷ The plaintiff in this case argued, among other things, that although the lighter passed that test, a reasonable manufacturer would have

40. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353 (1990); see 21 U.S.C. § 343-1 note (2006).

41. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60466.

42. Food Labeling: Nutrition Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

43. *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 254 (3d Cir. 2008) (“State law is not preempted whenever an agency has merely ‘studied’ or ‘considered’ an issue; state law is preempted when federal *law* conflicts with state law.”); see also *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 549–51 (2008) (finding state unfair and deceptive trade practices action not preempted where Federal Trade Commission suspended proposed rulemaking to require disclosure of cigarettes’ tar and nicotine contents after manufacturers submitted a voluntary agreement to disclose the contents).

44. Compare *Covington v. Arizona Bev. Co.*, No. 08-21894, slip op. at 6–12 (S.D. Fla. Sept. 11, 2009), and *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1030–34 (N.D. Cal. 2009), and *Hitt v. AriZona Beverage Co.*, No. 08-809 WQH (POR), 2009 WL 449190, at *4–6 (S.D. Cal. Feb. 4, 2009), with *Holk v. Snaple Beverage Corp.*, 574 F. Supp. 2d 447 (D.N.J. 2008), *rev’d*, 575 F.3d 329 (3d Cir. 2009).

45. *Holk*, 575 F.3d 329 (3d Cir. 2009).

46. *Bic Pen Corp. v. Carter*, 251 S.W.3d 500 (Tex. 2008).

47. 16 C.F.R. § 1201.3 (2009).

made the lighter safer because more effective child-resistant lighters were on the market.⁴⁸ So the plaintiff's theory of the case seemed to track the traditional consideration of federal standards in products cases, like the jury instructions mentioned earlier. Express preemption was not an issue because although the Consumer Product Safety Act has a preemption provision, it also has a savings clause that states that CPSC standards and regulations do not preempt common law claims.⁴⁹ The Texas Supreme Court held, however, that the damages claims were impliedly preempted because allowing state law to impose liability for not making a safer lighter would conflict with the CPSC's determination that its testing protocol set the appropriate balance between safety and other concerns.⁵⁰

One frustrating aspect of the preemption jurisprudence is that the courts that find conflict preemption have fairly consistently approached the preemption arguments as if the traditional state law civil justice system did not exist.⁵¹ This approach is remarkable because damages claims against manufacturers of approved drugs, medical devices, and automobiles are not *new* remedies. The availability of damages claims preexisted all of our regulatory statutes, including the Food, Drug, and Cosmetic Act,⁵² the Medical Device Amendments of 1976,⁵³ and the National Traffic and Motor Vehicle Safety Act,⁵⁴ and they have coexisted with those laws for decades. There is no evidence that manufacturers have had difficulty complying with federal requirements while also being held accountable to patients under state law for injuries caused by their products.

Nonetheless, this tendency to talk about what "would" happen if consumers injured by drugs, medical devices, automobiles, or other regulated products "could" sue for damages is revealing. Manufacturers' use of "would" is a clever tactic, whereby they shift

48. *Bic Pen Corp.*, 251 S.W.3d at 506.

49. 15 U.S.C. §§ 2072(c), 2074(a) (2006).

50. 251 S.W.2d at 508–09.

51. *See, e.g.*, Transcript of Oral Argument at 43, *Warner-Lambert v. Kent*, 552 U.S. 440 (2008) (No. 06-1498) (question from Justice Breyer: "Now, is that the law in most places? Where the FDA has approved a drug for use and the doctor follows the label and the label is all okay, is it the case that somebody can come in and say, despite that, this drug is on balance harmful, and I get compensation? This is a serious question. I'm not sure how it works.").

52. 21 U.S.C. §§ 301–99 (2006).

53. Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

54. 49 U.S.C. §§ 30101–70 (2006).

the landscape to suggest that plaintiffs are the ones seeking to do something new and questionable, when in fact the status quo allows the lawsuits and preemption would be the major sea change. And when judges speak of what “would” happen if tort claims could go forward against manufacturers of regulated products, they reveal, perhaps, a lack of familiarity with the history of product liability cases, which allows us to see not just what “would” happen but what *does* happen when these cases are litigated.⁵⁵ Or perhaps they buy into the defendants’ framing of the case, which is often presented as if the ruling on preemption is the ultimate ruling on the merits, and thus as if a finding for the plaintiff on preemption is a finding that the plaintiff wins the case.

IV. CONSUMER PERSPECTIVE

The attempt to transform federal compliance from evidence that is relevant to a merits defense into the basis for a legal preemption defense has been bad for consumers for a number of reasons. To begin with, the preemption discussion must proceed from a recognition that people will be injured by regulated products because, even in the best of circumstances, regulation simply cannot guarantee safety. And the best of circumstances rarely exist. To get back to the FDA example, two recent independent government reports have described dangerous shortcomings in FDA oversight of drug safety.⁵⁶ And a National Academies of Sciences’ Institute of Medicine report, prepared at the FDA’s request and released in September 2008, found that the nation’s drug safety system is impaired by “serious resource constraints that weaken the quality and quantity of the science that is brought to bear on drug safety; an organizational culture in [the FDA] that is not optimally functional;

55. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 122 (2d Cir. 2006) (“In fact, it is unclear what a manufacturer of a PMA-approved medical device *would* do when faced with such a jury verdict on a plaintiff’s common law claims, given that the manufacturer *would* nonetheless be unable to make any modifications affecting the device’s safety and effectiveness without obtaining further FDA approval. Moreover, it is certainly conceivable that different juries *would* reach conflicting verdicts about the same medical devices . . .”) (emphasis added), *aff’d*, 552 U.S. 312 (2008).

56. U.S. GEN. ACCOUNTABILITY OFFICE, GAO-06-402, IMPROVEMENT NEEDED IN FDA’S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS, (2006), *available at* www.gao.gov/cgi-bin/getrpt?GAO-06-402; COMM. ON THE ASSESSMENT OF THE U.S. DRUG SAFETY SYS., INST. OF MED. OF THE NAT’L ACADS., *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2006), *available at* http://www.nap.edu/openbook.php?record_id=11750&page=R1.

and unclear and insufficient regulatory authorities particularly with respect to enforcement.”⁵⁷ FDA employees report similar problems. Responding to surveys, employees have expressed discomfort with the pressure they feel to approve new drugs.⁵⁸ In a survey released in the summer of 2006, sixty percent of FDA employees who responded knew of cases “where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal or modification of FDA determinations or actions.”⁵⁹ Moreover, experience suggests that the FDA’s shortcomings undermine public health. In recent years, several drugs have been forced from the market for safety reasons—in some cases, long after the FDA became aware that the drug was causing serious harm. The diabetes drug Rezulin and the pain reliever Vioxx provide two well-known examples.⁶⁰ Thus, experience shows that regulatory approval is not a guarantee of safety; inevitably, some people will be injured by regulated products.

Proceeding from that premise, the most obvious consequence of the preemption defense for consumers is that, when the defense is successful, consumers are cut off from even the possibility of recovering any compensation for injury caused by regulated products. The defense leaves no room for consideration of what a reasonable manufacturer would have done in a particular situation. It leaves no room for factual distinctions between individual cases. It sweeps away traditional common law approaches to assessing fault and liability.

Furthermore, damages suits advance public health in several ways. First, product liability lawsuits help to uncover information that can lead to safer products. Material produced in litigation can help the public and the FDA to identify problems with particular drugs and can add to physicians’ and the public’s understanding of

57. COMM. ON THE ASSESSMENT OF THE U.S. DRUG SAFETY Sys., *supra* note 56, at 4.

58. UNION OF CONCERNED SCIENTISTS, VOICES OF SCIENTISTS AT FDA: PROTECTING PUBLIC HEALTH DEPENDS ON INDEPENDENT SCIENCE (2006), available at http://www.ucsusa.org/assets/documents/scientific_integrity/fda-survey-brochure.pdf; Janet Rehnquist, Dep’t of Health and Human Servs., FDA’S REVIEW PROCESS FOR NEW DRUG APPLICATIONS 9–17 (2003), available at <http://oig.hhs.gov/oei/reports/oei-01-01-00590.pdf>.

59. UNION OF CONCERNED SCIENTISTS, *supra* note 58, at 2.

60. Brooke A. Masters & Marc Kaufman, *Painful Withdrawal for Makers of Vioxx; Pulling of Arthritis Drug Raises Questions on Marketing, Safety Risks*, WASH. POST, Oct. 18, 2004, at A1; David Willman, *The Rise and Fall of the Killer Drug Rezulin*, L.A. TIMES, June 4, 2000, at A1.

the risks of the products and flaws in the regulatory system.⁶¹ The same is true with respect to other types of products. For example, suits against automakers led to disclosure of important information about the Ford/Firestone rollover problem.⁶²

Second, by deciding up front that the industry cannot be held accountable to consumers, preemption eliminates an important motivation for companies to make their products as safe as possible.

Third, and related to the prior point, the broad conflict preemption arguments espoused over the past several years ignore the reality that knowledge and technology are constantly advancing. For example, knowledge of a drug's risks, particularly long-term risks, is never complete at the time of initial marketing approval. In fact, only half of a drug's serious hazards are known and documented in the *Physicians' Desk Reference* seven years after the drug's approval.⁶³ Products liability lawsuits help to protect patients from drugs with undisclosed risks because the potential for being held liable for harm caused by their products provides a powerful incentive for drug companies to revise labeling in a timely manner, to improve products as soon as a defect is identified, and to remove from the market older products that do not provide the safety that newer ones offer.

A similar point is illustrated by motor vehicle regulation. Once issued, a vehicle safety standard issued by the National Highway Traffic Safety Administration (NHTSA) usually remains in place for many years, even decades. Technology, however, does not stand still. Therefore, while it might have made sense to issue a particular standard at a given point in time, one year later or the year after that, automakers may know that the standard is not adequate to protect safety and that a safer alternative is achievable. At that point, it makes little sense to allow the company to hide behind the regulatory standard as a shield from liability. For example, NHTSA only recently updated a roof crush resistance standard for passen-

61. See, e.g., David Brown, *Maker of Vioxx Is Accused of Deception*, WASH. POST, Apr. 16, 2008, at A1 (discussing article from the *Journal of the American Medical Association* evaluating information found in Vioxx discovery documents); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. AM. MED. ASS'N 308, 309 (2007) (offering several examples).

62. Megan Stack, *Ford, Firestone Settle Woman's Tire Lawsuit*, CJ ONLINE, Jan. 9, 2001, http://www.cjonline.com/stories/010901/bus_tiresuit.shtml; Jay Weaver, *Judge Cancels Order Sealing Firestone Files*, MIAMI HERALD, Sept. 30, 2000, at 4B.

63. Karen E. Lasser, et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J. AM. MED. ASS'N 2215, 2218 (2002).

ger cars that was first issued more than thirty-seven years ago.⁶⁴ Technology had changed tremendously during that time. Yet in 2005, when NHTSA proposed a new standard for roof strength, it said that the new standard should preempt damages claims.⁶⁵ In this case, we did not even need to wait years to see whether a stronger roof is achievable. Most cars already met the proposed standard, and some already exceeded it.⁶⁶

So today, it is often feasible to design a product or to revise a label to provide a level of safety greater than the level required by a 1990 safety standard or to make a product safer than the version approved in 1995, for example. Yet if compliance with the relatively old standard or the fact of the approval preempts damages claims, then an injured consumer can never show that the design (or indeed the standard) was outdated or that a reasonable manufacturer would have known that the approved warning was inadequate. Suppose that the FDA approved a drug and its labeling in 2003, but that the manufacturer received adverse event reports in 2004 showing that the product was causing an unanticipated adverse reaction or that physicians were misunderstanding something stated on the label. The manufacturer does not raise the issue with the FDA—it neither seeks to change its label unilaterally nor asks the FDA for approval of a new label. Eventually, the information will get out; the label will be revised or the drug withdrawn from the market. The question remains, though, what about the injured patients? Who bears the cost of the injuries? Historically, that question has been for a jury to decide, but the preemption doctrine is based on the notion that this question must be answered as a matter of law and in favor of the defendant.

64. *See* 49 C.F.R. § 571.216 (2008). Aside from non-substantive changes, the roof crush resistance standard issued in December 1971 was in effect until July 13, 2009. *See* Standard No. 216a; Roof crush resistance; Upgraded standard, 74 Fed. Reg. 22,347, 22,384–87 (May 12, 2009).

65. Federal Motor Vehicle Safety Standards; Roof Crush Resistance, 70 Fed. Reg. 49223, 49245–46 (proposed Aug. 23, 2005).

66. The commentary accompanying issuance of the final rule receded from the position that NHTSA had stated when the proposed rule was issued:

After considering the public comments on the proposal and considering today's final rule, NHTSA has reconsidered the tentative position presented in the NPRM [notice of proposed rulemaking] and do not currently foresee any potential State tort requirements that might conflict with today's final rule.

Without any conflict, there could not be any implied preemption.

Federal Motor Vehicle Safety Standards; Roof Crush Resistance; Phase-In Reporting Requirements, 74 Fed. Reg. 22,348, 22,382 (May 12, 2009).

V.

THE DECLINE OF “OBSTACLE” PREEMPTION

The Bush Administration’s effort to preempt state law damages claims suffered two recent and significant setbacks. First, Barack Obama won the 2008 presidential election, and all expect that the agencies’ efforts will now be cut back considerably, if not cease altogether. Two early indications are NHTSA’s final roof crush rule⁶⁷ and NHTSA’s March 29, 2009 Notice of Intent, which stepped back from the agency’s prior statement that federal corporate average fuel economy (CAFE) standards preempted state fuel economy standards, although it deferred a definitive statement on the agency’s position.⁶⁸ Then on May 12, 2009, President Obama issued a memorandum to the heads of the executive branch agencies in which he criticized the agencies’ practice under the prior administration of “announc[ing] that their regulations preempt State law, including State common law, without explicit preemption by the Congress or an otherwise sufficient basis under applicable legal principles.”⁶⁹ The memorandum instructs the agencies to limit statements of preemption to narrow circumstances and “to review regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles.”⁷⁰

Second, on March 4, 2009, the Supreme Court issued its decision in *Wyeth v Levine*, which asked whether FDA marketing approval of a drug impliedly preempted an injured patient’s failure-to-warn claim against the drug manufacturer.⁷¹ The Court’s decision soundly rejects the preemption preamble issued by the Bush Administration’s FDA in 2006, and it seems to resolve the issue of what weight a court should accord an agency’s statement about preemption—little to none.

The story of the *Wyeth* case starts in 2000, when Diana Levine went to a clinic for treatment of a migraine headache. A physician

67. *Id.*

68. Notice of Intent for Corporate Average Fuel Economy Standards; Effect Upon State Laws and Regulations, 74 Fed. Reg. 11,993 (Mar. 20, 2009).

69. Memorandum from Barack Obama, President of the United States, to Heads of Executive Departments and Agencies (May 20, 2009), *available at* http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption.

70. *Id.*

71. 129 S. Ct. 1187 (2009).

assistant at the clinic gave her one drug for the pain and another drug, Phenergan, for nausea. The physician's assistant injected the Phenergan through a method called "IV-push." Unlike administration by IV-drip, where the drug is delivered to the vein through a hanging IV bag, IV-push means that the drug is injected into the vein from a syringe. Unfortunately, either the syringe nicked Ms. Levine's artery or the drug escaped from the vein and came into contact with arterial blood. As a result, gangrene set in, eventually requiring amputation of Ms. Levine's arm. Phenergan's label warned that the drug can cause gangrene when it comes into contact with arterial blood. However, although this risk is much higher if the drug is administered by IV-push, as opposed to an IV-drip or an intramuscular injection, the label did not warn about the increased risks associated with IV-push. After her arm was amputated, Ms. Levine sued Wyeth, the drug's manufacturer, alleging state law claims of failure to warn and strict liability.⁷²

Wyeth moved for summary judgment, arguing that Ms. Levine's failure-to-warn claims were preempted under both conflict preemption and field preemption theories. The district court denied the motion.⁷³ After a four day trial, the jury returned a verdict for Ms. Levine and awarded her \$7,400,000.⁷⁴ In a post-trial motion for judgment as a matter of law, Wyeth again argued preemption, and the court again denied the motion.⁷⁵ The Vermont Supreme Court affirmed,⁷⁶ and the Supreme Court of the United States granted Wyeth's petition for certiorari.⁷⁷

The Supreme Court affirmed.⁷⁸ First, the Court considered Wyeth's argument that state law claims were preempted because it would have been "impossible" for the company to comply with both the state law duties underlying Ms. Levine's claims and federal labeling requirements.⁷⁹ Noting that FDA regulations allow companies to revise their labels in light of information acquired after

72. *Id.* at 1191-92.

73. *Levine v. Am. Home Prods., Inc.*, No. 670-12-01 Wncv, 2003 WL 25648135 (Vt. Super. Ct. Dec. 23, 2003), *aff'd sub nom.* *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), *aff'd* 129 S.Ct. 1187 (2009).

74. *See Levine v. Am. Home Prods., Inc.*, No. 670-12-01, 2004 WL 5456809, at *1 (Vt. Super. Ct. Jul. 30, 2004), *aff'd sub nom.* *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), *aff'd* 129 S. Ct. 1187 (2009).

75. *Id.*

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

77. *Wyeth v. Levine*, 128 S. Ct. 1118 (2008).

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

79. *Id.* at 1196.

approval, the Court rejected this theory.⁸⁰ The Court also rejected the argument that revising the label would have rendered the drug misbranded.⁸¹ The Court explained that a drug is not misbranded simply because a manufacturer has altered an FDA-approved label.⁸² Moreover, the Court stated that “the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning . . . is difficult to accept.”⁸³ Accordingly, the Court held that “absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”⁸⁴

Next, the Court turned to Wyeth’s theory that Ms. Levine’s inadequate warning claim was preempted because the state law duties underlying it would obstruct the objectives of federal drug labeling regulation.⁸⁵ The Court rejected this theory as well, stating that it “relies on an untenable interpretation of congressional intent and an overbroad view of an agency’s power to pre-empt state law.”⁸⁶ The Court disagreed with the notion that federal law establishes both a floor and a ceiling for drug regulation, finding that “all evidence of Congress’[s] purposes is to the contrary.”⁸⁷

Aside from the very powerful rejection of the conflict preemption argument, *Wyeth* is significant for the lack of deference it gave the FDA. The Court stated that the FDA’s 2006 preamble “does not merit deference.”⁸⁸ Noting that the FDA had stated when it issued the proposed rule that the regulation would not preempt state law, but then “articulated a sweeping position” asserting preemption when it issued the final rule, the Court stated that the “agency’s views on state law are inherently suspect in light of this procedural failure.”⁸⁹ The Court also stated that “the preamble is at odds with what evidence we have of Congress’[s] purposes, and it reverses the FDA’s own longstanding position without providing a reasoned explanation.”⁹⁰ Using strong language, the Court stated not only that the FDA’s preamble did not merit *Chevron* deference or even *Skid-*

80. *Id.* at 1196–99.

81. *Id.* at 1197.

82. *Id.*

83. *Id.*

84. *Id.* at 1198.

85. *Id.* at 1199.

86. *Id.*

87. *Id.*

88. *Id.* at 1201.

89. *Id.*

90. *Id.*

more deference,⁹¹ it stated that the FDA's position "is entitled to no weight."⁹² Similarly, the Court found that the government's amicus brief was "undeserving of deference," as its explanation of federal drug regulation "departs markedly from the FDA's understanding at all times relevant to this case."⁹³

In dismissing the FDA's views, the Court distinguished the FDA's position in *Wyeth* from the government's position in *Geier v. American Honda Motor Co.*⁹⁴ In *Geier*, holding that the Motor Vehicle Safety Act impliedly preempted state law product liability claims premised on the lack of airbags in the plaintiff's automobile, the Court relied extensively on the Federal Register notice and preamble that accompanied issuance of NHTSA's passive restraint rule.⁹⁵ Yet the Court did not find preemption based on what NHTSA had said about *preemption* during the rulemaking—in fact, the agency had not addressed preemption in the rulemaking. Rather, the Court looked to what the agency had said about the substantive purposes of the rule, and it found that allowing the case to go forward would frustrate that purpose. In contrast, with regard to drug labeling regulation, the FDA's commentary directly addressed preemption and suggested that *Geier* gave it authority to say, not what the agency hoped to achieve by fashioning the regulation as it did, but what the effect of that standard would be on consumers' ability to sue for injury. The government and industry had sought to use *Geier* as support for a general proposition that the courts should defer to an agency's views on preemption.⁹⁶ *Wyeth* rejects that proposition.⁹⁷

91. When Congress, in enacting a statute, has left a gap for an agency to fill, thereby delegating to the agency authority to elucidate a specific provision of the statute, courts will defer to the agency's interpretation of the provision if that interpretation is "reasonable." *Chevron U.S.A., Inc. v. Nat'l Res. Def. Council*, 467 U.S. 837, 843–44 (1984). Where Congress has not delegated such authority to the agency, the weight accorded to the agency's views "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

92. *Wyeth*, 129 S. Ct. at 1204.

93. *Id.* at 1203 n.13.

94. 529 U.S. 861 (2000).

95. *Id.* at 877–80.

96. See Brief for Petitioner at 48, 50 n.22, *Wyeth*, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 2273067; Brief for the United States as Amicus Curiae Supporting Petitioner, *supra* note 25, at 26.

97. *Wyeth*, 129 S. Ct. at 1203.

VI. CONCLUSION

After *Wyeth*, defendants will likely try these broad “frustration of purpose” or “obstacle” theories of preemption with considerably less frequency. Courts will likely accept them even less often. For example, if the FDA’s regulation of drugs, which is much more extensive than its regulation of food, does not ever preempt or almost never preempts state common law duties, it is hard to see how FDA regulation of foods could form the basis for preemption in any but the most unusual instances. As for drug cases, the question now is the same question that in some ways started us down this road about eight years ago: What about SSRI cases? Is there preemption in those cases? My personal view is no, but I have no prediction about what the lower courts will say.

Returning to preemption concerns more generally, many members of Congress are aware of and concerned about the expansion of preemption jurisprudence. Bills to overturn the *Riegel* decision are pending in the House and in the Senate,⁹⁸ and a number of pending bills include provisions intended to make clear that state law claims do not pose an obstacle to Congress’s purpose with respect to the subject matter of those bills, thereby forestalling broad conflict preemption arguments.⁹⁹

As *Wyeth* recognizes, conflict preemption is not a choice that an agency gets to make. Conflict preemption occurs where, as a matter of fact, an entity cannot comply with both state and federal law or state law actually interferes with the operation of federal law. Whether or not an administration favors tort reform as a matter of policy should be largely irrelevant. The policy decision belongs to Congress.

98. See Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009); Medical Device Safety Act of 2009, S. 540, 111th Cong. (2009).

99. See, e.g., Consumer Financial Protection Agency Act of 2009, H.R. 3126, 111th Cong. § 141 (2009); Hardrock Mining and Reclamation Act of 2009, S. 796, 111th Cong. § 308 (2009).