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An Economic Perspective on Preemption

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AN ECONOMIC PERSPECTIVE ON PREEMPTION

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Abstract: This Essay has two goals. The first is to present an economic theory of preemption as a choice among regulatory regimes. The optimal regime choice model is used to generate specific implications for the court decisions on preemption of products liability claims. The second objective is to extrapolate from the regime choice model to consider its implications for broader controversies about preemption.

INTRODUCTION

After decades of case law and commentary,[1] preemption remains a controversial topic. It has been viewed as part of a program to federalize substantial pieces of state law,[2] as a device through which federal government power expands,[3] and as a general source of legal doctrines in search of a basis in constitutional law.[4]

This Essay focuses on a specific area of controversy: preemption of products liability lawsuits. This is probably the most important area of the preemption controversy because it involves enormous investments by technology firms and government entities in regulatory infrastruc-

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[1] Preemption has been an issue in the case law for a long time, but intense academic interest has been relatively recent, and probably the result of conflicts between federal regulation and state tort law. One of the first federal cases to address the issue in the products liability setting is *Wood v. General Motors Corp.*, 865 F.2d 395 (1st Cir. 1988). The vast majority of articles on preemption have been published after 1990.

[2] *See* Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353, 1368–69 (2006).

[3] This is clearly an implication of the Issacharoff & Sharkey article, though their focus is on the government's role in controlling cross-state externalities. *See id.* at 1355–57, 1365–72. For a clear expression of the concern over preemption's effect on the balance of state and federal power, see Wyeth v. Levine, 555 U.S. 555, 582–604 (2009) (Thomas, J., concurring in judgment).

[4] *See* Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 807–08 (1994); *see also* Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 759–69 (2008).

ture. In spite of this focus on a specific area of preemption, the approach taken here can be generalized to other preemption disputes.

I hope to accomplish two objectives. The first is to present an economic theory of preemption as a choice among regulatory regimes.[5] The optimal regime choice model will be used to generate specific implications for the court decisions on preemption of products liability claims. More specifically, the regime choice model generates a positive theory of the preemption case law, reconciling several seemingly conflicting decisions. For example, the seemingly inconsistent U.S. Supreme Court decisions in *Geier v. American Honda Motor Co.*[6] in 2000 and in *Williamson v. Mazda Motor of America, Inc.*[7] in 2011, are easily reconciled within this framework.

The second objective is to extrapolate from the regime choice model to consider its implications for broader controversies about preemption.[8] The topic has been expanded by commentators into a foil for a range of opinions about the relationship between state and federal law.[9] The products liability preemption cases, in contrast, deal with a concrete question: should courts regulate, or should an agency, such as the Food and Drug Administration (FDA), regulate?[10] The answer to this question has immediate implications for the investments that firms make and the corresponding amount of injuries their products inflict on consumers. From this concrete problem, a much larger set of issues has emerged, many of which are capable of being answered independently of the concrete issues. It would simplify matters greatly if courts recognized the preemption defense, or some version of it, as having a basis in the common law, rather than requiring an explicit view of the Constitution's constraints on the federal government's power to regulate.

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[5] *See infra* notes 11–46 and accompanying text.

[6] 529 U.S. 861, 874, 886 (2000).

[7] 131 S. Ct. 1131, 1137–40 (2011).

[8] *See infra* notes 49–55 and accompanying text.

[9] *See, e.g.*, Gardbaum, *supra* note 4, at 808; Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. Rev. 1, 4 (2007); *infra* notes 103–105 and accompanying text.

[10] *E.g. Geier*, 529 U.S. at 894 (Stevens, J., dissenting) ("[T]he Supremacy Clause does not give unelected federal judges *carte blanche* to use federal law as a means of imposing their own ideas of tort reform on the States.").

I. A Model of Regulatory Regime Choice

To make the concrete problem in the preemption cases a bit clearer, consider a simple model of a products liability preemption dispute. Suppose a manufacturer of medical devices makes a "medical widget." The medical widget is approved by the FDA. A plaintiff is hurt by the medical widget and sues the manufacturer on the theory that the medical widget is defectively designed. The manufacturer walks into court and argues that the plaintiff's lawsuit should be dismissed because the medical widget is regulated by the FDA and its design has been approved by the agency.

The decision facing the court is at bottom a choice between regulatory regimes:[11] the court itself or the FDA. If the court finds that the plaintiff's lawsuit is preempted, it says in effect that the FDA will be the primary, and in some instances the sole, regulator of the design of the medical widget. If it finds that the plaintiff's lawsuit is not preempted, then it is saying, in effect, that the FDA's regulatory decisions will be subject to reconsideration by state (or federal) courts. After all, any finding that a design that was approved by the FDA is defective under products liability law will have the effect of encouraging firms to adopt designs that comply with the court's product-design views rather than, or in addition to, the product-design views of the FDA.

A defective design claim is, as many courts have noted, a species of negligence claim.[12] Under the increasingly standard risk-utility test in

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[11] On the economics of regulatory regime choice, see generally Edward L. Glaeser & Andrei Shleifer, *The Rise of the Regulatory State*, 41 J. Econ. Literature 401 (2003); Keith N. Hylton, *Preemption and Products Liability: A Positive Theory*, 16 Sup. Ct. Econ. Rev. 205 (2008); Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. Legal Stud. 357 (1984). The model in the Hylton article differs from the analysis of Shavell mainly by incorporating public choice issues into the analysis of regulatory choice. *See* Hylton, *supra*, at 206–07, 212–13. Although I will rely on the model in Hylton in the discussion of economics below, that model is an extension of Shavell's. *See id.* at 212–13.

[12] *See, e.g.*, Larsen v. Gen. Motors Corp., 391 F.2d 495, 503 (8th Cir. 1968) (holding that a manufacturer's duty of reasonable design rests on principles of negligence law); Volkswagen of Am., Inc. v. Young, 321 A.2d 737, 745 (Md. 1974) (holding that design defect products liability claims are governed by negligence principles); Bolm v. Triumph Corp., 305 N.E.2d 769, 772–74 (N.Y. 1973) (holding the manufacturer liable under general negligence principles for injuries caused by defects in construction or design); Tyson v. Long Mfg. Co., 107 S.E.2d 170, 173 (N.C. 1959) (holding that the plaintiff must show negligence in the design or construction of a machine in order for the court to find the manufacturer liable for negligence); *see also* William M. Landes & Richard A. Posner, *A Positive Economic Analysis of Products Liability*, 14 J. Legal Stud. 535, 553–54 & n.20 (1985) (citing cases); David G. Owen, *Design Defects*, 73 Mo. L. Rev. 291, 313–15 (2008) (applying Learned Hand's formula for negligence to design defect products liability, substituting "defect" for "negligence").

products liability law, a court compares the incremental risk of the specific product design that is challenged with its incremental utility, in comparison to some safer, feasible, alternative design.[13] If the incremental risk is notably in excess of the incremental utility, the product will be found to have a design defect.[14] If defective design liability works as desired, it will encourage firms whenever they have the choice between two designs to choose the relatively dangerous design only when the incremental utility from that design exceeds the incremental risk.[15] This phenomenon is analogous to the function of the negligence rule, which encourages an actor to choose the relatively safe course of action whenever the burden of that course is smaller than the incremental harm that would be caused by choosing the unsafe course of action.[16]

I have described the product-design decision and the negligence decision as discrete choice problems. Some economic models of negligence treat the choice problem as one of finding the overall optimal level of care.[17] Tort litigation, however, involves discrete choices, which are shaped by plaintiffs.[18] Plaintiffs generally come to court with negligence theories of their own construction.[19] The negligence cases that survive in court are almost always plausible cases in the sense that the burden of precaution is less than the incremental risk of not taking precaution. In the same sense, one should expect products liability cases often to have the same feature: a claim that seems plausible on its face because the plaintiff has identified a relatively safe alternative that is arguably comparable in function to the design that is challenged.

The discrete choice assumption is built into this model of regulatory choice. In a lawsuit, the plaintiff comes to court with a discrete choice problem.[20] In the regulatory phase, however, the agency considers a large number of potential choices.[21] The regulatory environment

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[13] *See* Hylton, *supra* note 11, at 212.

[14] *See id.*

[15] *See id.*

[16] *See* Owen, *supra* note 12, at 313–15.

[17] For an early and foundational model, within this vein, of the incentives created by negligence law, see John Prather Brown, *Toward an Economic Theory of Liability*, 2 J. Legal Stud. 323, 323–24 (1973).

[18] Mark F. Grady, *Untaken Precautions*, 18 J. Legal Stud. 139, 141 (1989).

[19] *Id.*

[20] *See id.*

[21] *See* James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 Colum. L. Rev. 1531, 1534–42 (1973) (arguing that courts applying the negligence standard are an improper forum to consider product-design issues because of the large number of tradeoffs).

could result in requirements that are inconsistent with the discrete choice approach merely because the comparison of many alternatives may produce a result that differs from that based on a comparison of two options.[22] This discrepancy in available choices is one possible source of inconsistency between the regulatory regime and the court regime, though I will not consider it here.

Faced with the risk of a lawsuit for a defective design, a firm that chooses to design its products to avoid liability will presumably suffer some compliance cost.[23] The most obvious compliance cost is the opportunity cost (forgone profit) of the alternative, risky design. Product liability actions based on defective design therefore involve the same incentive control issues as the ordinary negligence actions.

The benefits from regulation consist of the incremental social benefit from reducing injuries by opting for the relatively safe design. But this benefit has to be discounted by the additional utility society would have gained from the alternative, risky design. The net benefit from regulation is positive only if the social benefit from reducing risk exceeds the loss in utility.

The net benefit from product safety regulation is therefore made up of several components. One is the *risk-utility differential*, which is equivalent to a measure of the consumer welfare differential.[24] This

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[22] Consider, for example, the cycling of preferences under majority rule associated with the Condorcet paradox. *See, e.g.*, Dennis C. Mueller, Public Choice III, at 83–84 (2003).

[23] *See* A. Mitchell Polinsky, An Introduction to Law and Economics 113–14 (4th ed. 2011).

[24] The courts and commentators have set out descriptions of the risk-utility test in products liability law. One popular description was offered in John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 837–38 (1973). Wade proposed a seven-factor test for implementing the risk-utility test in products liability cases. *Id.* The first five factors of Wade's test summarize the key components of a risk-utility comparison. *Id.* at 837. They can be paraphrased as follows: (1) the "usefulness and desirability of the product," relative to the safe alternative; (2) the risk of injury generated by the product, relative to the safe alternative; (3) the availability (price and quantity) of the safe alternative; (4) the manufacturer's ability to make the safe alternative without impairing the usefulness of the product; and (5) the user's ability to avoid the danger by taking care. *Id.* The five factors described capture the determinants of the consumer welfare effect of choosing the challenged design instead of the safe alternative. *See id.* If consumers are fully aware of the dangers associated with the challenged design, then the five factors may be misleading as a description of the consumer welfare effect, because by choosing the challenged design over the safe alternative, consumers have revealed that their welfare is enhanced by consuming the challenged design. *See* Polinsky, *supra* note 23, at 115–16; Wade, *supra*, at 837–38. If the risk characteristics of the challenged design are obvious to consumers, then products liability can do nothing to affect the frequency with which the dangerous product is consumed on the market. *See, e.g.*, Polinsky, *supra* note 23, at 114–16.

must be positive for regulation to be socially beneficial. Another component is the compliance cost to the firm. The *net deterrence benefit* is the difference between the consumer welfare (risk-utility) differential and the firm's compliance cost.[25]

The consumer welfare differential is not unconnected to the compliance cost of the firm. In general, a superior product that enhances consumer welfare will often be more profitable to the firm. A regulatory order that prevents adoption of such a superior product reduces consumer welfare and increases compliance costs.

One other category of costs to consider is administrative costs. A specific regulatory regime might generate the greatest net deterrence benefit, yet its administrative costs may be so high that it is inferior to an alternative regulatory regime. Another category of costs consists of risk. In an environment where firms, the regulated entities, must invest before the regulatory decision is made, there is a social benefit from predictability.[26]

This discussion suggests an objective for the choice of optimal regulatory regime: choose the regime in which the net benefit from deterrence exceeds the administrative costs by the greatest amount. Thus, if B represents the consumer welfare differential from safety regulation, C the compliance cost, AC the administrative costs, and R the risk cost, Regime 1 is preferable to Regime 2 if $B_1 - C_1 - AC_1 - R_1 > B_2 - C_2 - AC_2 - R_2$. For comparison purposes, note that these terms would be defined differently in a routine case involving some safety precaution. In such a routine case, the benefit from deterrence would be the reduction in injury costs due to taking care, and the compliance cost would be the cost of taking care.

There are different yet equivalent ways of describing the choice between regulatory regimes. For example, the decision could be described as one of choosing the regime with the lowest sum of injury, compliance, administrative, and risk costs, subject to a given level of consumer welfare.[27]

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[25] *See* Hylton, *supra* note 11, at 216.

[26] *See* Alberto Alesina & Guido Tabellini, *Bureaucrats or Politicians? Part II: Multiple Policy Tasks*, 92 J. Pub. Econ. 426, 434–35 (2008).

[27] The cost minimization formulation of the objective of the tort system was proposed in Guido Calabresi, The Costs of Accidents: A Legal and Economic Analysis 26–31 (1970). Calabresi argued that the tort system should minimize the sum of injury costs, accident avoidance costs, and administrative costs. *Id.* at 26–28.

The "error-cost" approach is another version of the same decision process.[28] Suppose Regime 1 is preferable to Regime 2. An error leading to a choice of Regime 2 has identifiable costs in the form of lower consumer welfare, greater compliance costs, or greater administrative costs.

In the preemption setting, the regime choice decision is before a court. The court can either dismiss the tort suit for an injury caused by the medical widget on the ground that the suit is preempted by regulation, or entertain the lawsuit and issue a judgment. The factors that should determine the preemption decision are those that would determine the choice between regulatory regimes.

A. *The Consumer Welfare (Risk-Utility) Component*

The first step in assessing the choice between court and agency regulation is a consideration of the consumer welfare implications. What are the conditions that determine whether a particular regulatory regime has a preferable impact on consumer welfare? Three factors emerge: expertise, knowledge of local conditions, and political independence.

The first factor is expertise. Some agencies, such as the FDA, are staffed with experts on the issues that fall within the agency's scope of regulation. Courts, on the other hand, rely on non-expert juries, though they often are aided in their decision making by the adversarial presentations of experts.

Where knowledge of the relevant industry or technology is helpful in making an assessment of the welfare implications of safety regulation, an expert agency is clearly preferable to a jury. In terms of the framework developed, the net benefit from regulation is greater (other things being equal) in cases where agency expertise is helpful in reaching accurate assessments of the risk-utility trade-off. The design of a medical widget is the common example of a case where agency expertise is preferable to the expertise of a court.

A second factor is knowledge of local conditions. Although an expert agency can make a more accurate assessment where technological issues are at stake, a jury may still have an informational advantage where an assessment of the net welfare effect requires knowledge of local conditions or common practices.[29]

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[28] *See* Hylton, *supra* note 11, at 211–14.

[29] The same may be said, and of course has been said, of a judge's decision to consult a jury about a question of negligence. *See* Oliver Wendell Holmes, Jr., The Common Law

For example, consider the preemption of a nuisance claim. Nuisance lawsuits typically involve disputes concerning local conditions.[30] Because of the locality concern in nuisance law, local conditions are a factor that must be considered in the course of determining whether a specific activity is a nuisance.[31] A federal agency or statute that purports to preempt nuisance disputes should raise immediate concerns under the welfare test articulated here. The federal legislature, or a federal agency, is unlikely to know as much about local conditions in other areas of the country as do the people, including experts and potential jurors, who live there. It follows that implied preemption theories in the nuisance setting generally shift decision making to a less informed body.[32]

On the other hand, a medical widget, such as a new type of pacemaker, is unlikely to raise issues requiring knowledge of local conditions. The pacemaker is going to perform in a manner that will be determined by the technology and by a patient's personal conditions, which have nothing to do with local or common knowledge. Shifting decision making from the agency to the court, however, is likely to lead to more errors in the assessment of the consumer welfare impact of regulation.

A third factor that has to be considered is political independence.[33] Two common manifestations of a lack of political independence are vulnerability to industry capture and bias from pressure groups. The agency may have an information advantage, yet may also be vulnerable to control by members of the regulated industry. A court may be a superior forum in which to examine the net consumer welfare implications of regulation if the agency's decision making is subject to bias.

One important feature of preemption analysis in the common law is that courts are in a position to observe agency proceedings in an objective light. They are able to determine whether an agency is vulnerable to bias, and have made this determination in many cases.[34] The

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122–23 (Dover Publ'ns, Inc. 1991) (1881). Holmes offered a model of litigation in which the jury's role is to inform the court on common experience. *See id.*

[30] Richard A. Epstein, *Federal Preemption, and Federal Common Law, in Nuisance Cases*, 102 Nw. U. L. Rev. 551, 555–56 (2008).

[31] *See id.*

[32] Even where the nuisances cross state borders, there are arguments in favor of common law decision making rather than federal regulatory decision making. *See* Epstein, *supra* note 30, at 567–68 (2008) (advocating a federal common law approach, rather than federal preemption, in interstate nuisance cases).

[33] *See* Hylton, *supra* note 11, at 216–17.

[34] The best example is *Wilson v. Bradlees of New England, Inc.* 96 F.3d 552, 556–57 (1st Cir. 1996). In that case, Judge Michael Boudin rejected the preemption theory largely on

most recent example of this extraordinary advantage was observed in 2009 in *Wyeth v. Levine*, where the U.S. Supreme Court refused to defer to the agency's own description of the preemptive effect of its regulation on the ground that it did not consider the agency's position reliable and objective.[35]

On the welfare analysis offered here, when a court observes vulnerability to bias, it is appropriate for the court to look with suspicion on the agency process. A more accurate agency process may be inferior, in some circumstances, to a court that is less accurate but less vulnerable to bias.

B. *Compliance Costs*

The second component of this welfare analysis is the cost of compliance, to the extent that it can be separated from the consumer welfare component just discussed. In general, compliance cost is the reduction in profit to the regulated firm (or industry) that results from product safety regulation. This approach treats the compliance cost as the opportunity cost of not pursuing some alternative design or plan barred by regulation.

The consumer welfare component discussed in the previous Section will reflect some of the industry's costs of compliance.[36] If the regulatory authority requires the firm to produce a relatively safe alternative that is substantially more costly to supply than the risky product, that cost will be embedded into the product's price, which will reduce consumer welfare. Thus, a careful assessment of the consumer welfare change from regulation will include costs that are passed on to consumers. For example, if a product safety regulator banned all cars with less crash resistance than the typical tank, the price of cars would rise substantially as car manufacturers attempted to pass on the cost of producing tank-like cars. Consumer welfare could be enhanced to the extent that cars were more crash resistant. But few consumers would be

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the ground that the agency's regulations governing the flammability of pajamas had been written by the industry rather than by independent safety analysts. *Id.*

[35] 555 U.S. 555, 576–81 (2009). In particular, Justice John Paul Stevens rejected the FDA's description of preemptive effect on the ground that the description was (1) a bald assertion rather than a legal "explanation," which the Court could have considered in determining preemptive effect on its own; (2) inconsistent with the agency's former position on preemption; (3) inconsistent with Congress's "purposes" regarding preemption; and (4) developed without a formal rulemaking process. *Id.* at 576–79.

[36] *See supra* notes 29–35 and accompanying text.

able to afford the new crash-resistant cars, so consumer welfare would be reduced overall by the regulatory order.

The elements of compliance cost that are not incorporated into the consumer welfare component consist of lost profit opportunities. If the industry is required to make crash-resistant cars the fall in sales may result in an overall loss in industry profits, relative to the design option preferred by the industry.

In a perfectly competitive industry, the profit impact of regulation can be ignored without affecting the choice between regulatory regimes. The reason is that profits will be competed away by the process of entry. A court deciding whether to preempt a lawsuit would not necessarily commit an error if it did not even consider the profit impact of regulation. In monopolized industries or in industries in which innovation is an important part of the competitive process, however, the profit effect may be a part of the total welfare assessment. A regulatory order that substantially reduces industry profit could result in a reduction in investment in innovation—and hence a reduction in dynamic competition.

As a general rule, the loss in profits from a regulatory order is not factored into the legal framework in product safety regulation.[37] The risk-utility test applied in products liability regulation does not factor in the profit impact of a decision to adopt an alternative design. In addition, federal regulatory agencies, such as the FDA, do not appear to consider explicitly the profit impact of a regulatory order.[38]

At first glance, the absence of weight given to the profit impact would appear to distinguish the risk-utility analysis used in products liability law from the negligence test. The negligence test compares the reduction in expected losses caused by a precaution with the burden of that precaution. Products liability law, in contrast, does not take into account the full burden of being forced to adopt a relatively safe design option. But this comparison is incomplete. The negligence test looks at only a narrow definition of the burden of precaution. Lost profit opportunities are typically not part of the negligence analysis.

For example, if a driver takes greater care to avoid traffic injuries, the negligence analysis takes into account the burden of that care. But the negligence analysis does not consider the profits that were lost by taking additional care. If a driver said that he should be permitted to

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[37] *See* Robert W. Hahn, *The Economic Analysis of Regulation: A Response to the Critics*, 71 U. Chi. L. Rev. 1021, 1040 (2004).

[38] *See id.* ("Agencies typically estimate direct costs . . . . Such costs do not consider the lost profits, for example, that may be associated with a reduction in supply.").

drive with less care in order to reach a specific location where he could receive a prize of one million dollars, that argument would be rejected under the negligence test. Of course, if the profit opportunity is sufficiently large, the driver would not be deterred from speeding by the threat of liability.

In the same sense, product safety regulation typically does not consider the lost profit opportunities that would result from a firm's decision to opt for the relatively safe product design. Of course, if the profits from opting for the risky design are sufficiently large, the firm might still decide to produce the risky design and pay the damage awards that result.

This feature of the law is not easy to defend on economic grounds, but it is still defensible. Lost profit opportunities are difficult for courts to measure objectively, and the information is entirely within the hands of the regulated party. A test that took lost profit opportunities into account might be too easily distorted to favor the regulated entity. Moreover, in a competitive setting these opportunities will be transitory and, for this reason, are an infirm basis for long-range planning.

C. *Administrative Costs and Risk*

One regulatory regime could be superior to another regulatory regime in terms of its effect on consumer welfare, and yet be inferior overall because of high administrative costs. In other words, the additional deterrence benefits from the more accurate regulatory regime may not be enough to offset greater costs of administration.

In the choice between regulatory regimes, an ideal approach would take administrative costs into account. If the regulatory regime is administratively more expensive, then a court would preempt the lawsuit only if the consumer welfare gain from having the agency, instead of the court, assess consumer welfare effects, is unambiguous.

In most products liability cases, the administrative costs factor should point toward preemption. The agency has moved first by approving the product. If courts hear disputes over questions considered by the agency, then additional administrative costs are incurred.[39]

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[39] To the extent these administrative costs are borne by the regulated entities, they will often favor preemption. *See* Hills, *supra* note 9, at 29–30 ("Pro-preemption forces tend to be business and industry groups . . . , as the uniformity of regulation that preemption brings is good for business."); *see also* Michael S. Greve & Jonathan Klick, *Preemption in the Rehnquist Court: A Preliminary Empirical Assessment*, 14 Sup. Ct. Econ. Rev. 43, 53–54 (2006) (arguing that preemption is often asserted by businesses).

Suppose, however, that the design issue concerns information that was not examined by the agency. The manufacturer might be accused of failing to provide a proper warning of a risk associated with the product, where the specific warning issue was not considered by the agency that approved the product design.[40] The failure to warn claim could be considered by courts or by the agency. From this perspective, the administrative cost decision is not clear cut. The agency may be more expensive than the court.

Risk can be considered a part of administration. Setting expertise aside, courts involve multiple potential regulators, some of whom may be relatively uninformed and others motivated by distributional interests, thus resulting in conflicting answers. Meanwhile, the agency is one regulator. The risk factor is typically higher in courts.

Indeed, although lost profit opportunities are typically not part of the decision standard of regulatory agencies, regulators are likely to be aware of the investments that firms have made to gain approval. They are also likely to recognize that a late change in the regulatory standard could have a substantial profit impact on the firm. The agencies know that the firms are repeat players;[41] policies that discourage firms from investing can ultimately work to the agency's disadvantage. Because of the repeat play between agency and industry, some degree of cooperation is likely to emerge over time, most obviously in the provision of information and of agency personnel, who are often drawn from industry.[42] Courts, on the other hand, are not playing a long game with the

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[40] *See, e.g.*, *Wyeth*, 555 U.S. at 563 (relating the trial court's finding that the FDA "paid no more than passing attention" to the issue of whether to warn against a particular method of drug injection).

[41] For a discussion of the advantages repeat players enjoy over "one-shot" parties in the legal system, see Marc Galanter, *Why the "Haves" Come Out Ahead: Speculations on the Limits of Legal Change*, 9 Law & Soc'y Rev. 95, 96–103, 97 n.3, 107, 110–13 (1974). Galanter focuses on repeat players in litigation, though he lists firms regulated by agencies as repeat players, and their ability to secure favorable agency rules as an advantage. *Id.* at 107, 111–12.

[42] *See, e.g.*, Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. Chi. L. Rev. 821, 834 (2003) (suggesting that agencies may be biased toward industry because of their dependence on industry for information—a bias compounded by a "revolving door" between industry and agency employment); William T. Gormley Jr., *A Test of the Revolving Door Hypothesis at the FCC*, 23 Am. J. Pol. Sci. 665, 681 (1979) (proposing that former employees of a regulated industry are more likely to make agency decisions favorable to that industry). Agencies, who deal with the same industry groups on a routine basis, are less insulated from political pressure than are courts of general jurisdiction. *See* Richard A. Posner, *Theories of Economic Regulation*, 5 Bell J. Econ. & Mgmt. Sci. 335, 351 (1974).

> The terminal character of many judicial appointments, the general jurisdiction of most courts, the procedural characteristics of the judicial process, and

industry, or at least may not be doing so intentionally. Juries are obviously not repeat players and sometimes are motivated by the desire to reward a needy plaintiff.[43] Some courts may have an incentive to free ride on policies adopted by other courts: if courts in forty-nine states find that a particular design is defective, courts in the fiftieth state will have a strong incentive to find the same.[44] The free-riding incentive will tend to generate path-dependent regulatory policy from the state courts—i.e., regulatory decisions dependent on the order in which disputes are settled within the state courts. All of these factors suggest that the risk due to unpredictable regulatory standards is much greater in the courts than in the agencies.

More than unpredictability, *time-inconsistent regulatory policy* is an important risk associated with courts acting as product-design regulators.[45] The time-inconsistency problem arises when a firm must invest in the first period, and then government has the freedom to change its regulatory program in a later period.[46] The government may have an incentive to signal in the first period that it will maintain a consistent policy, and then sharply increase regulation or taxes in the second period. The first period signal of regulatory moderation is necessary in order to induce the firm to invest. But once the firm has invested, the government's rational, short-term strategy is to adopt a confiscatory tax or regulatory policy. Of course, such a policy could be rational in the short term and yet reduce social welfare in the long term. Regulatory agencies may have sufficient repeat business with industry that such a bait-and-switch game could prove ultimately harmful to the agency, or at least to

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> the freedom of judges from close annual supervision by appropriations committees, all operate to make the courts freer from . . . interest group pressures . . . than . . . the administrative agency, where these features are absent or attenuated.

Id. For an economics-based argument that industry captures agencies when wielding this political pressure, see George J. Stigler, *The Theory of Economic Regulation*, 2 Bell J. Econ. & Mgmt. Sci. 3, 3 (1971) ("[A]s a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit.").

[43] *See* Reid Hastie, David A. Schkade & John W. Payne, *Judging Corporate Recklessness*, *in* Cass R. Sunstein et al., Punitive Damages: How Juries Decide 77, 91–93 (2002) (finding that jurors often substitute their own sense of morality—influenced by jurors' sympathies for one party or another—for legal standards in assessing punitive damages).

[44] The free-riding incentive is discussed openly by the court in *Blankenship v. General Motors Corp.*, 406 S.E.2d 781, 783–84 (W. Va. 1991).

[45] *See* Stanley Fischer, *Dynamic Inconsistency, Cooperation and the Benevolent Dissembling Government*, 2 J. Econ. Dynamics & Control 93, 97–98 (1980).

[46] *See, e.g.*, *id.* On time consistency and regulation, see Alesina & Tabellini, *supra* note 26, at 434–35.

agency officials who wish to work in the regulated industry. But courts are removed from this long-term relationship and thus can revise regulatory policy without incurring a risk of either retaliation or being held accountable for a decline in innovation. A regulatory agency, in order to encourage investment, may have an incentive to bind itself to a consistent policy over a substantial period of time. Courts have no such incentive.

II. An Optimal Rule on Preemption

My purpose in the foregoing discussion has been to examine the economic factors that should lie behind a concrete decision on preemption—specifically, a decision on product safety regulation. Preemption is a decision to choose one regulatory regime instead of another, or one regulatory regime in addition to another. The economics of that choice can be examined at a high level of generality.

The foregoing examination of the economics behind the choice between alternative regulatory regimes has direct implications for "error-cost" arguments about preemption. As noted earlier, the error- cost analysis is another way of expressing the concerns in an economic analysis of the choice between regulatory regimes.[47] The economic factors identified in the previous discussion pinpoint the precise types of cost that arise as a result of an erroneous choice of regulatory regime.[48]

The most important component identified in the decision process is the effect of the product safety decision on consumer welfare. On the assumption that the common law standard applied by courts is efficient,[49] the court's standard generally should govern the product safety issue. If this is valid as a default assumption, the preemption question should turn on how well the court would apply the optimal standard in comparison to the agency.

The key factors influencing the application of the standard are expertise, local information, and political independence.[50] The effect

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[47] *See supra* note 28 and accompanying text.

[48] *See supra* note 28 and accompanying text.

[49] *See* Keith N. Hylton, *Information, Litigation, and Common Law Evolution*, 8 Am. L. & Econ. Rev. 33, 35 (2006); Landes & Posner, *supra* note 12, at 537–43 (presenting an efficiency justification for products liability doctrine). Although the common law is unlikely to be perfectly efficient, there are well understood pressures toward efficiency in the system. *See* Hylton, *supra*, at 35 (discussing how common law incorporates private information into legal standards); Paul H. Rubin, *Why Is the Common Law Efficient?*, 6 J. Legal Stud. 51, 53–57 (1977) (arguing that efficiency results from greater litigation pressure applied to inefficient rules).

[50] *See supra* notes 29–35 and accompanying text.

of regulation on industry profits is typically not part of the regulatory standard. The administrative cost and risk factors typically weigh in favor of letting the regulatory agency be the sole actor.[51]

The political independence factor suggests that courts should be less likely to find preemption if the agency is subject to influence or bias from interested parties.[52] Again, courts are in the unique position of being able to assess the degree to which the agency's regulatory approach is vulnerable to capture or bias.

The expertise and local information factors have similar implications for preemption, though pointing in different directions. If the common law standard governing liability (e.g., the risk-utility test) requires technical or industry information to make an accurate assessment, the court should be more likely to find preemption. In general, this will be the case when the common law standard and the agency standard are congruent. If, for example, the agency applies the risk-utility test (or a version of it) in determining whether a product should be approved, a court applying the same standard should defer to the agency, given the agency's superior expertise and information. Local information implies the opposite call on preemption. If the common law standard requires the consideration of local information, a common law tort claim should not be preempted.[53]

One other information issue concerns timing. When a common law claim arises, the court may be able to consider information that was not available to the agency when it made its decision. Thus, even if the agency has superior expertise and technological information, it may be unable to update its standard quickly in response to new information. The courts, on the other hand, may have a superior capacity to update the standard to incorporate new information.

This framework suggests a rule for preemption cases. *Where the agency's regulatory process is sufficiently rigorous and independent, a common law claim should be preempted if the regulatory standard and the common law standard are congruent, in the sense that the agency standard incorporates all of the factors that would be examined under the common law standard.* Where the agency's regulatory process is not rigorous and is vulnerable to capture or bias, courts should be reluctant to preempt common law claims.

This "congruence theory" implies some exceptions right away. If the common law standard takes advantage of information that is not

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[51] *See* Hylton, *supra* note 11, at 212–14.

[52] *See* Wilson v. Bradlees of New England, Inc., 96 F.3d 552, 556–57 (1st Cir. 1996); *supra* note 34 and accompanying text.

[53] *See* Holmes, *supra* note 29, at 122–23.

available to the agency—such as later developing information on product-related injuries—then preemption may be inappropriate. Similarly, if the common law standard relies on local information that would be unavailable to the regulatory agency, or not incorporated into the agency's decision process, preemption would be inappropriate.[54]

Although congruence theory sounds simple, it indicates that preemption depends on several variables: the information available to courts relative to the information available to the regulatory agency, time lags between the onset of claims and the framing of the regulatory standard, and the degree of agency independence. It is not equivalent to a simple regulatory compliance defense.[55] Moreover, the congruence theory is not implied by the language in most federal statutes; a search for legislative intent is unlikely to suggest congruence as a guideline for preemption.

III. Some Applications

A quick look at some of the prominent preemption cases suggests that the congruence rule offers an explanation for the outcomes, even though the courts have struggled to set out a theory of preemption. In an earlier article, I found evidence to support the congruence theory in a sample consisting of 243 federal court preemption disputes and 118 state court preemption disputes.[56]

The preemption case law on products liability has gone through three periods.[57] The first is before 1992, the year of the U.S. Supreme Court's decision in *Cipollone v. Liggett Group, Inc.*[58] In the pre-*Cipollone* period, courts seldom found preemption and generally examined the

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[54] One might argue that there will always be late-developing and local bits of information, and that for this reason, the congruence theory implies that preemption is never appropriate. I reject this position. It is impossible to escape the application of a rule of reason to these questions. Yes, there will always be late-developing information, but much of it will not be sufficiently important to change the reasonable assessment made in the earlier period. In other words, the late information will be anticipated in the design or in the warning developed in the earlier period.

[55] For sophisticated economic arguments in favor of the regulatory compliance defense, see generally Alan Schwartz, *Statutory Interpretation, Capture, and Tort Law: The Regulatory Compliance Defense*, 2 Am. L. & Econ. Rev. 1 (2000); W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 Seton Hall L. Rev. 1437 (1994).

[56] Hylton, *supra* note 11, at 206, 237 tbl. 4, 245 tbl. 6.

[57] *Id.* at 207.

[58] 505 U.S. 504 (1992).

issue in terms of implied rather than express preemption.[59] Many courts referred to regulatory agencies as setting minimum standards which could be supplemented by requirements imposed under state tort law.[60]

The second period of the preemption case law began with the *Cipollone* decision, which found that a federal statute (the Federal Cigarette Labeling and Advertising Act) expressly preempted state failure to warn claims based on inadequate cigarette labeling.[61] *Cipollone* led many courts to analyze preemption disputes in terms of the express preemption theory.[62]

The third period began in 1996 with the U.S. Supreme Court's decision in *Medtronic, Inc. v. Lohr*,[63] which rejected the express preemption approach of *Cipollone*. In *Lohr*, the Court found that defective design claims brought against the maker of a medical device were not preempted, even though the relevant statute contained a preemption provision that could be read, in the style of *Cipollone*, as expressly preempting state tort law.[64] Since *Lohr*, courts have returned to the implied preemption approach and have attempted to articulate reasons for preemption based on conflicts between state and federal law.[65]

Lohr itself is a decision that supports the congruence theory. The medical device in *Lohr*, a pacemaker, had been approved by the FDA under the "substantial equivalence" test, which permitted the marketing of devices that were equivalent to a device that was on the market before 1976.[66] It is obvious that the substantial equivalence test is not congruent to the risk-utility test that would be applied by a court in a defective design lawsuit. The risk-utility test is an attempt to assess the net consumer welfare effect of moving from a relatively safe design to a risky alternative. It requires a careful examination of the challenged design. The FDA's approval of the pacemaker in *Lohr* did not involve an assessment of the same information.[67] Because the common law stan-

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[59] Hylton, *supra* note 11, at 207–08 & n.4 (citing Wood v. Gen. Motors Corp., 865 F.2d 395 (1st Cir. 1988)).

[60] *Id.* at 207–08 & nn.3–4.

[61] 505 U.S. at 530–31.

[62] *See* Hylton, *supra* note 11, at 208 (citing King v. E.I. Dupont De Nemours & Co., 996 F.2d 1346 (1st Cir. 1993)).

[63] 518 U.S. 470 (1996)

[64] *Id.* at 501–03.

[65] *See* Hylton, *supra* note 11, at 209 (citing Lewis v. Brunswick Corp., 107 F.3d 1494 (11th Cir. 1997)).

[66] 518 U.S. at 477–80.

[67] *See id.* at 480.

dard was not congruent to the regulatory standard, preemption would have been inappropriate under the theory offered here.

Riegel v. Medtronic, Inc., involving a balloon catheter approved by the FDA, was decided by the U.S. Supreme Court in 2008 and provides the complementary result to *Lohr*.[68] The Supreme Court held that the plaintiff's common law design defect claim was preempted.[69] Unlike the medical device at issue in *Lohr*, the device challenged in *Riegel* had been approved under the rigorous premarket approval process, in which the FDA thoroughly examines the risk-utility tradeoffs associated with a proposed medical device.[70] Under the congruence theory, preemption would be appropriate because the FDA had considered, during a lengthy approval process, the same issues that would be examined in a common law product-design claim. Not preempting the plaintiff's claim would permit a relatively uninformed jury to contradict the design decisions of experts.[71]

Another prominent U.S. Supreme Court decision, *Geier v. American Honda Motor Co.*,[72] decided in 2000, can likewise be explained by the congruence theory. The plaintiff brought a defective design claim based on Honda's failure to install an airbag system.[73] The conflicting federal regulatory order was Federal Motor Vehicle Safety Standard 208, which provided several compliance options to car manufacturers.[74] The Court found that the plaintiff's claim was preempted by the federal standard.[75]

The *Geier* decision can be justified on the basis of congruence theory. In formulating the regulatory standard, the agency (the Department of Transportation) had taken into account the factors that would be considered by a court in applying the risk-utility standard.[76] The agency had considered the tradeoffs between the benefits and costs of additional safety, as well as the likelihood that consumers would actually accept, through market purchases or through general compliance,

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[68] *See* Riegel v. Medtronic, Inc. 552 U.S. 312, 321–30 (2008); *Lohr*, 518 U.S. at 501–03.

[69] *Riegel*, 552 U.S. at 321–30.

[70] *See id.* at 322–23; *Lohr*, 518 U.S. at 480.

[71] If a relatively uninformed jury took over the decision process of a group of experts, the expected costs of error associated with the decision process would be greater. In the theory set out here, it is important that the FDA's decision process is rigorous and not obviously under the control of a political faction. If the FDA's decision process were under the control of a political pressure group, a court would have a rational basis for refusing to find preemption. *See supra* note 42 and accompanying text.

[72] 529 U.S. 861 (2000).

[73] *Id.* at 865.

[74] *Id.* at 875–76.

[75] *Id.* at 866.

[76] *See id.* at 877–81.

more burdensome safety requirements.[77] Moreover, the agency conducted its analysis with a higher level of expertise than could be expected of a court.[78] There was no evidence of new information that had developed between the time of the agency's standard and the plaintiff's claim that would have led an objective observer to alter the agency's analysis.[79] Under these circumstances, the common law defective design claim required the application of a test that was congruent to that applied by the federal agency. The claim should have been preempted, as it was.

The *Geier* Court focused on the conflict between federal and state design requirements respecting airbags.[80] Under this Essay's analysis, however, the focus should be on the extent to which the federal regulatory process has exhausted the issues that would be important in a court's analysis of the defective design matter. The mere existence of potential conflicts should not be sufficient to find preemption. Indeed, if the conflict theory offered as the rationale in *Geier* were applied consistently, the Supreme Court would find preemption far more frequently than it does. There is almost always a potential for conflict between the safety standards implied by tort law and the standards imposed through regulation.

The U.S. Supreme Court's most recent decision on automobile safety standards, *Williamson v. Mazda Motor of America, Inc.*,[81] decided in 2011, seems at first glance to be inconsistent with *Geier*, but the two decisions can be reconciled and explained within the congruence model offered here.[82] In *Williamson*, the Court considered a later version of Federal Motor Vehicle Safety Standard 208, which gave car manufacturers a choice to install either lap belts or lap-and-shoulder belts in rear inner seats (e.g., "middle seats or those next to a minivan's aisle").[83] Mazda had installed only a lap belt in the rear aisle seat of the minivan the plaintiffs were driving when it was struck head-on by another car.[84] One family member, sitting in the rear aisle seat and wearing the lap belt, was killed in the accident; the other family members, who were wearing lap-and-shoulder belts, survived.[85] The Court held

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[77] *Id.* at 877–81.
[78] *See Geier*, 529 U.S. at 883.
[79] *See id.* at 877–81, 883–85.
[80] *See id.* at 881.
[81] 131 S. Ct. 1131 (2011).
[82] *See supra* notes 47–54 and accompanying text.
[83] *Williamson*, 131 S. Ct. at 1134.
[84] *Id.*
[85] *Id.*

that the regulation did not preempt the Williamson's product-design lawsuit against Mazda.[86]

Although it seems superficially that the plaintiffs' suit should have been preempted under the precedent of *Geier*, the cases are distinguishable in a manner that is relevant to the preemption model of this Essay. The Court found that the Department of Transportation had not conducted an analysis of the choice between lap-only and lap-and-shoulder belts at the same level of depth as the safety analysis in *Geier*.[87] The agency appeared to have given the manufacturers a choice between lap-only and lap-and-shoulder belts because it had no clear position on the safety question and, in the absence of a clear position, had chosen not to impose a significant cost burden on manufacturers.[88]

To put this in the terms of the congruence model, the Court found in *Geier* that the agency had considered the risk-utility issues, in addition to questions of compliance well beyond the scope of most judicial analyses of product-design disputes.[89] In *Williamson*, the agency's record indicated that it had not conducted a thorough risk-utility assessment—and, even if it had, it did not base its regulatory decision on that assessment.[90] In *Geier*, there was "congruence" in the sense that the agency had considered virtually all of the tradeoff issues that would have been raised by the plaintiff's design defect claim.[91] In *Williamson*, the record did not suggest that the agency had made a judgment based on a consideration of the risk-utility issues.[92]

The congruence model provides a concise explanation of the different decisions in *Geier* and *Williamson*. The Court's own explanation in *Williamson* is comparatively hard to understand. The Court distinguished *Williamson* from *Geier* on the ground that the Department of Transportation had not made the provision of *choice* to manufacturers a "significant objective" of its regulation in *Williamson*, unlike the regulatory program examined in *Geier*.[93] The Court's reasoning is likely to produce a great deal of confusion as lower courts attempt to determine how one distinguishes significant from insignificant objectives of federal regulation.

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[86] *Id.* at 1139–40.
[87] *Id.* at 1137–39.
[88] *Id.* at 1138–39.
[89] *See* 529 U.S. at 877–81.
[90] *See* 131 S. Ct. at 1138–40.
[91] *See* 529 U.S. at 877–81.
[92] *See* 131 S. Ct. at 1138–39.
[93] *Id.*

A final application is the U.S. Supreme Court's decision in *Wyeth v. Levine* in 2009.[94] The plaintiff brought a failure to warn claim against Wyeth after she contracted gangrene and had to have her forearm amputated, as a consequence of the injection of an anti-nausea drug into her vein.[95] The intravenous method of drug delivery carried a significant risk that the drug would enter an artery and cause gangrene.[96] The trial court found that Wyeth had failed to adequately warn of this risk.[97] Wyeth argued that the failure to warn claim should have been preempted because the firm's label for the anti-nausea drug had been approved by the FDA.[98]

The Supreme Court, however, found that FDA approval did not prevent Wyeth from updating its warning to include new information on the risk of gangrene, information which had been building up over time between the date of the FDA's approval and the date of the plaintiff's lawsuit.[99] In terms of the congruence theory, the plaintiff's common law claim did not require an analysis that was congruent to the FDA's analysis. The common law claim considered information that was available to Wyeth (specifically, post-approval experience with injuries caused by intravenous drug delivery) that was not available to the FDA at the time of approval.[100] Moreover, the FDA rules permitted drug firms to update their warnings to reflect post-approval information on risks.[101] Thus, as predicted under the congruence model, the claim was not preempted.[102]

IV. Problems with Preemption Theory

The term "preemption" has sufficient generality and lack of definition to constitute an attractive nuisance for legal theorists. It sounds like it means something deep and important. But it is unclear whether it means anything, in terms of an intelligible legal doctrine, in the absence of a specific application to a case.[103] The term has generated articles

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[94] *See* 555 U.S. 555 (2009).

[95] *Id.* at 558–59.

[96] *Id.*

[97] *Id.* at 562.

[98] *Id.* at 559.

[99] *Id.* at 569–73.

[100] *See Wyeth*, 555 U.S. at 568–73.

[101] *Id.* at 570–71.

[102] *Id.* at 581; *see supra* notes 47–54 and accompanying text.

[103] The preemption decisions involve regulatory matters that vary enormously. If courts tend toward optimal regulatory regime choices, the common law on preemption should vary according to the specific subject matter of regulation. Under the theory of this Essay, one

offering general theories of preemption, and will continue to generate more.[104] Most theories of preemption have offered wide-ranging discussions of various opinions on the relationship between state and federal power and the source of Congress's power to preempt state law.[105]

I have suggested so far that the theory of preemption, when viewed from an economic perspective, is simple and dependent on its concrete application, though the application involves consideration of several variables. If courts had been applying the congruence theory described here, most of the implied preemption decisions in the products liability area would have come out as they did. In other words, the congruence model provides a positive theory of the preemption case law.

The courts have failed to provide a consistent theory of the preemption case law. One major source of the preemption controversy concerns the extent to which legislative intent should determine the outcomes in preemption cases.[106] Legislative intent is difficult to divine in the vast majority of preemption disputes. Congress seldom makes its views clear on the extent to which a federal statute preempts state tort law.

Even if Congress were capable of making its views clear on the preemption question in every potential area of dispute, there would remain issues concerning its power to displace state law. Can Congress displace any state law? Should any statement that can be traced to some legislative authorization be assumed to prevail over state provisions that are inconsistent with it? These issues have made preemption a recurring topic of controversy on the Supreme Court.

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should predict the appearance of incoherence if one is searching for a general consistency in the preemption case law. Many scholars have referred to the apparent muddle of preemption. *See, e.g.*, Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2085–86 (2000); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 232–33 (2000).

[104] *See, e.g.*, Gardbaum, *supra* note 4, at 807–08 (discussing preemption's basis, if any, in the Supremacy Clause and the Necessary and Proper Clause, depending on the category of preemption); Hills, *supra* note 9, at 4 (arguing that preemption theories "need to accept the truism[] that the federal and state governments have largely overlapping jurisdictions"); Issacharoff & Sharkey, *supra* note 2, at 1355–58, 1365–72 (arguing that the Supreme Court's preemption doctrine has sought to establish "national regulatory uniformity" across states and between state and federal government); Merrill, *supra* note 4, at 759–69 (discussing preemption's basis in the Supremacy Clause and Necessary and Proper Clause); Nelson, *supra* note 103, at 225–32 (arguing that preemption decisions "affect[] . . . the distribution of authority between the states and the federal government").

[105] *See, e.g.*, Hills, *supra* note 9, at 4; Issacharoff & Sharkey, *supra* note 2, at 1355–58, 1365–72; Nelson, *supra* note 103, at 225–32.

[106] *See, e.g.*, Medtronic v. Lohr, 518 U.S. 470, 485–86 (1996); *infra* notes 117–120 and accompanying text.

A. *The Federal Power Problem*

Let us consider the power problem in a bit more detail. State tort laws protect people from injuries that can be attributed to negligence or some other legal breach, and these laws are understood to operate with a virtually unlimited scope. Congress's power to regulate, in contrast, is limited by the terms of the Constitution.

If Congress passes a law regulating some activity that is already regulated by state law, the first question that arises is whether the federal legislation is within the parameters of Congress's power. In the products liability setting, this question has not been a serious issue for the most part.[107] Markets in products that are regulated by federal agencies generally are national in scope, and modern conventional readings of Congress's power to regulate interstate commerce raise few if any concerns about the scope of authority. There are other settings in which the question of power presents a serious issue, however, even on the basis of conventional views of the legislature's authority. For example, suppose a federal statute claims to preempt all disputes over the design or the location of a facility, whenever those disputes are based on adverse health effects resulting from that facility. A specific case is the Telecommunications Act of 1996, which includes a provision that explicitly preempts nuisance suits based on the health effects related to the siting of a cell phone tower.[108] Although product-design questions appear to be within the accepted view of Congress's power to regulate under the Commerce Clause, the location issue is arguably outside of Congress's power.[109] The impact on interstate commerce of siting a cell phone tower on the right side of the street versus the left side of the street is trivial, whereas the impact on local conditions could be substantial.[110]

Even if we are considering a design issue affecting interstate commerce, there remains the issue of what constitutes a federal law for pre-

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[107] One exception is Justice Clarence Thomas's concurrence in *Wyeth v. Levine*, 555 U.S. 555, 582–88 (2009) (Thomas, J., concurring in judgment).

[108] Telecommunications Act of 1996, 47 U.S.C. § 332(c)(7)(B)(iv) (2006) ("No State or local government or instrumentality thereof may regulate the placement, construction, and modification of personal wireless service facilities on the basis of the environmental effects of radio frequency emissions to the extent that such facilities comply with the Commission's regulations concerning such emissions.").

[109] *See* United States v. Lopez, 514 U.S. 549, 559–68 (1995).

[110] *Lopez* would appear to require some attempt to balance Congress's interest in regulating interstate commerce with the state's interest in regulation. *See id.* at 574–83 (Kennedy, J., concurring). When the question is simply whether a cell phone tower should be put on one corner or another corner, the federal interest in regulating interstate commerce would appear to be minimal relative to the state's interest.

emption purposes. If Congress passes a statute that asserts state claims are preempted, this statute certainly qualifies as a law for preemption purposes. But if a federal agency adopts a regulation, or a statement of how its decisions should be interpreted ("optimal" as opposed to "minimal" standards),[111] are these rules and statements to be regarded as laws that have preemptive effect?[112]

Preemption doctrine rests on an unsteady foundation. If the composition of the courts changes, and judges begin to ask more probing questions about the federal legislature's power to preempt, some previous decisions on the scope of preemption may be overturned or reinterpreted as valid under grounds that are narrower than expressed in the initial decision.

These issues are troubling because if courts take the most expansive view of the federal legislature's power to preempt, either directly in statutes or indirectly through federal agencies, then rent-seeking schemes could replace state common law with rules specially designed to favor specific industries. For example, the provision of the 1996 Telecommunications Act that purports to preempt state nuisance claims over the location of cell phone towers may have been designed as a payoff to the telecommunications industry rather than a considered judgment about the most efficient forum for the resolution of nuisance claims.[113] Of course, it may have been necessary to get the industry to support the legislation, but courts should be reluctant to permit portions of state common law to be put on the trading table when industries negotiate with the legislature over regulatory statutes.

Suppose, for example, an industry approaches Congress and takes the position that it will support some specific proposed legislation in exchange for Congress's preempting all state laws that are related to the subject of the proposed legislation. Or, to take a more extreme case, suppose the industry urges Congress to place the industry under a federal regulatory regime in exchange for preempting all state laws governing the industry. If Congress accepts the industry's offer, should a

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[111] Richard Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. Tort L., no. 1, 2006 at 1–2, *available at* http://www.bepress.com/jtl/vol1/iss1/art4/ (click "download" to retrieve article); Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DePaul L. Rev. 227, 227–28 (2007).

[112] *See, e.g.*, Merrill, *supra* note 4, at 759–66 (discussing whether agency statements constitute laws with preemptive effect). If a regulatory agency can secure preemptive effect by merely asserting it in its own regulations, then we have arrived at something of a paradox. Although courts often claim that they must search for legislative intent, the decision to find preemption has been within the discretion of courts. *Id.* at 760.

[113] 47 U.S.C. § 332(c)(7)(B)(iv).

court uphold the agreement by preempting all state laws governing the industry?[114] If a court were to do so, the state would be denied the power to regulate firms in the industry operating within its borders, whereas the federal government would be the sole source of regulation—an outcome that would appear to contradict long-standing notions of the relationship between state and federal power.[115]

Even before any agreement is observed, however, the very notion that state laws could be put on the bargaining table between industry groups and federal legislators suggests a need for carefully drawn boundaries on the scope of preemption. The federal legislators' incentives may not be aligned with the welfare of the residents of a particular state, or state residents generally. Concentrated interest groups tend to have a greater influence on legislative processes than do diffuse interests,[116] such as those of consumers generally. As the scope of preemption expands, the risk of diffuse interests being traded off to the benefit of concentrated interests increases.

B. *Legislative Intent*

Legislative intent is another fertile source of instability in preemption law. Implied preemption is an established doctrine in the case law.[117] Yet courts continue to refer to legislative intent as the fundamental basis for preemption.[118]

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[114] For a theory of statutory interpretation that proposes a "contract enforcement" approach to reading statutes generally, see William M. Landes & Richard A. Posner, *The Independent Judiciary in an Interest-Group Perspective*, 18 J.L. & Econ. 875, 877–79, 885 (1975). A contract enforcement approach must nevertheless be restrained by the limits the Constitution places on the terms of such contracts. *Id.* at 875 (quoting James M. Buchanan, *Good Economics—Bad Law*, 60 Va. L. Rev. 483, 491 (1974)).

[115] The Federalist No. 45, at 237 (James Madison) (Ian Shapiro ed., Yale Univ. Press 2009) (describing the powers of the federal government as "few and defined," whereas those of the states are "numerous and indefinite"). Because the regulatory program enacted under this agreement would have to remain, at a minimum, consistent with constitutional constraints on federal legislative power, there would have to be some boundaries enforced by courts on the terms of such agreements. Precisely what those boundaries are appears to be a largely unexplored question in the preemption literature.

[116] *See generally* Mancur Olson, The Logic of Collective Action: Public Goods and the Theory of Groups (2d prtg. 1971). This basic observation of public choice theory provides the most serious welfare-based criticism of expansive theories of preemption.

[117] *See, e.g.*, *Wyeth*, 555 U.S. at 563–66; Riegel v. Medtronic, Inc., 552 U.S. 312, 344 (2008) (Ginsburg, J., dissenting); Geier v. Am. Honda Motor Co., 529 U.S. 861, 869–72 (2000). Many discussions of preemption break down the implied preemption case law into various subcategories, but my doubts of the value of this effort are probably even greater than those suggested by other scholars. *See, e.g.*, Merrill, *supra* note 4, at 739 (breaking down implied preemption into "field preemption," "conflict preemption," and "obstacle

The strategic basis for relying on a legislative intent argument is obvious. Where the source of preemption is the existence of a federal statute coupled with the Supremacy Clause, the case for preemption seems stronger if it seems to be a directive coming out of Congress rather than a finding made up by a court. But this introduces two sources of instability in the law. First, it is often difficult to find clear evidence of legislative intent. The preemption clauses are vague, and often coupled with equally vague saving clauses. To the extent that Congress can be said to have an opinion on preemption, that opinion is seldom made clear in federal statutes. Implied preemption arguments that are grounded in notions of legislative intent, such as those found in the U.S. Supreme Court's 2008 decision in *Riegel v. Medtronic, Inc.*, look unlikely to withstand questioning in later cases.[119]

The second problem with legislative intent is that it invites efforts to game the courts. Industries that negotiate with Congress over the design of federal regulation—whether the direct targets of the regulation or their competitors—will make every effort to secure language in the statute that influences the legislative intent findings of courts. Any hard and fast rule that requires courts to find clear evidence of legislative intent to preempt will give parties attempting to influence Congress a stronger incentive to write statutes that include language on the preemption issue.[120]

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preemption"); Nelson, *supra* note 103, at 230–32 (same). At their core, preemption decisions are determined by the specific regulatory choice problem facing a court. The creation of subcategories of implied preemption follows naturally from the effort to create a general legal theory of preemption, applicable to all disputes. I do not think such a general theory can be developed with any acceptable degree of rigor.

[118] *See, e.g.*, *Wyeth*, 555 U.S. at 563–66; *Lohr*, 518 U.S. at 485 (commenting that "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case" (alteration in original) (quoting Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963))).

[119] *See* 552 U.S. at 343–44. Even where the arguments can withstand rigorous scrutiny in later opinions, they produce short-term confusion by relying on imputations of intent that are often confusing and sometimes obviously fictional. One good recent example is the U.S. Supreme Court's theory in *Williamson v. Mazda Motor of Am., Inc.*, decided in 2011, that "choice" was not a significant objective behind the regulations examined in that case. 131 S. Ct. 1131, 1137–40 (2011). How can a lower court determine whether a specific objective was *significant* when examining a federal regulatory scheme? The Court's language in *Williamson* is likely to generate a spate of inconsistent rulings in the lower courts until the Court gets around to clarifying the meaning of "significance" in the *Williamson* decision. The congruence model of this Essay offers a simple way to understand *Williamson*, but the Court's own theory of intent is both difficult to understand and unlikely to offer guidance.

[120] One familiar argument against preemption is that the legislature should be required to state its views clearly. Some commentators think that this will force Congress to

C. *Another Path*

The core of all of these problems is the term "preemption" and its basis in the Supremacy Clause of the Constitution.[121] Although legal theorists have argued over the source of preemption, most courts have referred to the notion of federal law supremacy.[122] But once preemption is understood to rest on this basis alone, all of the problems examined here enter the analysis. These problems are avoidable.

Preemption, at least in the context of federal regulatory action, serves an important function that is independent of the relationship between state and federal power. The courts could put preemption analysis on a firmer basis by removing it from its dependence on the notion of federal supremacy. The functional work of preemption doctrine, especially in the products liability field, could easily continue under another name.

Courts have the power to find a common law basis for preemption doctrine, and are perfectly capable of doing so. The courts can continue to call it preemption, or they may choose to change the name, perhaps to "deference." If courts declare an independent common law basis for preemption, they may be able to safeguard preemption doctrine from the deeper issues concerning the balance between state and federal power. The doctrine would rest on state power alone—specifically, the power of a common law court to recognize compliance with federal regulation as a type of defense in a tort action.

I must distinguish the common law preemption theory suggested here, however, from a pure regulatory compliance defense—i.e., a doctrine that treats compliance by itself as a defense. A regulatory compliance defense goes too far under the theory of this Essay. The congruence theory of this Essay is not equivalent to a regulatory compliance defense. Under the congruence theory, a firm could comply with federal regulation, yet still be found liable because of informational differ-

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be absolutely clear. *See, e.g.*, Hills, *supra* note 39, at 16–39. For doubts about this approach, see Adrian Vermeule, Judging Under Uncertainty: An Institutional Theory of Legal Interpretation 118–48 (2006). Others think that agency processes should not be trusted. For an example of one article urging courts to search for clear intent to preempt, based largely on lack of trust of agency processes, see Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 Nw. U. L. Rev. 695, 695–99 (2008).

[121] *See* U.S. Const. art. VI, cl. 2.

[122] *See, e.g.*, Merrill, *supra* note 4, at 733–37.

ences, or because of a court's assessment of the capture vulnerability of a federal agency.[123]

The congruence theory offered here is based on a functional view of preemption that withdraws tort law when the difference between net deterrence benefits and administrative costs is likely to be greater under the regulatory regime than under the court regime. This functional view is largely independent of the issues surrounding the relationship between state power and federal regulatory power. Although court-based regulation has been described traditionally as a supplement to federal agency regulation, under certain conditions it can reduce overall welfare.[124] The case law suggests that courts have largely been successful in identifying the conditions under which court-based regulation reduces welfare; what is lacking is a straightforward theory and a stable legal foundation for the case law that has emerged.

Conclusion

I have focused on preemption in the products liability setting, which is admittedly special in some respects. It involves agencies that have developed sophisticated approaches to regulation. Because agency action involves so many variables, many of the cases will inevitably raise implied preemption issues; the legislature cannot possibly address all of the preemption questions in statutes, even if it were to try. Given the choice between two active regulatory regimes—the agency and the courts—society's welfare can be enhanced by discovering rules that channel some regulatory matters into the courts and leave others trapped within the agency.

Some other areas of preemption involve the direct displacement of state common law by the explicit terms of federal statutes. Where the legislature directly preempts some part of state common law through the terms of a statute, rather than indirectly through the action of a regulatory agency, the optimal regime choice framework of this Essay

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[123] The *Restatement (Third) of Products Liability* comes very close in its comment to section 4(b) (on regulatory compliance as a defense) to proposing the congruence theory of this Essay. *See* Restatement (Third) of Torts: Prod. Liab. § 4 cmt. e (1998). The *Restatement* notes in its comment to 4(b) that a regulatory compliance defense may be applicable when the regulation "was promulgated recently, . . . the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise." *Id.* Comment e, in my view, does a fair job of reflecting the case law on preemption in the products liability setting.

[124] *See* Hylton, *supra* note 11, at 212–14.

remains applicable, but it encounters greater difficulties than in the agency preemption context. Although in most cases the common law process is superior to legislative bodies in generating rules for the purpose of resolving controversies, this may not always be the case. State courts might adopt rules that frustrate contractual solutions to various types of market failure.[125] A federal regulation that preempts such rules could enhance society's welfare. The analysis of this Essay is still relevant to this scenario, but only after realizing that the regimes that are to be compared are markets versus regulators, rather than courts versus regulators.

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[125] *See, e.g.*, AT&T Mobility LLC v. Concepcion, 131 S. Ct. 1740, 1745, 1753 (2011) (holding that the Federal Arbitration Act preempts California's common law rule invalidating cell-phone arbitration agreement as unconscionable, because the rule frustrates Congress's objective of treating arbitration as a contractual solution). It is possible that welfare could be enhanced by preempting inefficient legal restrictions on contractual choice with respect to arbitration. *See generally* Keith N. Hylton, *Agreements to Waive or to Arbitrate Legal Claims: An Economic Analysis*, 8 Sup. Ct. Econ. Rev. 209 (2000) (discussing arbitration as a solution to a type of market failure). More specifically, litigation often occurs under conditions in which the private and social incentives for litigation diverge, because the plaintiff does not internalize the full social costs of litigation. Steven Shavell, *The Social Versus the Private Incentive to Bring Suit in a Costly Legal System*, 11 J. Legal Stud. 333, 333–34 (1982). The incentives for arbitration and waiver agreements to be formed are greatest precisely when the private and social incentive to litigation diverge to the greatest degree. *See* Hylton, *supra*, at 223–30, 263. Because of this, arbitration is, in some cases, a Coasean solution to socially inefficient litigation. *See id.* at 222. Arbitration can improve the joint welfare of plaintiffs and defendants when the arbitration forum is less expensive and more accurate than a court. *See id.* at 223, 225–26, 263. And even if the arbitration forum is less accurate than a court, an agreement to arbitrate could enhance the joint welfare of the parties if the cost savings are sufficient. *Id.* at 263. Given this, a federal law that preempts state legal impediments to the formation of arbitration agreements could enhance social welfare.