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PREEMPTION AND PRODUCTS LIABILITY: A POSITIVE THEORY

Keith N. Hylton

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Abstract

In a large number of products liability lawsuits, sellers assert that plaintiffs' claims should be rejected because their products fall under some federal regulatory regime, and that the regulatory statute takes precedence over or "preempts" state tort law. This paper is an attempt to set out a positive theory of the doctrine on preemption of products liability claims. The federal case law is largely consistent with an approach that seeks to minimize the costs of erroneous decisions to preempt tort lawsuits. In particular, two factors explain many of the outcomes of the preemption cases in federal courts: agency independence and the degree of congruence between the regulatory and common law standards.

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I. Introduction

In a large number of products liability lawsuits, sellers assert that plaintiffs' tort claims should be rejected because their products fall under some federal regulatory regime, and that the regulatory statute takes precedence over or "preempts" state tort law. This paper is an attempt to set out a positive theory of the doctrine on preemption of products liability claims.

The case law on products liability preemption is full of references to legislative intent. These references suggest that if one were to read the preemption provisions of the statutes, one could predict which tort claims would be preempted and which would not. But anyone who takes the time to read the statutes and case outcomes would be disabused of this notion. The preemption provisions in the statutes are ambiguous. The different case outcomes are difficult to reconcile on the basis of the statutory language.

To be sure, the legislative intent approach has faded somewhat. It reached a high point with the Supreme Court's decision in *Cipollone v. Liggett Group, Inc.*¹ Recent Court decisions have moved toward an "implied preemption" approach that looks for actual conflicts between common law and federal regulations. Preemption doctrine is in many respects unsettled. Still, the references to legislative intent remain in much of the established case law and in many new decisions.

My aim is to show that preemption doctrine can be explained largely by objective factors that do not require the divining of Congress's intent. The federal case law is largely consistent with an approach that seeks to minimize the costs of erroneous decisions to preempt tort lawsuits. In particular, two factors explain many of the outcomes of the preemption cases: *the degree of congruence between the regulatory and common law standards and the perceived degree of agency independence.*

After setting out an "error cost" model, and using it to explain federal preemption case law, I conduct an empirical analysis using samples of federal and state preemption cases. The empirical analysis can be viewed as preliminary, or as a more rigorous version of the argument based on case law, because there is a possible sample-selection bias that my sample (court opinions) will not permit me to correct. Still, results from the federal case sample are quite consistent with my arguments based on the case law and the predictions of the model. The probability of preemption increases with the degree of congruence between the regulatory and common law standard, and agency review processes that are perceived to be independent and rigorous result in higher rates of preemption. The state case sample does not fit the model as well, in part because of sparseness of the sample, and in part because the state courts appear to have a less deferential, or more interventionist, approach to preemption cases.

Although this paper's focus is on preemption law, a closely related literature examines the optimal combination of regulation and litigation as law enforcement

¹ 505 U.S. 504 (1992).

mechanisms.² Since a decision by a court to preempt litigation leaves regulation as the sole enforcement mechanism, studying optimal preemption is equivalent to studying the optimal combination of regulation and litigation. However, this paper differs from the previous economic literature in several ways: by examining a particular area of law, products liability; by offering a positive theory of the case law on preemption, and by conducting an empirical test of the theory using preemption case outcomes in federal and state courts.

II. Law and Literature: An Overview

Preemption of products liability claims is still a rapidly developing area of the law, which should not surprise anyone given that products liability itself began, more or less, in the late 1960s with the publication of Section 402A of the Second Restatement of Torts. Indeed, the first federal court opinion to focus on the preemption question in products liability appears to be *Wood v. General Motors*,³ decided in 1988.⁴

Under standard preemption analysis courts examine *express* and *implied* preemption. Express preemption occurs when the federal statute at issue says clearly that it preempts state law tort claims. Under the Constitution's Supremacy clause, courts are bound to follow a federal statute's unambiguous instruction to preempt state law. Implied preemption, in contrast, occurs in the absence of clear preemption instructions and takes two forms: field and conflict preemption. The former is said to occur when federal regulation is so extensive that it leaves virtually no room for the states to regulate. The latter is said to occur when there is a conflict between federal and state law, such that it would be virtually impossible to comply with both.

Congress seldom speaks clearly with respect to preemption. As a consequence, few if any federal regulatory statutes express an unambiguous legislative intent to preempt state tort law. The case law seldom found express preemption of tort claims until the Supreme Court's decision in *Cipollone*, which dramatically altered the doctrine.⁵ In *Cipollone*, the Court found that the Federal Cigarette Labeling and Advertising Act expressly preempted state law failure to warn claims based on inadequate cigarette labeling. The relevant portion of the statute, section 5(b), said:

² See Steven Shavell, A Model of the Optimal Use of Liability and Safety Regulation, 15 *Rand J. Econ.* 271-80 (1984); Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 *J. Legal Studies*, 357-74 (1984) (hereinafter, Shavell, Liability for Harm); Edward L. Gleaser & Andrei Shleifer, The Rise of the Regulatory State, 41 *J. Econ. Literature* 401-25 (2003); Chenggang Xu & Katherina Pistor, Law Enforcement under Incomplete Law: Theory and Evidence from Financial Market Regulation, Columbia Law School Working Paper No. 222, available at http://ssrn.com/abstract_id=396141.

³ 865 F.2d 395 (1st Cir. 1988).

⁴ Another early substantial treatment appears in Abner Mikva's opinion in *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984), a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) case. There are several cases predating *Wood* and *Ferebee* that touch on the preemption issue, but only tangentially and without focus. Many of these cases are included in the sample used in the empirical section of this paper.

⁵ Indeed, before *Cipollone*, the trend ran largely against finding preemption, under either an express or implied theory. Many courts held that federal regulatory statutes provided only minimum standards, which could (and should) be supplemented by state tort standards.

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.⁶

The Supreme Court concluded that this provision “sweeps broadly,”⁷ preempting both state statutory and common law rules.

Cipollone turned preemption doctrine on its head, though only for a brief period. Before 1992 (the date of *Cipollone*) courts talked largely in terms of implied preemption, since no court could safely conclude, on the basis of the language typically found in a federal statute, that Congress intended to bar private tort suits. Immediately after *Cipollone*, courts began finding evidence of legislative intent to preempt in language that was considered to “sweep broadly,” like the language of the statute in *Cipollone*. For example, in *King v. E.I. Dupont De Nemours & Co.*,⁸ the First Circuit read the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to preempt failure to warn claims based on language in the statute that seemed similar to the language of the preemption provision in *Cipollone*. Some scholars argued that express preemption had become the dominant mode of analysis, and implied preemption theories had been abandoned.⁹

The *Cipollone* period came to an end in 1996 with the Supreme Court’s decision in *Medtronic, Inc. v. Lohr*.¹⁰ In *Lohr*, the Court stared at a preemption provision that looked very much like the one in *Cipollone* and concluded that it did not preempt state tort law. The plaintiff had brought failure to warn, negligence, and strict liability claims against Medtronic when her pacemaker failed. The pacemaker had been approved for marketing by the Food and Drug Administration under the Medical Devices Amendment Act of 1976. The statute sets out a two-tiered review scheme for “Class III” medical devices, such as the pacemaker, which have the greatest impact on life. The two-tiered review involves either a rigorous pre-market approval process or a designation that the product is substantially equivalent to a device that was on the market before 1976. If the product meets the “substantial equivalence” test, it does not have to undergo the pre-market approval process, and is approved for marketing as long as it is no more dangerous or less effective than the earlier comparable device. The plaintiff’s pacemaker in *Lohr* had been approved for marketing under the substantial equivalence test.

Although the preemption provision of *Lohr* was virtually identical to that of *Cipollone*, the Court, which split in three ways, was unanimous in the view that it did not preempt defective design claims. The plurality offered several lawyerly distinctions between the regulation in *Lohr* and that in *Cipollone*. However, the one distinction on

⁶ 15 U.S.C.A. §1334(b).

⁷ *Cipollone*, 505 U.S. at 521.

⁸ 996 F.2d 1346 (1st Cir. 1993).

⁹ See, e.g., Richard A. Epstein, *Cases and Materials on Torts* 851 (6th ed. 1995).

¹⁰ 518 U.S. 470 (1996).

which the whole Court agreed was that the substantial equivalence test led to no regulatory requirements that could come into conflict with state tort law.

Since 1996 the lower courts, following *Lohr*, have returned to a focus on implied preemption analysis. Under this approach, courts look for evidence of a potential conflict between federal regulation and the specific requirements implied by the plaintiff's tort theory. For example, in *Lewis v. Brunswick Corp.*,¹¹ the Eleventh Circuit, confronting a preemption provision that looked similar to that in *Cipollone*, concluded that the plaintiff's negligence and defective design claims were preempted. This was not because of the language of the preemption provision. It was because the plaintiff's theory, in the court's view, would have required the defendant boat maker to install a safety device – a propeller guard – that the Coast Guard had decided not to require pursuant to its duty under the Federal Boat Safety Act.

The Supreme Court appears to have entered an advanced stage of implied preemption analysis in recent years with its decisions in *Geier v. Am. Honda Motor Co.*,¹² *Sprietsma v. Mercury Marine*,¹³ and *Bates v. Dow Agrosciences*.¹⁴ In this new stage, the Court is applying implied preemption analysis in a conservative manner, refusing to find preemption unless there is evidence of a serious conflict between federal regulation and state tort law. In *Geier* the Court found such evidence when it looked at the potential conflict between Federal Motor Vehicle Safety Standard 208 and the plaintiff's defective design claim based on the defendant car manufacturer's failure to install an airbag. The Court found that the plaintiff's claim was preempted because it would have conflicted with the Department of Transportation's decision to provide compliance options for car manufacturers.

Sprietsma, on the other hand, found that the plaintiff's demand for a propeller guard was not preempted by the Federal Boat Safety Act, the opposite result of the Eleventh Circuit in *Lewis*. In spite of the different result, the Court did not reject the implied preemption approach of *Lewis*, it simply applied the analysis with greater caution and skepticism toward broad claims of preemption. After looking closely at the Coast Guard's analysis of the propeller guard issue, the Court decided that its refusal to adopt a uniform propeller guard requirement did not preclude a court from finding that a particular boat design was defectively dangerous because it failed to include a propeller guard.

The Court's most recent preemption case, *Bates*, found that defective design and manufacture claims were not preempted by FIFRA, and information-based claims (failure to warn and fraud) were preempted only if they required information disclosure that was not parallel to the requirements of the statute.¹⁵ This is a clear rejection of the approach

¹¹ 107 F.3d 1494 (11th Cir. 1997).

¹² 529 U.S. 861 (2000).

¹³ 537 U.S. 51 (2002).

¹⁴ 544 U.S. 431 (2005).

¹⁵ *Id.* at 444-48.

to FIFRA analysis adopted by some courts – e.g. *King* – during the express preemption period.

Many commentators have noted the confusion and uncertainty in preemption doctrine, and some have urged the enactment of a regulatory compliance defense in order to bring certainty to the law. Viscusi (1994) argues that a regulatory compliance defense would be desirable in areas in which the federal regulatory scheme provides optimal or excessive deterrence.¹⁶ He offers the drug approval process under the Food, Drug, and Cosmetic Act as a case study of an area in which a regulatory compliance defense would be socially desirable. Schwartz argues that courts (or legislators) should adopt a general (default rule) regulatory compliance defense because it is more likely that an erroneous decision to set the standard of care too low will be corrected by Congress than an erroneous decision to set the standard of care too high.¹⁷

In the remainder, I will reject both views – i.e., that preemption doctrine is in a state of confusion and that a regulatory compliance defense is necessary. The case law is largely defensible on economic grounds. In addition, some of the cases that seem to be in tension, such as *Geier* and *Sprietsma*, are reconcilable within this paper’s framework. The empirical analysis of preemption cases in this paper further supports the view that the case law has a rational basis. However, the empirical analysis also supports Viscusi’s charge with respect to the drug approval process under the Food, Drug, and Cosmetic Act. For the period of the sample used below (1971-2002), courts appear to be unjustifiably reluctant to preempt tort suits involving drugs approved by the Food and Drug Administration. But this appears to be a special case rather than an example of a general deficiency in the courts.

III. Theory of Preemption Doctrine

A. Error Cost Model

The theoretical issues in preemption analysis are old and were largely dealt with in Holmes’s discussion of the jury in *The Common Law*.¹⁸ Holmes asked whether society should prefer to have the judge or the jury determine negligence. Holmes presented a model in which the judge decides whether to give the negligence question to the jury. He concluded that in order for the law to become more predictable over time, the judge would have to take an increasingly large share of negligence determinations under his control. The jury would be consulted, under Holmes’s scheme, when the judge did not

¹⁶ W. Kip Viscusi, Steven R. Rowland, Howard L. Dorfman, Charles J. Walsh, The Effect of Products Liability Litigation on Innovation: Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense, 24 Seton Hall L. Rev. 1437 (1994).

¹⁷ Alan Schwartz, Statutory Interpretation, Capture, and Tort Law: The Regulatory Compliance Defense, 2 Am. L. & Econ. Rev. 1 (2000).

¹⁸ Oliver Wendell Holmes, Jr. *The Common Law* 122-27 (Boston: Little, Brown and Company, 1881). Though taking a very different approach from this paper, Robert Rabin noticed the similarity between the agency-court question and the judge-jury problem analyzed by Holmes. See Robert Rabin, Reassessing Regulatory Compliance, 88 Geo. L.J. 2049 (2000).

have enough experience with similar cases to be able to set the optimal standard of care on his own. In these cases, the jury would serve as a source of information on the costs and benefits of requiring additional care, and on the state of community norms.

One could describe Holmes's model as a choice between two decision processes for choosing the optimal legal standard, both subject to error. The jury has an advantage in terms of its access to local information and to norms that change over time. The disadvantage of the jury is that it has a higher error variance than does the judge.

The preemption question can be treated as a slightly more complicated version of the problem of choosing between judge and jury. In the preemption case, the choice is between letting courts decide the standard of care in each case or letting an agency determine it once and for all.

Assume the question is whether a product design should be deemed "unreasonably dangerous" on the basis of a comparison of the incremental risk and utility the design offers in comparison to a safer alternative. As courts have noted, this is similar to a negligence determination.¹⁹ To simplify the analysis, I will assume that the risk-utility test is the optimal standard, as well as the common law standard.²⁰ Should courts determine the appropriate risk-utility trade off in every individual case, or should an agency determine the risk-utility standard once?²¹

The economic approach to this question compares the sum of expected error and administrative costs under the two regimes. By expected error costs, I mean the expected costs of "false convictions" and of "false acquittals." This requires an assessment of the likelihood of erroneous decisions in favor of the plaintiff or the defendant, and their concomitant costs. The approach I will explain here is similar in some respects to a model set out by Shavell,²² but there are substantial differences and the conclusions differ too.

The administrative costs under the two regimes (courts versus agency) are easy to compare. Until precedents are set and respected among the individual courts, the case-by-case system in the courts has higher administrative costs, since it involves many

¹⁹ E.g., *Volkswagen of Am. v. Young*, 321 A.2d 737 (Md. 1974).

²⁰ For the argument that the common law of products liability has converged, or is in the process of converging, on economically optimal legal standards, see William M. Landes & Richard A. Posner, *A Positive Analysis of Products Liability*, 14 J. Leg. Stud. 535 (1985). The framework of this paper rejects the notion that a simple strict liability rule would be appropriate for all types of products liability claim. One reason is that the causation issues that would be generated by such a rule would make it unpracticable.

²¹ I do not consider the assumption that agencies use risk-utility analysis as a restrictive one for this model. If agencies seek optimal results, the risk-utility standard is a desirable approach. If agencies do not seek optimal results, then the argument for preemption becomes extremely weak and largely uninteresting. In addition, the risk-utility standard builds in the assumption that both agencies and courts evaluate the standard on the basis of objective information with respect to risks and potential harms. This approach rejects the notion that policy preferences drive the implementation of the risk utility test.

²² Shavell, *Liability for Harm*, supra note 2.

determinations of the risk-utility standard rather than one. Thus, a narrow focus on administrative costs favors the agency regime.²³

The error costs under the two regimes are ambiguous a priori. Setting aside error probabilities for the moment, it is hard to say whether the actual costs of false acquittals are greater than those of false convictions in products liability cases. False acquittals mean that products that are unreasonably dangerous remain on the market, injuring consumers. False convictions mean that products that are not unreasonably dangerous are driven from the market by lawsuits, also harming consumers. Given this ambiguity, I see no need to try to separate false-conviction and false-acquittal costs in the analysis below. I will focus on error probabilities.

Consider the error probabilities in products liability litigation. Three factors determine the likelihood of error. First, the *expertise* of the agency is a factor that suggests that errors are less likely under the agency regime wherever expertise on product risk characteristics and utility is valuable in setting the optimal (or common law) standard.²⁴ Second, the jury's superior *knowledge of local conditions or norms* is a factor that suggests errors are less likely under the court regime whenever local knowledge is valuable in setting the right standard.²⁵ Third, *political distortion* is a factor that suggests that errors are less likely under the court regime, where the risk of such distortion is low.²⁶

By political distortion, I refer to the public choice concerns that enter whenever one takes a question away from the jury and puts it in the hands of a government agent. Agency officials may come under the influence of the parties whom they are supposed to regulate. In instances where the government agency has come under the influence of the regulated firm, the agency's standard may be biased in favor of the firm.

These three factors – agency expertise, local knowledge, and political distortion – do not exhaust the list of factors that could be considered in determining the preemption issue. Society has, in addition, an interest in providing predictability. A regime that has less potential to be accurate ex post may be preferable because it is more predictable ex ante. Consider, for example, the choice between a custom rule and a negligence rule for medical malpractice. However, it is difficult to say how much ex-post accuracy potential should be sacrificed in order to gain additional predictability. For this reason, I will rely largely on the three factors identified above. However, the need for predictability is a tie-breaking factor that leans (like the desire to minimize administrative costs) in favor of the agency regime.

²³ Richard C. Ausness, The Case for a “Strong” Regulatory Compliance Defense, 55 Md. L. Rev. 1210 (1996). My conclusion (and that of Ausness) differs from that of Shavell, *Liability for Harm*, supra note 2, which argues that administrative costs are lower in the courts.

²⁴ Shavell, *Liability for Harm*, supra note 2, at 369.

²⁵ *Id.*, at 366.

²⁶ Shavell's analysis does not take political distortion (or rent seeking) into account. In addition to this important distinction, there are some features of Shavell's model that are excluded from this analysis (e.g., the risk of judgment-proof parties) because they do not improve the model's ability to explain preemption law.

The three factors identified here suggest no clear general societal preference for the court or agency regime. Whether tort claims should be preempted by federal regulation depends on a weighing of these factors. It is possible, however, to go further and suggest a specific approach to preemption questions.

A finding of preemption should depend largely on two considerations. First, as a threshold matter, was the agency's determination independent, in the sense that it was not overly influenced or biased by some interested party? If a court finds substantial evidence that the agency did not act independently, then it should not find the tort claim preempted. The reason is that political influence, if left unchecked, feeds on itself and grows. If firms know that they can acquire tort immunity by putting themselves under phony regulatory regimes, they will bid for this type of protection. A firm that faces a potential tort liability of \$5 million would rather invest \$4 million in setting up a regulatory regime that provides immunity.

The second consideration is the degree of congruence between the agency's standard and the standard that would be used by the court. This consideration encompasses the first two (expertise, local knowledge) of the three factors (expertise, local knowledge, political distortion) that influence the overall likelihood of error. Superior expertise on the part of the agency should lead the court to favor preemption, provided that the agency's standard is equivalent to that of the common law (which is assumed to be optimal). In contrast, if local knowledge is important in applying the common law standard, the fact that the agency employs a standard different from the common law should be a sufficient basis to deny preemption.

Time lags are important in determining the degree of congruence between the agency's regulatory standard and the common law standard. Suppose the agency issues a standard in period one, and new risk information arises in period two indicating that the agency's standard is suboptimal. Since the common law standard would adapt to take the new risk information into account, the agency standard would no longer be congruent if it did not also adapt to reflect the new information.

B. Examples and Illustrations

Consider some examples to flesh out this argument. Federal Motor Vehicle Safety Standard 208, issued by the Department of Transportation, at one time gave car makers options with respect to passive restraint systems. The agency, from the evidence that has emerged, appears to be independent, and it appears to base its standard on a weighing of incremental risks and utility, the same factors that would be considered under the common law standard in a products liability action. On the basis of agency expertise, this analysis suggests that preemption of state law design-defect claims under Standard 208 is desirable. The state law design-defect claim requires the court to apply the same test as that applied by the agency in setting its standard. Moreover, the agency has an advantage in terms of expertise. A rule of preemption minimizes error under these conditions. It avoids an outcome in which a less expert jury reexamines the methodology

of a more expert agency. However, preemption would be inappropriate under this analysis if the defendant seller did not comply with the agency's regulations or if the agency's standard is not equivalent to the common law standard.

As a second example, consider a nuisance claim. Nuisance claims, as a general rule, require knowledge of local environmental conditions in assessing whether the defendant's conduct constitutes an "unreasonable invasion."²⁷ In other words, the common law standard for nuisances relies on local information. Given this, there is no strong basis for a rule favoring preemption of nuisance claims in a case where a federal agency sets a standard that is claimed by defendants to preempt nuisance suits. For example, the 1996 Telecommunications Act appears to preempt nuisance suits based on health concerns related to the siting of cell phone towers.²⁸ A court, however, is likely to take additional information into account (e.g., nearness of a grade school or hospital, or other emission sources) in determining whether a cell phone tower should be deemed a nuisance. Under this paper's framework, it would be inefficient, as a general rule, to preempt nuisance suits under the siting provision of the 1996 Telecommunications Act.

More generally, we can use this framework to predict where products liability lawsuits are most likely to be preempted by federal regulation. Products liability lawsuits can be grouped into three types: manufacturing defect, design defect, and failure to warn. Manufacturing defect claims cover cases in which the plaintiff is injured because of a glitch in the widget production line. One out of a thousand widgets are made dangerously defective by this glitch, and the plaintiff happens to have bought that one in one thousand defect. These claims are governed by strict liability, which means that courts forgo any inquiry into the seller's fault. Design defect claims cover cases in which the plaintiff alleges that the product is unreasonably dangerous because its risks are too large relative to its benefits, in comparison to some feasible safer alternative. These claims are governed by "consumer expectation" and "risk-utility" tests – and for simplicity I will focus on the risk-utility test. Failure to warn claims cover cases in which the plaintiff sues on a negligence theory for the seller's failure to provide notice of the dangerous attributes of a product.

It follows from the foregoing that, of the three products-liability claim types, manufacturing defect claims should be preempted least frequently. A federal regulatory agency could not, without incurring an enormous expense, set a standard governing manufacturing glitches that could be used to preempt tort claims efficiently. Suppose the agency were to preempt all tort claims when the glitches occurred at a rate of one per thousand or less. In order to enforce this scheme, the agency would have to monitor the production process of every regulated entity, which is infeasible. If a manufacturing defect were to occur, it would be quite difficult for a court to determine *ex post* whether the manufacturer had complied with the agency's standard, unless government agents had monitored the plant so closely that objective records of failure rates could be brought into

²⁷ See, e.g., William L. Prosser, *Handbook of The Law of Torts* 580-81 (St. Paul: West Publishing Co., 4th ed. 1971).

²⁸ Pub. L. No. 104 – 104, § 704, 110 Stat. 56 (1996).

court. It follows, then, that preemption should be infrequent and generally limited to those cases in which government agents regularly inspect regulated entities.

In contrast, error-cost minimization implies that design defect and failure to warn claims should be preempted with substantial frequency, under the appropriate conditions. If an agency has considered the factors that a court would weigh in conducting a risk-utility analysis, and concluded that the product is on net beneficial to consumers, then courts should defer to the agency's decision if it is reached in an independent manner. However, if the agency is merely rubber stamping the safety standards developed by the industry, then it is not acting independently, and the argument for preemption weakens.

There are different degrees of agency independence. The highest degree of independence is observed when the agency's staffing, methodology, and data are invulnerable to bias from industry influence. Perhaps the closest to this ideal is the Food and Drug Administration, which is independent with respect to methodology and staff,²⁹ but relies on regulated firms to supply data on the effects of new drugs. Even here, the scientific standards governing drug trials are so high that we may just as well treat this as a case of independence with respect to data as well. On the other extreme, one finds the Consumer Product Safety Commission, which at least at one time relied on industry to design flammable product safety standards.³⁰ Under this paper's framework, preemption should be more probable as the agency's independence increases – and this will lead to differences in observed preemption rates for design and warning claims.

In addition to evidence of agency independence, the frequency with which design defect and failure to warn claims will be preempted should be a function of the degree of congruence between the regulatory and common law standards. Congruence is almost always satisfied in the case in which the agency determines its standard by weighing risks and benefits for every individual product type. For example, if (as is not the case) the Department of Transportation evaluated the risks and benefits of every car design, then each regulatory standard governing each car would be determined by a standard that is congruent with the common law standard. On the other hand, where an agency issues a generic standard that covers all product types, congruence will be satisfied only if the risk-benefit calculus is also generic across product types.

The congruence factor implies that the frequency of preemption should be greater in failure to warn cases than in design defect cases. Risk information issues are often generic across product classes. For example, a warning on the importance of wearing a

²⁹ The FDA forms advisory committees to solicit the opinions of expert scientists and physicians on the safety and efficacy of drugs and medical devices. To encourage the committees' independence, the FDA recruits members from a broad range of qualified candidates. See, e.g., Dixie Farley, Getting Outside Advice for 'Close Calls' <http://www.fda.gov/fdac/special/newdrug/advice.html>. However, since advisory committees consist almost entirely of pharmaceutical industry consultants and researchers, some have argued that there is considerable scope for the pharmaceutical industry to influence the drug approval process. See, e.g., Dennis Cauchon, FDA Advisers Tied to Industry, USA Today 10A (September 25, 2000). On the other hand, interested parties are the ones most likely to be the best informed. Given this, high scientific standards are probably the ultimate guarantee of independence.

³⁰ See *Wilson v. Bradlees of New England, Inc.*, 96 F.3d 552 (1st Cir. 1996).

seat belt should not depend greatly on the design of the car; similarly, a warning governing the risks of smoking cigarettes should not need to vary greatly depending on the type of cigarette – at least for most cigarettes commonly marketed. Questions of safety in design, in contrast, are often highly dependent on the type of product. It is less likely, in comparison to warning standards, that an agency will be able to issue a generic design safety standard that reflects product-specific risk-utility concerns.

The one factor that cuts against the prediction of a higher rate of preemption in failure to warn than in design cases is that of time lags. Information standards should be less costly to revise than design standards. When new risk information makes the original agency standard obsolete, the agency standard loses its congruence with the common law standard. Hence, in comparison to design standards, information standards should be revised or at least be capable of being revised more frequently in response to new risk information in order to justify preemption.

This approach, in addition to being consistent with error cost minimization, is emerging as explicit doctrine in the courts. I consider some of the cases consistent with this approach in the following part.

C. Application to Cases

The model just developed provides a ready explanation for *Lohr*, as well as the Supreme Court's later treatment of preemption of products liability claims in *Geier*, *Spietsma*, and *Bates*. Recall that the plaintiff's pacemaker in *Lohr* had been exempted from the FDA's pre-market approval process because it was "substantially equivalent" to a device that was on the market before 1976.

Under the theory presented here, state law defective design claims should be preempted by the MDA in the case of Class III devices that undergo the pre-market approval process. In contrast, the Class III devices that meet the substantial equivalence test should not be shielded from liability under preemption doctrine. The reason is that the FDA's pre-market approval process involves a careful consideration of the risk and utility characteristics of the proposed medical device. These are precisely the issues that would be examined by a court under the risk-utility test that would be applied in a products liability lawsuit. Put another way, the federal regulatory standard and the tort law standard are congruent. Since the FDA has greater expertise than a jury, and since the issue is one that does not require any special local knowledge of jurors, error costs are minimized by preempting design defect claims brought against products that have undergone the FDA's pre-market approval process. The majority of federal courts have found that the MDA preempts such claims.³¹

³¹ The Seventh Circuit found that the MDA preempted such a claim in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); the Eighth Circuit in *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994); the Fifth Circuit in *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001). The Sixth Circuit accepted the reasoning of these cases in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000). In *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. 1997), a case involving a Class II medical device (tampons), the Ninth Circuit suggested acceptance of the same reasoning. The only federal appellate court to explicitly reject this argument is the Eleventh Circuit in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

In the case of a medical device that is approved under the MDA's substantial equivalence test, these arguments for preemption do not hold. The substantial equivalence test is not congruent to the tort standard. It does not involve the same consideration of risks and benefits as would be undertaken by a court hearing a design defect claim. Since the underlying legal tests are not similar, preemption would be inappropriate under this framework.

The Supreme Court's decision in *Geier* can be squared with this framework. To be sure, the fact that it was a five to four decision suggests that the Court may sometimes have a destabilizing rather than clarifying effect on tort preemption doctrine. Still, the outcome, a finding that the Federal Motor Vehicle Safety Standard 208 preempts state law design defect claims for failure to install an airbag, is entirely consistent with the vast majority of federal court decisions, and should be seen in this context as a continuation of settled doctrine.

The key result of *Geier* is that it put more doctrinal distance between current preemption law and the express preemption focus of *Cipollone*. The Court rejected the defendant's effort to shield itself from tort suits on the basis of *Cipollone* and the words used in the preemption provision of the National Traffic and Motor Vehicle Safety Act. The Court pointed to the existence of a "saving" clause – a boilerplate provision in federal regulatory statutes that says that compliance with the statute does not exempt anyone from liability under common law – as a reason for refusing to find a legislative intent to preempt the plaintiff's claim. The Court then went on to apply standard conflict analysis, and concluded that since the Department of Transportation had considered the risk and utility issues that would be analyzed in a common law design defect claim, a decision not to preempt would permit state courts to reach conclusions that actually conflict with the federal regulatory scheme.

The Court's description in *Geier* of the development of Standard 208 suggests that preemption is the appropriate result under this paper's framework. Standard 208 appears to have been developed and modified over time independently by the Department of Transportation. It did not result from the agency rubber stamping a privately-developed industry standard. To be sure, the auto industry has influence within the agency. However, in the highly publicized setting of auto safety regulation, reputation concerns provide a check on the degree to which agency officials will work on behalf of the industry.³² No high level agency official with an eye on his political future would want to be viewed as having sacrificed public safety to protect auto industry profits. In addition, the department's level of expertise surpasses that of the typical jury. There are no special local concerns that would justify a decentralized process in which juries decide the appropriate level of safety features in car designs. Since the agency appears to develop its rules independently and the jury has no informational advantage, error costs are minimized by preempting air bag law suits under Standard 208.

³² Consider the fact that two of the former department heads, William Coleman and Elizabeth Dole, are famous political figures who would lose enormous investments in reputational capital if they were seen as mere stooges for the auto industry during their tenures as Transportation Secretary.

As I noted earlier, the conclusion of *Geier* seems to be contradicted by that of *Sprietsma*, which rejected the preemption defense. To see the contradiction, recall that *Sprietsma* held that the Coast Guard's decision not to require propeller guards did not preempt a state law defective design claim based on the absence of a propeller guard. The Court argued in *Sprietsma* that a decision not to impose a uniform propeller guard requirement should not preclude a trial court from finding that a propeller guard would be desirable in the case of a particular boat design. The Court argued in *Geier* that a decision not to impose a uniform airbag requirement should preclude a trial court from finding that an airbag would be desirable in a particular car design.

The conflict between *Geier* and *Sprietsma* is superficial and largely dependent on how the decisions are described. Moreover, the decisions can be reconciled under the framework of this paper. The key difference is that a decision to require airbags in *Geier* would be tantamount to a uniform airbag requirement. After all, if an airbag would be desirable on risk-utility grounds in the car driven by the plaintiff in *Geier* (a 1987 Honda Accord), why would it not be desirable in every other car that has a manual or automatic safety belt system – i.e., all other cars?

In a system designed to minimize error costs, there is no reasonable alternative to preemption in *Geier*. It may sound plausible at first glance to argue, as did the dissenting Justices in *Geier*, that the Department of Transportation's decision should be treated as a minimum that should not preclude an individual court from finding that a particular car design was defective because it failed to include an airbag. But this approach leads to an unraveling of the regulatory structure. If you find one car design defective because it fails to include an airbag, there is nothing to prevent you finding that they are all defective for the same reason. And given that the Department of Transportation, an expert body, had already weighed the relevant risk-utility factors, any different conclusion reached by a jury would probably be erroneous.

The unraveling problem is not clearly suggested by the regulations in *Sprietsma*. The Coast Guard's decision not to impose a uniform propeller guard requirement was based on its conclusion that the risk-utility factors were dependent on the particular boat design. A propeller guard might be desirable for one particular design and undesirable – say because it substantially reduced engine speed – for another. Unraveling is not an issue if a finding that one particular boat design is defective because it does not include a propeller guard does not imply that all boats without propeller guards are defectively designed.³³

In terms of the error-cost framework presented here, the different conclusions in *Geier* and *Sprietsma* can be reconciled on the basis of the similarity between the regulatory standard and the common law standard. Because there were no special design-

³³ In other words, *Sprietsma* is defensible only if the unraveling problem is not serious in that case. In interpreting the Coast Guard as having concluded that it was not, the Supreme Court rejected the position taken by several lower courts that had looked at the propeller guard issue. See, e.g., *Davis v. Brunswick Corp.*, 854 F.Supp. 1574, 1580 (N.D. Georgia 1994).

specific features that would have made an airbag appropriate for only one car design, the regulatory standard in *Geier* was a uniform product standard that applied to every car design. The Department had, in effect, considered the same risk-utility factors that would be examined by a trial court in a design defect action based on the absence of an airbag. The regulatory and the common law standards were congruent.

Spreitsma is not a case in which the regulatory and common law standards were congruent. The Coast Guard had not issued a uniform standard. It had only decided not to issue a uniform standard because design variations made such a standard ineffective. The Coast Guard removed itself from the propeller guard question, leaving it to boat manufacturers and other regulatory sources to find optimal safety features.

Bates is easily seen to be consistent with this paper's framework. FIFRA sets out labeling requirements, and should therefore be viewed as a regulatory standard governing the disclosure of information. Common law on failure to warn is congruent, in the sense of this paper's model, to the FIFRA regulatory standard. However, design defect claims are not congruent to the FIFRA regulatory standard. The Court's conclusion that design defect claims are not preempted while information-based claims are preempted, to the extent they are not parallel with the regulatory standard,³⁴ would be predicted by the error-cost model of this paper.

One federal appellate decision that clearly falls within this paper's framework is Judge Boudin's opinion in *Wilson v. Bradlees of New England, Inc.* The plaintiff Wilson brought suit against the defendants on failure to warn and negligence theories after her daughter was severely burned when her sweatshirt caught fire. The defendants argued that Wilson's tort claims were preempted by the Flammable Fabrics Act. The court, after examining the history of the federal flammability standard, concluded that it was an industry-developed standard that had been adopted without independent testing or modification by the Consumer Product Safety Commission. In Judge Boudin's view, this was enough to decide the case. Citing Learned Hand's *TJ Hooper* opinion for the proposition that industry standards should not determine common law negligence standards, the court held that Wilson's claims were not preempted.

The majority of federal court preemption decisions are consistent with the analysis in *Wilson* and this paper's framework,³⁵ though this is hard to see at first because most of them hew closely to analyzing the text of the statute at issue. *Wilson* is one of the exceptional opinions in which a federal court looks under the layer of statutory text and inquires into the function of preemption doctrine. The Restatement of the Law Third, Products Liability, captures the current state of preemption doctrine not with its provision on the regulatory compliance defense, section 4(b), but with its comment to that provision. After saying in 4(b) that regulatory compliance does not preclude "a finding

³⁴ Where the information-based claim is parallel to the regulatory requirement, the plaintiff's tort action is not preempted because it is essentially a negligence claim based (failure to warn) on the breach of a statutory standard.

³⁵ See Part IV of this paper (empirical section).

of product defect,”³⁶ the Restatement notes in its comment to that provision 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.”³⁷ The Restatement Third would have come closer to describing what federal courts are actually doing if it had inserted the language from this comment into provision 4(b).

D. Failure to Warn

This framework’s implications for failure-to-warn cases are straightforward. The common law standard governing failure to warn cases is a negligence test that compares the risks that probably would be avoided by a warning with the cost of a warning. If the federal regulatory agency that oversees product labeling examines the same issues in determining whether a warning should be required, and no new risks materialize after the federal standard is issued, then the federal regulatory standard is congruent with the common law standard. Congruence, under this framework, is a necessary condition for preemption of failure to warn claims.

Some statutes, notably the MDA and FIFRA, require a federal agency to regulate product labeling in order to safeguard health. In many of these cases the agency’s standard is congruent with the common law standard.

For example, the FDA has the authority under the MDA to classify products according to whether they pose slight (Class I), moderate (Class II), or serious risk to human health (Class III). For products in the serious risk category (Class III), the FDA examines the seller’s proposed product under its “pre-market approval process,” which requires the seller to submit a detailed application which is reviewed by a panel of experts.³⁸ For the products in the moderate risk category (Class II), the FDA has the authority to require warnings and product specifications (e.g., performance standards, post-market monitoring) if it considers the health risks substantial³⁹ – and courts have interpreted this statutory grant of authority to mean that the agency has the primary responsibility to determine the risks that need to be revealed to the consumer and how those risks should be reported.⁴⁰

In view of the FDA’s charge under the MDA – to protect the public health by assuring that medical devices are safe and effective⁴¹ – and the comprehensiveness of the pre-market approval process, one should expect the agency to require warnings for Class III devices in every instance in which it would be negligent not to require one and

³⁶ Restatement (Third) of Torts: Products Liability § 4(b) (1998).

³⁷ Restatement (Third) of Torts: Products Liability § 4 cmt. e (1998).

³⁸ See, e.g. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1419 (5th Cir. 1993).

³⁹ *Id.* at 418.

⁴⁰ *Id.* at 1421.

⁴¹ See, e.g., *Stewart v. International Playtex*, 672 F.Supp. 907, 909 (D.S.C. 1987); *Brooks v. Howmedica Inc.*, 236 F.3d 956, 965 (8th Cir. 2001).

perhaps in other instances as well. In addition, there are no local concerns that would lead one to think that a jury would be able to bring any special knowledge to the determination of an appropriate warning. Given this, substituting the decision of a court over that of the agency increases the likelihood of error. The same can be said of Class II devices, though the likelihood of preemption should be lower for them than for Class III devices since they are approved under a less rigorous process.

In the cases of both the MDA and FIFRA, there are expert agencies (FDA in the former, EPA in the latter) applying a standard that is congruent with the common law standard to a problem of risk regulation that does not require the input of special local concerns. This paper's framework predicts that courts should find state tort actions for failure to warn preempted under these conditions, which is what one finds (see appendix Table A2). The interesting question is why some claims are not preempted.

One exception in which failure to warn claims are not preempted even though the federal regulatory standard is congruent with the common law standard is when the seller fails to comply with the regulatory standard.⁴² When the seller fails to comply with the regulatory standard, a decision against preemption is equivalent to holding the seller liable for failing to meet the regulatory standard.

The failure to warn cases also provide instances in which the federal regulatory standard does not appear to be congruent with the common law standard. The model presented here predicts that the preemption rate should be low, which appears to be true.

For example, consider failure to warn claims involving products regulated by the Food, Drug, and Cosmetic Act (FDCA). In reviewing proposed labels for drugs, the FDCA does not require the FDA to apply the sort of rigorous review required under the MDA for Class III medical devices. Indeed, the original purpose of review under the FDCA was to prevent the "misbranding" of drugs,⁴³ not to establish a uniform regime for determining the risks that must be conveyed to consumers. FDCA regulations explicitly allow for sellers to modify labels as new risk information comes to light.

Given the differences between the FDCA and MDA, the level of congruence between the common law standard and the regulatory standard is generally lower in the case of the FDCA. There is a wider variance in regulatory standards under the FDCA than under the MDA. Animal drugs, for example, are approved under a process in which the agency takes a passive approach. Post approval monitoring is less frequent than under the MDA. There is a higher likelihood in this regime that a seller could negligently fail to modify a label to reflect new risk information that comes to light after its product is approved for marketing.

A general rule that approval of a product label under the FDCA immediately implies preemption of tort claims would be inconsistent with this paper's framework. In

⁴² *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005); *Natl. Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994).

⁴³ See *Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908 (5th Cir. 1987).

fact, the rate of preemption under the FDCA is low (see appendix Table A2). However, this can be taken as no more than weak confirmation of the framework at best. Many of the FDCA cases are decided on the basis of precedent without much discussion of the underlying purpose of preemption doctrine. The rate of preemption is too low, given that there are cases (e.g., vaccines) in which the FDA's process under the FDCA is indistinguishable from its process under the MDA.

E. Failure to Comply with the Regulatory Standard Generally and Fraud on the Agency

While failure to comply with the regulatory standard is often cited as a potential reason for denying preemption (and for imposing liability as well), the effect of an allegation that the defendant failed to comply with the regulatory standard is mixed. A substantial number of products liability claims are preempted even though the plaintiff claims that the defendant failed to comply with the regulatory standard.

This framework suggests a reason why a claim that the defendant failed to comply with the regulatory standard does not generally lead to a denial of preemption. The core of the explanation is the ease with which a court can determine compliance with the regulatory standard. If a court can determine failure to comply with the regulatory standard easily, then there is no great risk of error when a court holds a defendant liable for failing to comply.⁴⁴

On the other hand, if the court cannot easily determine failure to comply with the regulatory standard, there is a great risk of error when a court denies a defendant's preemption claim. If the regulatory agency has not itself determined that the defendant breached its standard, then permitting such a claim to be litigated would subject the agency to second-guessing in court. Of course, it is a different case if the agency has determined that the plaintiff failed to comply with its standard.⁴⁵

There is a special type of failure to comply known as "fraud on the agency." In these cases, a plaintiff argues against preemption on the ground that although the defendant complied with the agency's regulatory standard, that standard itself was biased

⁴⁴ The only reason a court would not hold a defendant liable is that the plaintiff's claim has no counterpart in the common law. For example, if the common law says clearly that the defendant owes no duty of care toward the plaintiff, the court should not hold the defendant liable for a breach of a regulatory standard.

⁴⁵ This argument suggests that an alleged failure to comply is more likely, other things being equal, to lead to a rejection of the preemption defense in the failure to warn case than in the design defect case. Failure to comply with an agency's labeling requirement is usually easy to determine. The court can read the agency's labeling requirement just as well as anyone else, and can easily spot a failure to comply. However, this is not so often true of design defect claims. Regulatory design standards are sometimes detailed and complicated, in other instances as vague as the common law negligence standard. For a court to determine whether the defendant complied would be equivalent in these cases to second guessing the agency's determination. In the case of an expert, independent agency, this approach increases the likelihood of error. This argument suggests that courts should be quicker to deny the preemption defense in failure to warn cases because the risk of error is lower. There were too few cases involving allegations of noncompliance and to perform a reliable test of this claim. However, my sample provides some weak support for this hypothesis, see note 67, *infra*.

as a result of the defendant's submission of fraudulent information. For example, a plaintiff might urge, under this theory, that a court not find his claim against a medical device seller preempted by the MDA when there is evidence that the seller's product was approved for marketing on the basis of false information given by the defendant to the FDA.

From an error-cost minimization perspective, there is a strong argument against preempting a plaintiff's tort claim when the defendant supplied false information to the agency, the agency relied on that information in setting its standard, and the resulting standard was biased as a result. In this case there is no basis for believing that the agency standard is more accurate than the court-determined standard. Moreover, finding preemption in this case encourages firms to defraud regulatory agencies in order to gain immunity from effective regulation and from tort suits.

The difficulty in applying this approach is that it leaves little of the preemption rule intact. Every plaintiff who can find evidence to support the claim that the defendant supplied false information to the agency will assert it. If courts had to determine the validity of the plaintiff's assertion in each case, there would be relatively little left of the preemption rule. Instead of directly substituting the agency's standard with the court's standard, this approach leads to an indirect substitution that occurs through litigating over the existence and effect of the defendant's alleged fraud.

While relying on a different rationale, the Supreme Court rejected the "fraud on the agency" theory as an exception to preemption doctrine in *Buckman Co. v. Plaintiffs' Leg. Comm.*⁴⁶ The majority opinion noted that a fraud exception would distort the incentives of product sellers who approach the FDA for approval, since they would be aware that approval might not shield them from tort litigation for failing to comply with the plaintiff's hypothetical version of the true agency standard. Justice Stevens's concurring opinion in *Buckman* argued that the plaintiff's claim should not be preempted in a case in which the agency itself had determined that the seller had acted fraudulently and had taken action to correct the regulatory error.

The position taken in the Stevens concurrence seems the most consistent with the framework of this paper. If tort claims are limited to those "fraud on the agency" cases in which the agency has actually determined that the seller acted fraudulently and taken action to correct the fraud, then there is little risk that the fraud exception will swallow a large part of the preemption rule. Under these conditions, only a small number of plaintiffs will be able to take advantage of the fraud exception. In addition, given the risk that the sanctions imposed by an agency may be insufficient to deter fraud, tort liability provides reliable compliance incentives by internalizing the harms caused by the seller's fraud.

While *Buckman* did not explicitly reject the existence of a fraud exception in the case in which the agency itself has determined that the seller acted fraudulently, its analysis, which is centered on the argument that state tort law has little interest in

⁴⁶ 531 U.S. 341 (2001).

protecting federal agencies from fraud, leaves little room for it. The flaw in *Buckman*'s broad rejection of the fraud theory is that it encourages the very sellers who would attempt to defraud an agency to lobby the legislature to weaken the agency's enforcement tools. If fraudulent sellers can be sure that the sanctions for fraud will be limited to those imposed by the federal regulatory agency, they will have incentives to seek legislation and administrative orders that constrain agency sanctions against fraud. The long run result could be an increase in fraudulent applications. In short, there is nothing in the *Buckman* approach to constrain the costs of political distortion, a factor that must always be taken into account in the regulatory setting.

F. Summary of Implications

The implications of the error-cost model can be summarized as follows. First, the likelihood that a plaintiff's products liability claim (design defect, failure to warn, or manufacturing defect) will be preempted increases with the degree of congruence between the agency's standard and the common law. Second, the likelihood of preemption increases with the perceived independence and rigor of the agency's review process. Third, preemption is more likely in failure to warn than in design defect claims. Fourth, preemption is unlikely in manufacturing defect claims. Fifth, preemption is unlikely when the defendant has failed to comply with the agency's standard.⁴⁷ However, where there is a mere allegation of noncompliance preemption may result because of the court's concern for the risk of error. Similarly, where there is an allegation of fraud on the agency, preemption is likely to be the result given the risk of court error. I have argued that the case law is consistent with these predictions. The remaining part of this paper looks for evidence to support these claims in a regression model.

IV. Empirical Analysis

A. Data and Model

To this point I have argued that the modern preemption case law is consistent with an approach that seeks to minimize the costs of error. In this part I will examine the empirical evidence that preemption doctrine has always been consistent with this approach. This part will try to identify the factors that are most important in explaining the results of the preemption cases.

Table 1 provides a summary of the results from federal and state products liability preemption cases, running from the 1970s to 2002.⁴⁸ The table reports the number of

⁴⁷ The sample of cases, discussed in the next section, includes no cases in which there was a finding that the defendant failed to comply with the agency standard (if such cases existed, they probably settled before trial). As a result, the fifth claim cannot be tested directly. However, there are many cases involving allegations of noncompliance.

⁴⁸ The first state case is from 1971, the first federal case is from 1976. Both federal and state samples run up to 2002. To gather the cases, I performed identical searches on Westlaw and Lexis using general search terms relating to preemption (e.g., "federal preemption of state law claims"), using both "natural language" and "terms and connectors" searches. Within the extensive search results that came up, I ignored cases

cases and the number of claims, since an individual case can involve more than one claim that a court must decide whether to bar on the basis of preemption. Each case in the table is either a trial or appellate court decision.

The sample described in Table 1 excludes United States Supreme Court cases. The reason is that the Supreme Court operates with fewer constraints than the lower courts. As the *Cipollone* experience illustrates, the Court has shown a willingness in the preemption area to strike off in a new direction, radically changing settled doctrine.⁴⁹ Given this, the most accurate statistical picture of the doctrine is provided by the bulk of cases meandering through the lower courts. In any event, excluding U.S. Supreme Court products liability preemption decisions reduces the sample by only five cases for this period.

Table 1 shows that federal courts are considerably more likely to find preemption than are state courts. Of the total claims, federal courts found 61 percent preempted while state courts found 42 percent preempted.⁵⁰ For failure to warn claims, federal court preemption rate is 74 percent, while the state court preemption rate is 53 percent, which is statistically significant at the conventional five percent level.⁵¹ For design defect claims, the federal and state court preemption rates are 46 and 34 respectively. This difference is not statistically significant.

Table 1 also shows that the preemption rate for failure to warn claims is substantially larger than that for design defect. For example, the overall preemption rate in the sample for failure to warn claims in federal court is 74 percent, while that for design defect claims in federal court is 46 percent, a statistically significant difference.⁵²

The high preemption rate for failure to warn cases confirms one prediction of the “error cost” framework set out previously in this paper. The model predicts that failure to warn cases should have a relatively high preemption rate because it is easier for regulatory agencies to issue a generic safety standard in the risk assessment context. Risk assessment issues tend to be generic across a product line – i.e., not varying by individual brand. Given their generic quality, warning standards will frequently be congruent with the test applied by a court examining a failure to warn claim brought against the

relating only to ERISA. The cases that came from this initial search were shepardized, and additional cases were added as a result. Finally, when reading cases, if a case was cited that had not otherwise turned up in initial search stages, I added that case to the sample.

⁴⁹ As another example of this willingness to deviate from settled law, consider *Geier*, which was a 5-4 decision. Given that *Geier* is entirely consistent with prior law, as reflected in the vast majority of appellate court decisions, it is surprising that four justices voted against the majority’s decision.

⁵⁰ This difference is statistically significant at the ten percent level and almost significant at the more conventional five percent level. Under the hypothesis that federal and state courts are equally likely to find a claim preempted, the preemption rate should come to 55 percent in both systems (take the sum of 156 and 50, and divide by the sum of 255 and 120). The chi-squared statistic is $[(61-55)^2 + (42-55)^2]/55 = 3.73$, which, at one degree of freedom, is close to the five percent significance threshold of 3.84.

⁵¹ The chi-squared statistic is $[(74-68)^2 + (53-68)^2]/68 = 3.84$, which, at one degree of freedom, is (just) significant at the five percent level.

⁵² The chi-squared statistic is $[(74-61)^2 + (46-61)^2]/61 = 6.46$, which at one degree of freedom is statistically significant at the one percent level.

manufacturer of a specific product. A higher degree of congruence between the regulatory and court standards implies a higher rate of preemption under the framework, which is confirmed in Table 1. This is different from the case of design defects, which often vary within a product line depending on the particular brand of the product (convertible car versus sport-utility vehicle), making it less likely that the regulatory standard will be congruent with the common law standard.

There are too few manufacturing defect claims to offer a useful statistical comparison of preemption rates. Of the three manufacturing defect claims in the federal sample, two were preempted. Both of the manufacturing defect claims in the state sample were preempted. However, closer inspection reveals that even within this small sample, the outcomes are consistent with the argument of the previous part of this paper, which predicted a low preemption rate because of low congruence levels. Both of the preempted federal claims were decided on special grounds unrelated to the degree of congruence between the regulatory and common law standards.⁵³

⁵³ One claim was preempted on the basis of a broad reading of *Cippolone*; the other on the basis of a special provision for investigational devices in the MDA.

TABLE 1

	FEDERAL	STATE
TOTALS		
Total # Cases	200	99
Total # Claims	255	120
Total # Preempted	156 (61%)	50 (42%)
Total # Not Preempted	99 (39%)	70 (58%)
BY CLAIM TYPE		
FAILURE TO WARN		
Total # Claims	133	51
Preempted	99 (74%)	27 (53%)
Not Preempted	34 (26%)	24 (47%)
DESIGN DEFECT		
Total # Claims	119	67
Preempted	55 (46%)	23 (34%)
Not Preempted	64 (54%)	44 (66%)
MANUFACTURING DEFECT		
Total # Claims	3	2
Preempted	2 (67%)	0
Not Preempted	1 (33%)	2(100%)

Table 2 shows the preemption outcomes broken down by claim and by period. I divided the periods into pre-*Cipollone*, *Cipollone* to *Lohr*, and post-*Lohr*. In the failure to warn cases, both federal and state, one sees a sharp increase in the preemption rate in the *Cipollone* period, which remains high in the post-*Lohr* period as well. The preemption rate for failure to warn claims in the federal case sample jumped from 60 percent in the pre-*Cipollone* period to 87 percent in the *Cipollone* period, a statistically significant difference.⁵⁴ In the state courts, the preemption rate for failure to warn claims jumped from 12.5% to 77%. Over the *Cipollone* period many courts, following the Supreme Court's lead, found state products liability claims preempted on the basis of a legislative intent inferred from words used in federal regulatory statutes.

Table 2 suggests that *Cipollone* led to different results in the federal and state design defect cases. For design defect claims in federal courts, the preemption rate is roughly the same in the pre-*Cipollone* and *Cipollone* periods (50 percent and 47 percent respectively). In the state cases, however, the preemption rate jumps from 12.5 percent pre-*Cipollone* to 36 percent in the period between *Cipollone* and *Lohr*, which is statistically significant.⁵⁵ The fact that the preemption rate for design defect claims remained unchanged in the federal cases after *Cipollone* is inconsistent with academic commentary at the time predicting important consequences for preemption law in general. In the federal courts, *Cipollone*'s immediate impact appears to have been limited to the failure to warn cases. Of course, the sample of state design defect cases may be too small to justify any confident conclusions about the difference in *Cipollone*'s impact on state and federal courts.

Setting the sample size concern aside, what would explain *Cipollone*'s apparently different effects on federal and state design defect cases? The difference is probably attributable to the approaches to preemption taken by federal and state courts. By the time of the *Cipollone* decision, federal courts had already begun to develop a body of preemption law governing design defect cases. State courts, however, had for the most part adhered to a strong anti-preemption preference as a rule of statutory interpretation. The Supreme Court rejected the anti-preemption preference in *Cipollone*, which had a much greater impact on state than on federal courts.

An alternative explanation for *Cipollone*'s different effects on state and federal preemption rates could be based on settlement activity – or “selection effects.”⁵⁶ No doubt settlement incentives are affecting the sample preemption rates in both federal and state courts. But the selection effects story seems an unlikely explanation. To rely on selection effects, one would have to believe that trial selection incentives differ in state and federal courts, which seems implausible.

⁵⁴ This difference is statistically significant at the five percent level. The chi-squared (one degree of freedom) statistic for this difference is 5.

⁵⁵ The chi-squared statistic is $[(12.5-30)^2 + (36-30)^2]/30 = 11.41$, which, at one degree of freedom, is statistically significant at the one percent level.

⁵⁶ See George Priest & Benjamin Klein, The Selection of Disputes for Litigation, 13 J. Leg. Studies 1, 1984; Keith N. Hylton, Asymmetric Information and the Selection of Disputes for Litigation, 22 J. Leg. Studies 187 (1993).

Whatever the reason for the difference in *Cipollone*'s impact in state and federal courts, the state and federal preemption rates for design defect claims converge in the post-*Lohr* period. The preemption rate for design defect claims in federal court is 43 percent in the post-*Lohr* period, and the state preemption rate is 38 percent. This difference is not statistically significant. While this seems to suggest convergence of state and federal law on preemption of design defect claims, the figures in Table 2 are insufficient to support such a conclusion. The regression analysis below will suggest that there has been, at most, a weak convergence of state and federal preemption law on design defect claims.⁵⁷

B. Regression Analysis

1. Variables and Model

Recall that this framework points to two key factors as determinants of the likelihood of preemption: agency independence and the level of congruence between the agency's regulatory standard and the common law standard. In order to subject the model to a more rigorous test I set up a Probit model for determining the probability of preemption for a particular claim. The model uses dummy variables for the particular agency and statute to control for the agency's process (e.g., agency independence, agency expertise). The model also uses dummy variables that code for the level of congruence between the agency's standard and the common law standard.

The congruence variable distinguishes four classes or types. ***Congruence Level One*** applies to all claims for which the agency's regulatory standard fails to impose any product-specific requirements that govern the plaintiff's claim. The simplest example would be a regulation that merely classifies or identifies a product without imposing any requirement on the seller whatsoever.⁵⁸ Another example is the substantial equivalence test under the MDA, under which the FDA approves a medical device for marketing as long as it is no more dangerous or less effective than an earlier comparable device.

Congruence Level Two applies to all claims for which the agency's regulatory standard imposes only generic minimum product standards. Several regulatory statutes are understood as setting out generic minimum safety standards for products. For example, the FAA (Federal Aviation Act), FBSA (Federal Boat Safety Act), CAA (Clean Air Act), FDCA (Food Drug and Cosmetics Act) all fall in this category.

⁵⁷ The reader may ask why I have not also looked for evidence of convergence in the failure to warn claims. There is no need because there is no suggestion in Table 2 that the effects of *Cipollone* were different in the state and federal courts with respect to the failure to warn claims. *Cipollone* caused a substantial jump in preemption rates for both federal and state failure to warn claims.

⁵⁸ *Ginochio v. Surgikos, Inc.*, 864 F.Supp. 948 (N.D. Cal. 1994).

TABLE 2

	<i>1972 – Cipollone (6/24/92)</i>	<i>Cipollone – Lohr (6/26/96)</i>	<i>Lohr – 2002</i>
FAILURE TO WARN			
Federal:			
Total # Claims	47	38	48
Preempted	29 (60%)	33 (87%)	37 (77%)
Not Preempted	18 (40%)	5 (13%)	11 (23%)
State:			
Total # Claims	8	13	30
Preempted	1 (12.5%)	10 (77%)	16 (53%)
Not Preempted	7 (87.5%)	3 (23%)	14 (47%)
DESIGN DEFECT			
Federal:			
Total # Claims	42	32	45
Preempted	21 (50%)	15 (47%)	19 (42%)
Not Preempted	21 (50%)	17 (53%)	26 (58%)
State:			
Total # Claims	8	22	37
Preempted	1 (12.5%)	8 (36%)	14 (38%)
Not Preempted	7 (87.5%)	14 (64%)	23 (62%)
MANUFACTURING DEFECT			
Federal:			
Total # Claims	0	1	2
Preempted:	0	1 (100%)	1 (50%)
Not Preempted	0	0	1 (50%)
State:			
Total # Claims	1		1
Preempted	0		0
Not Preempted	1 (100%)		1 (100%)

Congruence Level Three applies to claims for which the agency’s regulatory standard imposes a menu of options. This applies to only one statute and one agency: the National Traffic and Motor Vehicle Safety Act (NTMVSA) and the Department of Transportation, respectively. In particular, Federal Motor Vehicle Safety Standard (FMVSS) 208 provided car manufacturers with the option to choose between safety belts and air bag systems. The menu-of-options standard applies to only the subset of NTMVSA cases involving FMVSS 208. There are other cases, examining other safety standards imposed under the NTMVSA, that do not involve menu-of-options style standards.

Congruence Level Four applies to claims for which the agency’s regulatory standard exhibits the greatest degree of product specificity. These are claims for which the agency’s regulatory standard comes very close to, if not being identical with, the common law standard governing the plaintiff’s claim. For example, if the plaintiff’s claim is a design defect claim and the agency’s standard requires it to examine the risk and utility features of every product design, then the claim would fall within the “congruence level four” category. Design defect claims involving Class III medical devices – devices that have been subjected to the FDA’s rigorous pre-market approval process – are generally in this category.

Table 3 provides definitions of the variables used in the regression analysis.⁵⁹ The agencies and statutes are related, as shown in the appendix Table A1.⁶⁰ Because of this, it was impossible to control for all of the agencies and all of the statutes at the same time in the regression analysis. For example, the fact that the Department of Transportation implements safety regulations under five statutes in this sample (Hazardous Materials Transportation Act (HMTA), Locomotive Inspection Act (LIA), Federal Boat Safety Act (FBSA), National Traffic and Motor Vehicle Safety Act (NTMVSA), Federal Aviation Act (FAA)) implies that it would be impossible (due to collinearity) to include in one regression dummy variables for all five statutes and the agency as well.

2. Interpretation Issues

In the probit regressions below, I have assumed that the independent or explanatory variables have an impact consistent with the theory set out in this paper on the probability that a claim is found preempted by a court. One difficulty with this approach is that we observe preemption only within the sample of litigated cases. Since the litigated cases are not a random sample of all of the disputes in which preemption is

⁵⁹ The single equation Probit regressions are based on an assumption that the variables listed in Table 3 are exogenous. This seems defensible. For example, the claim type variables (e.g., DESDEF, FAILWARN) are the clearest candidates for endogeneity. But plaintiffs are likely to assert every plausible (or nonfrivolous) theory of liability, irrespective of the associated probability of preemption.

⁶⁰ One special case shown in the table is that of Section 211 of the Clean Air Act. Although the Clean Air Act is administered by the EPA, I have linked Section 211 to Congress. The reason is that the two CAA claims in the sample involve a question of preemption under Section 211, not any particular agency rules or practices.

an issue, the estimated relationship between the likelihood of preemption and the independent variables may be biased by litigants' decisions to settle or litigate.

To see this, suppose P_p is the probability that a claim is preempted. The regression model assumes P_p is impacted by the independent variables in Table 3. Suppose P_p^{lit} is the probability that a litigated case is preempted. While the basic theory leads to predictions on the relationship between P_p and the independent variables, we observe only P_p^{lit} . If the probability of settlement is P_s , the relationship between P_p and P_p^{lit} is $P_p = (1 - P_s)P_p^{lit}$, or

$$P_p^{lit} = \frac{P_p}{(1 - P_s)}.$$

This implies that as long as the variables that are hypothesized to influence P_p also influence the settlement probability P_s , any attempt to estimate the marginal impact of one of the variables on the preemption likelihood may be biased by its impact on settlement.

The "sample selection" bias identified here is a general problem that applies to any attempt to use court decisions in a regression analysis. The general way to control for this type of bias is to use information on settled cases,⁶¹ but my sample is one of reported cases and does not contain this information. One might think that the problem could be avoided easily by not conducting an empirical investigation, but the problem is present even in analyses that simply discuss reported cases.

Given the possibility of sample selection bias, the probit regression results below must be interpreted with care. The regression estimates are reliable tests of the theory set out earlier in this paper if the marginal impacts of the independent variables in Table 3 on the settlement decision are negligible. On the other hand, one could interpret the results as measuring the effects of the independent variables within the sample of litigated cases.⁶² In this case the estimated coefficients reflect a combination of direct effects on the preemption probability and effects on settlement, which is more difficult to interpret. The discussion below adopts the former interpretation.

Again it is important to stress that the settlement bias problem cannot be avoided in a sample that relies on reported court opinions. Moreover, the problem exists whether one does an empirical analysis or a less formal discussion of the case law. Given this, the regression analysis below should be viewed as another way of discussing the case law – a way that makes greater use of the sample and allows one to make consistent comparisons within the sample.

⁶¹ See, e.g., W. Kip Viscusi, The Determinants of the Disposition of Product Liability Claims and Compensation for Bodily Injury, 15 J. Legal Stud. 321 (1986).

⁶² Even if the marginal impacts of the independent variables on settlement decisions are not trivial, the results reported below still contain useful information concerning the theory of this paper. If the results are consistent with the theory presented earlier, they suggest that offsetting or countervailing settlement-bias effects are not so large that they overwhelm the hypothesized effects of the independent variables.

C. Federal Court Sample

The first set of regression results are given in Table 4. The data are from federal cases only. The results in Table 4 include controls only for the agencies, not for the statutes. Still, the regression model viewed in its entirety performs relatively well, with an R-squared statistic of 44 percent.

The only agency variables that are statistically significant in Table 4 are those for the Coast Guard, which implements regulations under the Federal Boat Safety Act, and Congress, which is not an agency but is the body that wrote the Federal Cigarette Labeling Act and Section 211 of the Clean Air Act. The agency variables should be understood as measuring impact relative to the Environmental Protection Agency – the variable which was excluded from this regression in order to avoid collinearity. Because this regression makes no attempt to control for statute effects, the “Congress” coefficient should be understood as reflecting the impact of the Federal Cigarette Labeling and Advertising Act (FCLAA) – in other words, the two effects cannot be distinguished in this regression.

The positive and significant **COASTGUARD** effect provides some support to this paper’s claim that agency independence has played an important role in preemption analysis. To be sure, this result reflects past experience, in which the Coast Guard’s regulations under the FBSA have been given preemptive effect by the vast majority of courts. This is unlikely to remain after the *Sprietsma* decision. But the Coast Guard effect appears to have been powerful, given that all of the FBSA claims involved (and indeed were described by deciding courts as involving) only minimum safety standard regulations (congruence level two).

The core of this paper’s thesis is tested and validated by the results for the congruence level variables. Those results show that the probability of preemption increases as one moves from congruence level one (excluded from the regression) to congruence level four. Using congruence level one (no binding regulations) as the base for comparison, the regression results show that the probability of preemption increases by .55 if the congruence level is changed from one to two (minimum standards). The preemption probability increases by roughly .56 if the congruence level is changed from one to three (menu of options). The preemption probability increases by .75 if the congruence level is changed from one to four (product specific regulations).

The variable **DESDEF**, which codes for whether the plaintiff’s claim is a defective design, has a negative and statistically significant coefficient of -.268. This means that if you hold constant case and court characteristics, a defective design claim is less likely to be preempted than a failure to warn claim. This confirms one of the predictions of the error-cost framework: that regulations governing information provision to consumers are more likely to preempt state tort claims than are design regulations. The reason is that optimal information-provision standards are more likely to be generic across product type – e.g., a seat belt warning is unlikely to vary depending on the type of

car. This, in turn, implies the degree of congruence between the common law standard and the regulatory standard should be greater.⁶³

The result for the variable **MANDEF**, which codes for whether the plaintiff asserts a manufacturing defect theory, is inconsistent with the error cost model of this paper. The model predicts a negative coefficient, because it is extremely costly for an agency to design an enforceable regulatory standard governing manufacturing defects. However, Table 4 reports a positive coefficient of .28. The result is attributable to the small number of manufacturing defect claims in the sample (three). As I noted earlier, two of the claims were preempted on special grounds unrelated to the degree of congruence between the regulatory and common law standards.

The court level variable, **COURTLEV**, which distinguishes cases decided by appellate courts, shows that the probability of preemption increases by a marginally significant .14 if the deciding court is an appellate court (though this variable was insignificant in the subsequent regression reported in Table 5). The positive result for **COURTLEV** is to be expected, given that preemption is a question of law, and the primary role of appellate courts is to ensure that lower courts remain consistent with the law.

The remaining significant coefficients from the Table 4 are those for **PERIOD1**, which codes for the pre-*Cipollone* time period, and **PERIOD3**, which codes for post-*Lohr* time period. Both are negative, indicating that the probability of preemption is lower in both periods than in the *Cipollone* period. This result is consistent with the summary data reported in Table 2, which show the highest preemption rates during the *Cipollone* period. The preemption rate has fallen after the *Cipollone* period, but not to the level observed before *Cipollone*.

The key contribution of the **PERIOD** variables, above what was conveyed by the summary data in Table 2, is to show that even after controlling for case and court characteristics, the *Cipollone* decision appears to have had a big impact on preemption law. To be sure, much of the impact was short-lived, since implied preemption theory has overtaken express preemption theory as the dominant approach in the federal courts today. However, the lasting effect of *Cipollone* was to permanently reverse the presumption against preemption adopted by many courts before *Cipollone*.

The insignificant coefficient for **COMPLIED** shows that an alleged failure to comply with the agency's standard does not significantly reduce the probability that the plaintiff's claim will be preempted. This is consistent with this paper's framework.

⁶³One might argue that congruence with the common law standard is insufficient by itself to explain the significant coefficient on **DESDEF**. Since the regression already controls for degree of congruence, one might think that the coefficient for **DESDEF** should be zero. However, the congruence variables code for different levels of product specificity in regulations. A precise measure of congruence is unattainable. Information standards differ from product-design standards in the sense that product specificity may not be a necessary feature of an optimal information rule. The negative **DESDEF** coefficient (alternatively, the positive effect of a *failure-to-warn* claim classification) may be capturing the effect of cases in which the optimal information standard is generic rather than product specific.

Recall that in order to evaluate an alleged failure to comply in some defective-design cases, a court would have to replicate the agency's regulatory process. The weak impact of an allegation of failure to comply suggests that federal courts are reluctant to engage in second guessing the agency's process – which avoids errors generated by having a less-expert court review the actions of a more-expert agency. Federal courts are putting a high evidentiary burden on plaintiffs who claim that the defendant failed to comply with the agency's regulation.

Similarly, the statistically weak coefficient for **FRAUD**, which codes for cases in which the plaintiff presents a fraud-on-the-agency theory, indicates reluctance on the part of federal courts to second guess agency processes. Indeed, the positive estimate for the **FRAUD** variable suggests that courts may be more likely to preempt the plaintiff's claim when he asserts a fraud-on-the-agency theory. This is also consistent with this paper's framework. Fraud-on-the-agency claims demand a serious incursion on the part of the court into the agency's process. Courts sensitive to the error costs generated by such an approach would be reluctant to accept these demands.

Table 5 reports results from a regression that controls for statute effects.⁶⁴ In this regression, the excluded statute is FIFRA, so the results should be understood as capturing the statute's effect in comparison to FIFRA. For the variables describing claim characteristics (e.g., type of claim and congruence level), the results are largely the same as in the previous regression which controlled for agency effects.⁶⁵

The significant statute variables are those coding for the FCLAA (Federal Cigarette Labeling and Advertising Act), FBSA (Federal Boat Safety Act), FDCA (Food, Drug, and Cosmetic Act), FHSA (Federal Hazardous Substances Act), and MDA (Medical Devices Act). With the exception of the **FDCA** variable, the variables for each of these statutes entered with a positive coefficient, implying that they increase the likelihood of preemption (relative to FIFRA) after controlling for claim type and characteristics.

The positive **FCLAA** coefficient suggests that the significant "Congress" effect from the previous regression probably reflects the impact of the FCLAA. This follows from the fact that the other set of claims involving a regulatory standard set out in a federal statute, Section 211 of the Clean Air Act, were held not to preempt state law tort claims. The FCLAA is a special case of a specific product warning adopted by Congress. Courts have routinely held that the warning adopted by Congress preempts failure to warn claims against cigarette manufacturers after 1969.⁶⁶ However, courts have also held that the FCLAA does not preempt design defect claims against cigarette manufacturers.

⁶⁴ The sample did not contain enough variation to control for both statute and agency effects. Regressions that attempted to control for both came out poorly because of collinearity.

⁶⁵ The estimate for congruence level 3 is smaller than in Table 4, but this is probably due to the presence of the NTMVSA dummy. The NTMVSA dummy codes for cases that are largely congruence level 3 cases. An upper bound on the congruence level 3 effect can be estimated by taking the sum of the **CONLEV3** and **NTMVSA** effects, which is .668.

⁶⁶ *Cipollone*, 505 U.S., at 530-31. The *Cipollone* Court also held that the 1965 FCLAA did not preempt state law failure to warn claims. *Id.* at 519-20.

The positive **MDA** (medical devices statute) coefficient suggests that even after controlling for claim type and characteristics, the medical devices statute has a relatively high rate of preemption. This is due in part to the presence in the sample of cases involving the Investigational Devices Exception to the MDA. Under this exception, which governs experimental devices such as new pacemaker designs, courts have held claims preempted even though the FDA's review process falls short of the type of examination that would be carried out under a careful balancing of risk and utility. In particular, the investigation devices exemption applies to product designs that have not been put into practice.

More importantly, the negative and statistically significant **FDCA** coefficient shows that the federal courts have been unusually reluctant to defer to the FDA's process under the FDCA. The **FDCA** coefficient implies that relative to FIFRA, claims under the FDCA are less likely to be preempted by a probability differential of .42. This supports the charge in Viscusi et al (1994) that courts have adopted an unjustifiably low preemption rate with respect to drugs regulated under the FDCA. However, this problem appears to be limited to the FDA's process under the FDCA. No other statute effect in Table 5 has a negative and significant coefficient. Moreover, the FDA's process under the MDA appears to be treated with a great deal more respect by federal courts than its process under the FDCA.

The weak positive coefficient for **FDA** in Table 4 shows that FDA regulation by itself has no significant effect, either in increasing or lowering, the likelihood of preemption. The coefficient estimates in Table 5 for **MDA** and **FDCA**, however, show that the agency's process under these statutes does have a significant impact on the likelihood of preemption. Claims involving the FDCA are substantially less likely to be preempted than is the norm, while claims involving the MDA are slightly more likely to be preempted. This undercuts the claim by Viscusi et al (1994) that it would be socially desirable to have a general regulatory compliance defense for products approved by the FDA and agencies with similarly rigorous approval processes.

The **FHSA** (hazardous substances statute) effect is positive and significant. This statute is administered by the Consumer Product Safety Commission, which also administers the CPSA (product safety statute). Again, the result shows that the agency's *process* rather than the agency itself has the most important effect on preemption. The FHSA is unique in its degree of specificity. The statute governs warnings on hazardous substances. It does not regulate product design. Courts have generally held that it preempts failure to warn claims and does not preempt design claims. Faced with such specific regulations governing warnings, courts have found it easy to preempt failure-to-warn lawsuits.

Table 5A presents predicted preemption probabilities based on the regression model used for Table 5. As expected, preemption probabilities increase with the congruence level, though there are exceptions. The high predicted preemption rates in the case of **CONLEV3** reflect sample constraints: the **CONLEV3** category of regulation

is observed only in the NTMVSA cases, which have very high preemption rates. In other words, the **CONLEV3** and **NTMVSA** observations are virtually the same. However, if in light of this one focuses on the first, second, and fourth rows of Table 5A, the results show predicted preemption rates increasing substantially with each move upward in the congruence level variable.

The results in Table 5A address the calls for expansive regulatory compliance defenses in Schwartz (2000) and Viscusi et al. (1994). The high predicted preemption rates, some greater than 90 percent, beginning at **CONLEV2** and continuing to **CONLEV4**, undermine the argument for a general regulatory compliance defense. The one special case that supports Viscusi is the column of predicted preemption rates under the FDCA, which appear to be too low. Outside of this special case, predicted preemption rates vary by case type in a manner consistent with an effort on the part of courts to minimize the expected costs of erroneous decisions.

D. State Court Sample

Because the pool of preemption disputes in state courts is smaller than that in federal courts, the sample of cases from state courts is smaller than that from federal courts. This made it difficult to control for agency and statute effects and at the same time avoid collinearity. For this reason I dropped the dummy variables controlling for agencies and statutes in the state sample regressions. For the same reason, I was forced to exclude the **MANDEF** variable and its observations from the regressions.

The results of the simplest regression model for the state observations appear in Table 6. This regression makes no attempt to control for agency and statute effects. Because of this, and because of the smaller sample, the R-squared statistic, at 18 percent, is considerably lower than those reported from the federal sample. In addition to the sample differences, the lower R-squared may reflect a greater level of inherent unpredictability in the state cases.

The most glaring results in Table 6 are the positive and highly significant period variables (**PERIOD2** and **PERIOD3**). They show that the effect of *Cippolone* in the state courts was much more dramatic than in the federal courts. While *Cippolone* increased the probability of preemption by roughly .20 in the federal courts (see Table 5), it raised the probability of preemption by roughly .5 in the state courts.

The second noticeable difference between the state and federal court results is that the variable **COMPLIED**, which indicates that the plaintiff made no allegation of non-compliance by the defendant with the agency's regulations, enters with a positive and marginally significant coefficient. In other words, state courts are less likely to preempt when the plaintiff alleges that the defendant failed to comply with the federal regulatory standard. This suggests that the state courts are less deferential toward agency review processes than are the federal courts.

Although the state courts are less deferential toward agency review processes, they still behave in a manner consistent with this paper's error-cost framework. One implication of the model is that the effect of compliance on the probability of preemption should be greater in the case of failure to warn claims than among other types of claim. The reason is that it is easier to accurately assess compliance in the typical failure to warn claim than in the typical design defect claim. The model's prediction was confirmed in a later regression, not reported in the table.⁶⁷

The third and most important difference between the state and federal sample is the weak result for congruence level four (**CONLEV4**). State courts appear to be no more likely to find such claims preempted than they are for claims with the lowest congruence level, which is a disturbing result if valid.

In order to examine more closely how the state courts have treated cases of the highest congruence level, I ran a second regression including interaction terms for **CONLEV4** and the period variables. The results are reported in Table 7. They reveal that the **CONLEV4** effect has declined over the three periods within the state sample. **CONLEV4** has a greater positive impact on the likelihood of preemption than **CONLEV2** in the first period (pre-*Cippolone*). The two effects are roughly the same in the second period (after *Cippolone* and before *Lohr*), and the **CONLEV4** effect diminishes in the third period (post-*Lohr*).

The declining effect of the highest congruence level is the result of two evolutionary processes in the state courts. One, already discussed, is the effect of *Cippolone*, which made state courts more likely to preempt cases of the second and third congruence levels. This process probably explains the rough equality between the effects of congruence level two and congruence level four in the second period. The second evolutionary process is the result of *Lohr*. The weak estimated effect, in the post-*Lohr* period, of the highest congruence level variable shows how state courts have responded to *Lohr*. A substantial percentage of the state courts in this sample, unlike the federal courts, read *Lohr* as imposing an exceptionally high burden on defendants who claim that federal regulation should have a preemptive effect.⁶⁸

⁶⁷ In a separate regression I included interaction terms for **COMPLIED**, **FAILWARN**, and **DESDEF**. They provided weak support for the model's implication that the effect of compliance on the probability of preemption should be stronger in the case of failure to warn claims. (The reason is that since the risk of error should be lower in failure to warn cases, courts should be less concerned about the potential costs of denying the preemption defense.) The coefficient for the interaction of **COMPLIED** and **FAILWARN** was 2.99 (t-statistic 1.35). The coefficient for the interaction of **COMPLIED** and **DESDEF** was .152 (t-statistic .58). A similar pattern was observed in the federal sample. In a regression similar to that in Table 5, but including interaction terms, the coefficient for the interaction of **COMPLIED** and **FAILWARN** was -.158 (t-statistic -.94) and that for **COMPLIED** and **DESDEF** was -.346 (t-statistic -1.47). Of course, one reason why these results are so weak is that the plaintiffs' assertions of noncompliance may be unsupported by any evidence in most cases. As I noted earlier, any clear case of noncompliance would have settled out of court, so all of the cases in which **COMPLIED** = 0 involve contested assertions of noncompliance.

⁶⁸ Many state courts in the sample appear to have adopted the approach of the Eleventh Circuit in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999). In particular, the following twelve states in the state court sample have at least one post-*Lohr* decision rejecting preemption in a case involving the highest congruence level (**CONLEV4**): Michigan (state appeals court), Missouri (Supreme Court), Illinois

The results of the empirical analysis of the state cases must be interpreted with care, given the relatively small sample, and the consequent failure to control for agency and statute effects. Because of these weaknesses, the state sample results do not shed light on the importance of the perception of agency independence, or of respect for the rigor of the review process required by the regulatory statute.

With these shortfalls in mind, one lesson suggested by the sample of state cases is that state courts do not seem to be as sensitive to error cost concerns as the federal courts. They are quicker to second-guess the agency's process by refusing to preempt claims even when the agency has adopted a rigorous process, and when the plaintiff alleges that the defendant failed to comply with the agency's regulations. These findings should not be taken as a rejection of the error cost model, which is largely confirmed by the federal court sample. However, they do show that the model simply does not fit as well to the sample of state court decisions.

The state sample results may reflect the redistributive bias found in Tabarrok and Helland (1999).⁶⁹ Tabarrok and Helland found that state courts give higher awards when the defendant is an out-of-state corporation, and that this redistributive tendency is enhanced in states with elected judiciaries. Most of the products liability cases in the state sample probably involve out-of-state corporate defendants. The greater reluctance in the states to preempt claims that have undergone the most rigorous agency review processes, as well as those in which the plaintiff alleges noncompliance with agency standards, may reflect redistributive incentives.

V. Conclusion

The literature and much of the case law on preemption continue to focus on legislative intent as the primary theory of the preemption decisions. Intent, as a theory, is proposed sometimes in the positive sense, as a theory that explains the actual case outcomes, and sometimes in the normative sense, in the belief that a requirement of clear legislative intent as a necessary condition for preemption would force Congress to state its own preferences clearly. This paper has rejected the intent-based approach, as both futile and unnecessary. The preemption case law can be explained by objective factors.

Admittedly, legislative intent must play some role in preemption analysis. If Congress preempted state tort lawsuits in absolutely unambiguous language, that would presumably settle the matter. However, the preemption provisions in federal statutes are almost never stated in unambiguous language. The statutory language almost always

(Supreme Court), California (appeals court), New York (appeals court), Oregon (appeals court), Kentucky (Supreme Court), Washington (appeals court), Texas (appeals court), Montana (Supreme Court), Indiana (Supreme Court), Wisconsin (appeals court). Although not reported in the regression tables, I also ran a regression similar to that in Table 7 on the federal sample. Unlike the results for the state sample, the effect of **CONLEV4** does not decline over time in the federal sample.

⁶⁹ Alexander Tabarrok and Eric Helland, *Court Politics: The Political Economy of Tort Awards*, 42 *J. Law & Econ.* 157 (April 1999).

leaves courts with several degrees of freedom on the preemption question. In view of this, some theory other than legislative intent is necessary to explain the actual case outcomes – or to provide a normative theory of preemption.

This paper has offered an alternative to the intent-based theory of preemption. The theory offered here envisions the preemption question as if it were a choice between two decision processes, federal agencies and trial courts, both subject to error. The optimal preemption rule minimizes the costs of erroneous decisions to commit to the agency process. I have argued that this approach favors preemption when there is a high degree of congruence between the regulatory and common law standards. The case law appears to be consistent with this theory.

TABLE 3

VARIABLE DEFINITIONS

Variables	Definition
Dependent Variable: PREEMPT	Dummy variable equaling one if claim is preempted, zero otherwise
Independent Variables: CONLEV1	Dummy variable equaling one if claim is of congruence level one (no specific requirement)
CONLEV2	Dummy variable equaling one if claim is of congruence level two (generic minimum standard)
CONLEV3	Dummy variable equaling one if claim is of congruence level three (menu of options standard)
CONLEV4	Dummy variable equaling one if claim is of congruence level four (highly specific regulations)
DESDEF	Dummy variable equaling one if claim asserts defective design theory
FAILWARN	Dummy variable equaling one if claim asserts failure to warn theory
MANDEF	Dummy variable equaling one if claim asserts manufacturing defect theory
COURTLEV	Dummy variable equaling one if deciding court is an appellate court, zero if trial court
COMPLIED	Dummy variable equaling one if defendant complied with regulation, zero if allegation of noncompliance
FRAUD	Dummy variable equaling one if plaintiff asserts fraud on agency theory
PERIOD1 (PERIOD2, PERIOD3)	Dummy variables coding for period of claim (pre- <i>Cipollone</i> = period 1, post- <i>Cipollone</i> to <i>Lohr</i> = period 2, post- <i>Lohr</i> = period 3)

TABLE 4
Federal Court Sample Regression Results with Agency Effects

Variable	Marginal Effect	Standard Error	T Stat	Significance level
COURTLEV*	.143	.082	1.74	.083
DESDEF**	-.268	.108	-2.48	.013
MANDEF**	.285	.123	2.31	.021
CONLEV2**	.552	.099	5.58	.000
CONLEV3**	.559	.062	9.06	.000
CONLEV4**	.754	.094	8.01	.000
PERIOD1**	-.396	.113	-3.48	.000
PERIOD3*	-.237	.121	-1.96	.050
COMPLIED	-.118	.105	-1.12	.263
FRAUD	.132	.199	.66	.508
FDA	.045	.108	.42	.673
CPSC	.033	.198	.17	.867
DOT	.148	.169	.87	.382
CONGRESS**	.352	.077	4.60	.000
COAST-GUARD**	.347	.060	5.80	.000

Probit using **PREEMPT** (claim preempted =1, not preempted = 0) as dependent variable, on federal sample and controlling for agency effects.

Number of observations = 243

Pseudo R2 = 0.43

Log Likelihood = -89.48

** statistically significant at the five percent level

* statistically significant at the ten percent level

Note: Observations associated with dummies for FAA and HUD agencies were dropped because of missing observations or lack variation in the sample.

TABLE 5
Federal Court Sample Regression Results with Statute Effects

Variable	Marginal Effect	Standard Error	T Stat	Significance level
COURTLEV	.102	.089	1.14	.254
DESDEF**	-.271	.124	-2.19	.029
MANDEF	.265	.118	2.25	.025
CONLEV2**	.553	.092	6.00	.000
CONLEV3**	.549	.064	8.50	.000
CONLEV4**	.760	.096	7.90	.000
PERIOD2**	.282	.087	3.26	.001
PERIOD3*	.141	.095	1.49	.137
COMPLIED	-.156	.107	-1.45	.148
FRAUD	.119	.206	.57	.566
MDA	.181	.102	1.78	.075
FHSA**	.309	.070	4.45	.000
NTMVSA	.119	.198	.60	.549
FBSA**	.332	.058	5.67	.000
CPSA	-.106	.290	-.37	.714
FDCA**	-.419	.188	-2.22	.026
FCLAA**	.379	.062	6.08	.000

Probit using **PREEMPT** (claim preempted =1, not preempted = 0) as dependent variable, on federal sample and controlling for statute effects.

Number of observations = 237

Pseudo R2 = 0.52

Log Likelihood = -73.39

** statistically significant at the five percent level

* statistically significant at the ten percent level

Note: Observations associated with dummies for FAA, LIA, NMHCSSA, HMTA, and CAA statutes were dropped because of missing observations or lack of variation in the sample.

TABLE 5A
 Predicted Preemption Rates by Congruence Level and Agency

	<i>MDA</i>	<i>FHSA</i>	<i>NTMVSA</i>	<i>FBSA</i>	<i>CPSA</i>	<i>FDCA</i>	<i>FIFRA</i>	<i>FCLAA</i>
CONLEV1	.010	.142	.006*	.151	.001	.000	.002*	.200*
CONLEV2	.532*	.909	.451*	.915*	.221	.056	.315	.941
CONLEV3	.985	.999	.975*	.999	.907	.694	.946	.999
CONLEV4	.749*	.973	.680	.975	.430	.160	.544	.984

Notes: “*” denotes the “in sample” predicted values. The predicted values assume DESDEF=1, MANDEF=0, COMPLIED=1, COURTLEV=1, PERIOD3=1, PERIOD2=0, FRAUD=0.

TABLE 6
 State Court Sample Regression Results

Variable	Marginal Effect	Standard Error	T Stat	Significance level
COURTLEV	-.124	.203	-.61	.541
DESDEF**	-.403	.123	-3.28	.001
CONLEV2*	.408	.224	1.82	.069
CONLEV3**	.556	.177	3.14	.002
CONLEV4	.165	.247	.67	.503
PERIOD2**	.545	.154	3.53	.000
PERIOD3**	.501	.139	3.61	.000
COMPLIED*	.216	.131	1.64	.100
FRAUD	.020	.412	.05	.960

Probit using **PREEMPT** (claim preempted =1, not preempted = 0) as dependent variable, on state sample.

Number of observations = 118

Pseudo R2 = 0.18

Log Likelihood = -66.37

** statistically significant at the five percent level

* statistically significant at the ten percent level

TABLE 7
State Court Sample Regression Results with Period Interactions

Variable	Marginal Effect	Standard Error	T Stat	Significance level
COURTLEV	-.075	.201	-.37	.708
DESDEF**	-.410	.126	-3.25	.001
CONLEV2*	.454	.221	2.05	.040
CONLEV3**	.630	.156	4.03	.000
(CONLEV4) x (PERIOD1)**	.554	.196	2.82	.005
(CONLEV4) x (PERIOD2)*	.445	.263	1.69	.091
(CONLEV4) x (PERIOD3)	.050	.265	.19	.851
PERIOD2**	.570	.195	2.93	.003
PERIOD3**	.658	.137	4.80	.000
COMPLIED*	.222	.131	1.71	.088
FRAUD	.014	.429	.03	.973

Probit using **PREEMPT** (claim preempted =1, not preempted = 0) as dependent variable, on state sample, and interacting congruence level four with period variables.

Number of observations = 118

Pseudo R2 = 0.20

Log Likelihood = -64.04

** statistically significant at the five percent level

* statistically significant at the ten percent level

Appendix
TABLE A1
Federal Agencies and Statutes

FDA Food and Drug Administration	}	MDA (Medical Devices Amendment) FDCA (Food, Drug and Cosmetics Act)
Congress	}	FCLAA (Federal Cigarette Labeling and Advertising Act) CAA, §211 (Clean Air Act)
HUD (Housing and Urban Development)	}	NMHCSSA (National Manufactured Home Construction and Safety Standards Act)
DOT (Department of Transportation)	}	HMTA (Hazardous Materials Transportation Act) LIA (Locomotive Inspection Act) (Fed. Railroad Admin.) FBSA (Federal Boat Safety Act) (Coast Guard) NTMVSA (National Traffic and Motor Vehicle Safety Act) FAA (Federal Aviation Act) (Fed. Aviation Admin.)
CPSC (Consumer Product Safety Commission)	}	CPSA (Consumer Product Safety Act) FHSA (Federal Hazardous Substances Act)
EPA (Environmental Protection Act)	}	FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) CAA

TABLE A2

Preemption Rates by Agency and by Statute (federal sample)

<i>Agency</i>	<i>Design Defect Claims</i>	<i>Failure to Warn Claims</i>
FDA	39%	64%
EPA	0	78
CPSC	20	71
FAA	0	0*
<i>Statute</i>		
MDA	46	80
FCLAA	0*	100
FDCA	20	11
FBSA	91	100
NTMVSA	67	83
FHSA	0*	100*
FIFRA	0	77

* based on 4 or fewer cases.