

*VERY PRELIMINARY AND INCOMPLETE*

## **PREEMPTION AND PRODUCTS LIABILITY: A POSITIVE THEORY**

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## Introduction

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 case law on products liability preemption is replete with 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 quickly disabused of this notion. The preemption provisions in the statutes are often 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 *Cipolone v. Liggett Group, Inc.*<sup>1</sup> 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 case law is largely consistent with an approach that seeks minimize the costs of erroneous decisions to preempt tort lawsuits. In particular, two factors explain a many of the outcomes of the preemption cases: agency independence and the degree of congruence between the regulatory and common law standards.

## Law and Literature: An Overview

Preemption of products liability claims is still a young and rapidly developing area of the law, which should not surprise anyone given that products liability itself began 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*, decided in 1988.<sup>2</sup>

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

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<sup>1</sup> 505 U.S. 504 (1992).

<sup>2</sup> Another early substantial treatment appears in Abner Mikva's opinion in *Ferebee* 1988, a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) case.

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 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 *Cippolone*, which dramatically altered the doctrine.<sup>3</sup> In *Cippolone*, 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:

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.<sup>4</sup>

The Supreme Court concluded that this provision "sweeps broadly,"<sup>5</sup> preempting both state statutory and common law rules.

*Cippolone* turned preemption doctrine on its head, though only for a brief period. Before 1992 (the date of *Cippolone*) courts largely talked 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. After 1992, courts following the lead of *Cippolone* began finding evidence of legislative intent to preempt in language that was considered to "sweep broadly," like the language of the statute in *Cippolone*. For example, in *King v. E.I. Dupont De Nemours & Co.*, 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 *Cippolone*. Some scholars argued that express preemption had become the dominant mode of analysis, and implied preemption theories had been abandoned.<sup>6</sup>

The *Cippolone* period came to an end in 1996 with the Supreme Court's decision in *Medtronic, Inc. v. Lohr*. In *Lohr*, the Court stared at a preemption provision that looked very much like the one in *Cippolone* 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

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<sup>3</sup> Indeed, before *Cippolone*, the trend ran largely against finding preemption. Many courts held that federal regulatory statutes provided only minimum standards, which could (and should) be supplemented by state tort standards.

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

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 – 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.

Although the preemption provision of *Lohr* was virtually identical to that of *Cippolone*, 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 *Cippolone*. However, the one distinction on 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.*, the Eleventh Circuit, confronting a preemption provision that looked similar to that in *Cippolone*, concluded that it preempted the plaintiff’s negligence and defective design claims. 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 has entered an advanced stage of implied preemption analysis with its recent decisions in *Geier* and *Sprietsma*. In this new stage, the Court is starting to apply 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 care 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.

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 optimal in areas in which the federal regulatory scheme provides optimal or excessive deterrence.<sup>7</sup> He offers the drug approval process under the Federal Drug and Cosmetic Act as a case study of an area in which a regulatory compliance defense would be socially desirable. Schwartz (2000) 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.

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.

### Theory of Preemption Doctrine

The theoretical issues in preemption analysis are old and were largely dealt with in Holmes's discussion of the jury in *The Common Law*.<sup>8</sup> 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 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.

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<sup>7</sup> W. Kip Viscusi, Steven R. Rowland, Howard L. Dorfman, Charles J. Walsh, The Effect of Products Liability Litigation on Innovation: Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense, 24 Seton Hall L. Rev. 1437 (1994).

<sup>8</sup> 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. (2000).

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.<sup>9</sup> To simplify the analysis, I will assume that the risk-utility test is the optimal standard, as well as the common law standard.<sup>10</sup> Should courts determine the appropriate risk-utility trade off in every individual case, or should an agency determine the risk-utility standard once?

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 administrative costs under the two regimes (courts versus agency) are relatively 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 determinations of the risk-utility standard rather than one. Thus, a narrow focus on administrative costs favors the agency regime.<sup>11</sup>

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 probabilities 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. 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. Third, “*political distortion*” is a factor that suggests that errors are less likely under the court regime, where the risk of such distortion is high.

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

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<sup>9</sup> E.g., Volkswagen v. Young.

<sup>10</sup> 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 Landes and Posner, Product Liability article, J Leg. Stud.

<sup>11</sup> Richard C. Ausness, The Case for a “Strong” Regulatory Compliance Defense, 55 Md. L. Rev. 1210 (1996).

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.

The three factors identified here suggest no clear 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.

Consider two examples to flesh out this argument. Federal Motor Vehicle Safety Standard 208 gives 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.

For the 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."<sup>12</sup> 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. 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 (and perhaps not at

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<sup>12</sup> See, e.g., Prosser.

all). 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 likely to be 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 court. It follows, then, that preemption should be infrequent and generally limited to those cases in which government agents 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.

As the case law makes clear, there are different degrees of agency independence. The highest degree of independence is observed when the agency's staffing, methodology, and data are immune from industry influence. This is unlikely to be observed in any agency. Perhaps the closest to this ideal is the Food and Drug Administration, which is independent with respect to methodology and staff,<sup>13</sup> 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.<sup>14</sup> Under this paper's framework, preemption should be more probable as the agency's independence increases – though independence is not necessarily the deciding factor.

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, under this framework, 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 design aspect of every car, 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.

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<sup>14</sup> See *Wilson v. Bradlees of New England, Inc.*, 1<sup>st</sup> Cir.

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 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.

#### 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* and in *Sprietsma*. 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. Several courts – probably the majority – have found that the MDA preempts such claims.<sup>15</sup>

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<sup>15</sup> The Seventh Circuit found that the MDA preempted such a claim in *Mitchell v. Collagen Corp.* The Eighth Circuit in *Martello* (1994). The Fifth Circuit in *Martin v. Medtronic*, 254 F. 3d 573 (2001); Sixth

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 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 is 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 have a destabilizing rather than clarifying effect on tort preemption doctrine. Still, the outcome, a finding 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 strong check on the degree to which agency officials will work on behalf of the industry.<sup>16</sup> 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.

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Circuit accepted this reasoning in *Kemp*. The only federal appellate court to explicitly reject this argument is the Eleventh Circuit in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (1999).

<sup>16</sup> Consider the fact that two of the former department heads, William Coleman and Elizabeth Dole, are famous political figures who would lose an enormous investment 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. One could argue that the Coast Guard's decision in *Sprietsma* is indistinguishable from that of the Department of Transportation in *Geier*. In *Sprietsma*, the Coast Guard decided that the risk-utility factors did not imply that a uniform propeller requirement would be desirable. In *Geier*, the Department of Transportation decided that the risk-utility factors did not imply that a uniform airbag requirement would be desirable. 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. A careful look suggests that they are not in conflict, and 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 safety belt system – i.e., all other cars? There is nothing in the facts of *Geier* to suggest anything special about the plaintiff's car that would have made an airbag more productive, in terms of minimizing accident losses, in *Geier*'s car than in any other car. The same point should have been apparent to the Department of Transportation. Indeed, the Department's motivation for adopting Federal Motor Vehicle Safety Standard 208 was to establish *uniform safety requirements* based on an analysis of risk-utility factors.

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 in

this case if a finding that one particular boat design is defective because it does not include a propeller guard does not imply that all boat designs are defective.<sup>17</sup>

In terms of the framework presented earlier, the different conclusions in *Geier* and *Spreitsma* can be reconciled on the basis of the similarity between the regulatory standard and the common law standard. Because there were no special design-specific features that would have made an airbag appropriate for only one, or a subset, of car designs, the regulatory standard in *Geier* was a uniform product standard that applied to every product 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 in this instance.

*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.

The federal appellate decision that most 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 vast majority of federal court preemption decisions are consistent with the analysis in *Wilson* and this paper's framework,<sup>18</sup> 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 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 of product defect," the Restatement notes in its comment to that provision (?) that a regulatory compliance defense may be applicable when the regulation "was promulgated

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<sup>17</sup> In other words, *Spreitsma* 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).

<sup>18</sup> See empirical section. *Wilson* in first. Other circuits have issued decisions that fit this framework. Lewis I have talked about already. *Martin* and *Papike* should be mentioned quickly to point out spread of approach to other circuits. *Lewis* in 11<sup>th</sup>. *Martin* in 6<sup>th</sup>. *Papike* in 9<sup>th</sup> (check).

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.” The Restatement Third would have come closer to describing what courts are actually doing if it had inserted the language from this comment into provision 4(b).

### 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 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.<sup>19</sup> 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 substantial<sup>20</sup> – 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.<sup>21</sup>

In view of the FDA’s charge under the MDA – to protect the public health by assuring that medical devices are safe and effective<sup>22</sup> – 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 perhaps in other instances as well. In addition, there are no special 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,

<sup>19</sup> See, e.g. *Stamps v. Collagen Corp.*, 984 F.2d 1416 (1993), at 1419.

<sup>20</sup> *Id.* at 418.

<sup>21</sup> *Id.* at 1421.

<sup>22</sup> See, e.g., *Stewart v. International Playtex*, 672 F.Supp. 907, 909 (D. S. Carolina 1987). (more)

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. (Refer to tables with preemption rates here) The interesting question is why some claims are not preempted.

The two types of cases in which failure to warn claims are not preempted even though the federal regulatory standard is congruent with the common law standard are those in which (1) the regulatory standard imposes no discernible warning requirement on the seller,<sup>23</sup> and (2) the seller fails to comply with the regulatory standard.<sup>24</sup> In the first case, a decision against preemption makes sense from an error minimization perspective. There is no possibility in this case of displacing a more accurate agency-determined standard with a less accurate court-determined standard. Further, finding preemption in the first case would encourage firms to seek regulation for no other reason than to defeat tort claims. In the second case, where 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,<sup>25</sup> 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.

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<sup>23</sup> See, e.g., Truxillo, MDA case.

<sup>24</sup> See Bank of Commerce 1994 case.

<sup>25</sup> See Osburn case, 1987.

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 fact, the rate of preemption under the FDCA is low. However, this can only be taken as weak confirmation of the framework. Many of the FDCA cases appear to be decided on the basis of precedent without much discussion of the underlying purpose of preemption doctrine. The rate of preemption is probably too low, given that there are cases in which the FDA's process under the FDCA is indistinguishable from its process under the MDA.

#### 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 reason for denying preemption in failure to warn cases, the more general effect of a failure to comply with the regulatory standard is mixed. A substantial number of products liability claims, particularly design defect 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 always lead to a denial of preemption, and why the claim would be more successful in failure to warn than in design defect cases. 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. 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.

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, in effect, subject the agency to second-guessing in court. The result would be that every plaintiff would claim that the defendant breached the regulatory standard, and there would be no preemption. Of course, it is a different case if the agency has determined that the plaintiff failed to comply with its standard.

This explains why preemption defenses are often rejected in failure to warn cases in which the plaintiff claims that the defendant failed to comply with the regulatory standard, while they are not as frequently rejected in design defect cases. 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.

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 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 will assert in every case that the defendant supplied false information which led to a biased standard. If courts had to determine the validity of the plaintiff’s assertion in each case, there would be nothing 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*. 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 the preemption rule. 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 protecting federal agency's 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.

### Empirical Analysis

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 the present. The table reports the number of 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 does not include both the trial and appellate outcomes for the same case. Where both trial and appellate court opinions were available, I included only the appellate decision (or, in the case of state courts, the highest appellate decision) in the sample.

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 *Cippolone* experience illustrates, the Court has shown a willingness in the preemption area to strike off in a new direction, radically changing settled doctrine.<sup>26</sup> 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.

One other set of cases that could have been excluded but were not are the remanded versions of earlier federal cases. In other words, the federal cases described in Table 1 "double count" some cases by including the result from the first appellate court decision and the result from a second decision that was issued because the case was remanded to the appellate court for reconsideration. The total number of such cases in the sample is

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<sup>26</sup> 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, it is surprising that four justices voted against the majority's decision.

six. The reason for including both the first and the second versions of these cases, rather than only the first or only the second, is that the two different versions provide an accurate representation of change in the doctrine.

Table 1 shows that for design defect and failure to warn claims, federal courts are considerably more likely to find preemption than are state courts. Of the total claims, federal courts found 58 percent preempted while state courts found 41 percent preempted. This difference is statistically significant at the five percent level.<sup>27</sup> For failure to warn claims, federal court preemption rate is 76 percent, while the state court preemption rate is 55 percent, which is statistically significant at the one percent level.<sup>28</sup> For design defect claims, the federal court and state court preemption rates are 47 and 32 respectively. This difference is significant at the ten percent but not at the more conventional five percent level.

Table 1 also shows that the preemption rate for failure to warn claims is substantially larger than that for design defect and manufacturing defect claims. For example, the overall preemption rate in the sample for failure to warn claims in federal court is 76 percent, while that for design defect claims in federal court is 47 percent, a statistically significant difference.<sup>29</sup>

The high preemption rate for failure to warn cases confirms one prediction of the “error cost” framework set out in the previous section of 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 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.

Consistent with the argument of the previous part of this paper, Table 1 shows that the frequency with which claims are found preempted is substantially lower in the manufacturing defect claim category than in the design defect and failure to warn categories. The percentage of manufacturing defect claims found preempted is zero in both the federal and state cases. Manufacturing defect claims are defined as instances in

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<sup>27</sup> 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 160 and 48, and divide by the sum of 262 and 116). The chi-squared statistic is  $[(61-55)^2 + (41-55)^2]/55 = 4.22$ , which, at one degree of freedom, is significant at the five percent level.

<sup>28</sup> The chi-squared statistic is  $[(72-70)^2 + (28-70)^2]/70 = 25.26$ , which, at one degree of freedom, is significant at the one percent level.

<sup>29</sup> The chi-squared statistic is  $[(76-62)^2 + (47-62)^2]/62 = 6.79$ , which, at one degree of freedom, is statistically significant at the one percent level.

which the plaintiff claims that the manufacturer's product deviates from its own specifications, and courts rejected preemption claims in every one of these cases in the sample.

TABLE 1

	FEDERAL	STATE
<b>TOTALS</b>		
Total # Cases	206	96
Total # Claims	262	116
Total # Preempted	160 (61%)	48 (41%)
Total # Not Preempted	102 (39%)	68 (59%)
<b>BY CLAIM TYPE</b>		
<b>FAILURE TO WARN</b>		
Total # Claims	137	51
Preempted	104 (76%)	28 (55%)
Not Preempted	33 (24%)	23 (45%)
<b>DESIGN DEFECT</b>		
Total # Claims	122	62
Preempted	57 (47%)	20 (32%)
Not Preempted	65 (53%)	42 (68%)
<b>MANUFACTURING DEFECT</b>		
Total # Claims	2	3
Preempted	0	0
Not Preempted	2 (100%)	3(100%)

Table 2 shows the preemption outcomes broken down by claim and by period. I divided the periods into pre-*Cippolone*, *Cippolone* 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 *Cippolone* 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 62 percent in the pre-*Cippolone* period to 87.5 percent in the *Cippolone* period, a statistically significant difference.<sup>30</sup> Over the *Cippolone* 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 *Cippolone* 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-*Cippolone* and *Cippolone* periods (49 percent and 50 percent respectively). In the state cases, however, the preemption rate jumps from 12.5 percent pre-*Cippolone* to 37 percent in the period between *Cippolone* and *Lohr*, which is statistically significant.<sup>31</sup> The fact that the preemption rate for design defect claims remained unchanged in the federal cases after *Cippolone* is inconsistent with academic commentary at the time predicting important consequences for preemption law in general. In the federal courts, *Cippolone*'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 *Cippolone*'s impact on state and federal courts.

Setting the sample size concern aside, what would explain *Cippolone*'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 *Cippolone* 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 *Cippolone*, which had a much greater impact on state than on federal courts.

An alternative explanation for *Cippolone*'s different effects on state and federal preemption rates could be based on settlement activity – or “selection effects.” 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.

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<sup>30</sup> This difference is statistically significant at the one percent level. The chi-squared (one degree of freedom) statistic for this difference is 29.6.

<sup>31</sup> The chi-squared statistic is  $[(12.5-30)^2 + (37-30)^2]/30 = 11.84$ , which, at one degree of freedom, is statistically significant at the one percent level.

Whatever the reason for the difference in *Cippolone*'s impact in state and federal courts, the state and federal preemption rates for design defect claims appear to 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 37 percent. This difference is not statistically significant, suggesting convergence of state and federal preemption law on design defect claims.<sup>32</sup>

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 (see Ginochio (Cal. 1994)). 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.

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<sup>32</sup> Should I also look for evidence of convergence in the failure to warn claims? There is no need because there is no suggestion in the table that the effects of *Cippolone* were different in the state and federal courts with respect to the failure to warn claims. *Cippolone* caused a substantial jump in preemption rates for all failure to warn claims, both state and federal. Perhaps I should put a footnote in to this effect.

TABLE 2

	<b>1972 – Cipollone (6/24/92)</b>	<b>Cipollone – Lohr (6/26/96)</b>	<b>Lohr – Present</b>
<b>FAILURE TO WARN</b>			
Federal:			
Total # Claims	47	40	50
Preempted	29 (62%)	35 (87.5%)	40 (80%)
Not Preempted	18 (38%)	5 (12.5%)	10 (20%)
State:			
Total # Claims	8	13	30
Preempted	1 (12.5%)	10 (77%)	17 (57%)
Not Preempted	7 (87.5%)	3 (23%)	13 (43%)
<b>DESIGN DEFECT</b>			
Federal:			
Total # Claims	41	34	47
Preempted	20 (49%)	17 (50%)	20 (43%)
Not Preempted	21 (51%)	17 (50%)	27 (57%)
State:			
Total # Claims	8	19	35
Preempted	1 (12.5%)	7 (37%)	13 (37%)
Not Preempted	7 (87.5%)	12 (63%)	22 (63%)
<b>MANUFACTURING DEFECT</b>			
Federal:			
Total # Claims	0	1	1
Preempted:	0	0	0
Not Preempted	0	1 (100%)	1 (100%)
State:			
Total # Claims	1		2
Preempted	0		0
Not Preempted	1 (100%)		2 (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 provides 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. The names of the variables representing the various statutes and agencies are summarized in the appendix (see table AX). The agencies and statutes are related, as shown in the appendix Table AX.<sup>33</sup> 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.

#### Federal Court Sample

The first set of regression results are given in Table 4. The data are from federal cases only. The results include controls only for the agencies, not for the statutes. The only agency variables that are statistically significant in this regression 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 implements the Federal Cigarette Labeling Act and the Clean Air Act. The agency variables should be understood as measuring impact relative to the Environmental Protection Agency – the variable for 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

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<sup>33</sup> 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.

understood as reflecting the impact of the Federal Cigarette Labeling Act – in other words, the two effects cannot be distinguished in this regression.

The positive and significant **COASTGUARD** coefficient 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 going to change in the future as a result of 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 .52 if the congruence level is changed from one to two (minimum standards). The preemption probability increases by .54 if the congruence level is changed from one to three (menu of options). The preemption probability increases by .7 if the congruence level is changed from one to four (product specific regulations).

The variable **DEFDES**, which codes for whether the plaintiff's claim is a defective design or failure-to-warn claim, has a negative and statistically significant coefficient of -.31. 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 other types of 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.

One might argue that congruence with the common law standard is insufficient by itself to explain the result for **DEFDES**. Since the regression already controls for degree of congruence, one might think that the coefficient for **DEFDES** should be zero. However, the congruence variables code for different levels of product specificity. Information standards differ from product-design standards in the sense that product specificity may not be a necessary feature of an optimal information rule. This implies that even if optimal information standards should be product specific in some cases, there will be others in which they are not. The model in this paper suggests that the negative **DEFDES** coefficient (alternatively, the positive effect of a *failure-to-warn* claim classification) is capturing the effect of residual cases in which the optimal information standard is generic rather than product specific.

The court level variable (**COURTLEV**), which distinguishes cases decided by appellate courts, shows that the probability of preemption increases by .15 if the deciding court is an appellate court. This 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. In their role as guardians of the law, federal appellate courts will not only seek to ensure consistency in the case law. They will also seek to anticipate the Supreme Court's view of the cases that come before them. Appellate courts have stronger reputational incentives to do this than do the trial courts, since failure leads to public reversals by the Supreme Court.

The remaining significant coefficients from the Table 4 are those for **PERIOD1**, which codes for the pre-*Cippolone* 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 **PERIOD2**, which is the *Cippolone* period. This result is consistent with the summary data reported in Table 2, which show the highest preemption rates during the *Cippolone* period. The preemption rate has fallen after the *Cippolone* period, but not to the level observed before *Cippolone*.

The key contribution of the **PERIOD** variables, above what was conveyed by the summary data in Table 3, is to show that even after controlling for case and court characteristics, the *Cippolone* decision appears to have had a very 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. However, the lasting effect of *Cippolone* was to permanently reverse the “presumption against preemption” adopted by many courts before *Cippolone*.

The insignificant coefficient for **COMPLIED** shows that compliance with the agency's standard does not significantly improve the probability of preemption, and conversely an alleged failure to comply does not significantly reduce the probability of preemption. The latter claim is more significant, and is consistent with this paper's framework. 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 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. Given this, courts are putting a high evidentiary burden on plaintiffs who claim that the defendant failed to comply with the agency's regulation.

Similarly, the 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 courts to second guess agency processes. Indeed, the positive coefficient for **FRAUD** suggests that courts may be *more likely* to preempt the plaintiff's claim when he asserts a fraud-on-the-agency theory. Why would this be? Since fraud-on-the-agency claims demand a serious incursion on the part of the court into the agency's process, courts may feel a need to send a clear signal that they will not be used for this purpose.

Table 5 reports results from a regression that controls for statute effects.<sup>34</sup> 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.

The significant statute variables are those coding for the MDA (Medical Devices Amendment), FCLAA (Federal Cigarette Labeling and Advertising Act), FBSA (Federal Boat Safety Act), and FHSA (Federal Hazardous Substances Act). Each of these variables entered with a statistically-significant, positive coefficient, implying that they increase the likelihood of preemption after controlling for claim type and characteristics.

The positive **FCLAA** coefficient shows 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 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.<sup>35</sup> However, courts have also held that the FCLAA does not preempt design defect claims against cigarette manufacturers.

The positive **MDA** (medical devices statute) coefficient shows that even after controlling for claim type and characteristics (e.g., congruence level), the medical devices statute has a relatively high rate of preemption. This is due in large 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.

The **MDA** effect shows that although the FDA regulation by itself does not raise the likelihood of preemption (see Table 4 results), certain parts of the agency's process generate high preemption rates. While the FDA's preemption rate with respect to the FDCA is low, its preemption rate with respect to the MDA is high.

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

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<sup>34</sup> 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.

<sup>35</sup> *Cippolone*, at \_\_\_. The *Cippolone* Court also held that the 1965 FCLAA did not preempt state law failure to warn claims.

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 warning lawsuits.

[State Court Sample]

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>Cippolone</i> = period 1, post- <i>Cippolone</i> to <i>Lohr</i> = period 2, post- <i>Lohr</i> = period 3)

TABLE 4

Variable	Marginal Effect	Standard Error	T Stat	Significance level
<b>COURTLEV*</b>	.153	.078	1.95	.051
<b>DESDEF**</b>	-.311	.107	-2.92	.004
<b>CONLEV2**</b>	.517	.089	5.77	.000
<b>CONLEV3**</b>	.537	.057	9.33	.000
<b>CONLEV4**</b>	.701	.097	7.23	.000
<b>PERIOD1**</b>	-.420	.112	-3.74	.000
<b>PERIOD3*</b>	-.213	.118	-1.80	.072
<b>COMPLIED</b>	-.074	.068	.155	.877
<b>FRAUD</b>	.178	.168	1.06	.290
<b>FDA*</b>	.006	.106	.05	.957
<b>CPSC**</b>	-.005	.198	-.02	.981
<b>DOT</b>	.107	.169	.63	.527
<b>CONGRESS**</b>	.306	.087	3.51	.000
<b>COAST-GUARD**</b>	.333	.061	5.42	.000

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

Number of observations = 248

Pseudo R2 = 0.44

Log Likelihood = -90.93

\*\* statistically significant at the five percent level

\* statistically significant at the ten percent level

TABLE 5

Variable	Marginal Effect	Standard Error	T Stat	Significance level
COURTLEV	.122	.082	1.48	.138
DESDEF**	-.381	.118	-3.21	.001
CONLEV2**	.475	.083	5.70	.000
CONLEV3**	.492	.064	7.66	.000
CONLEV4**	.622	.106	5.86	.000
PERIOD2**	.253	.078	3.25	.001
PERIOD3**	.185	.087	2.13	.033
COMPLIED	-.010	.130	-.08	.938
FRAUD	.179	.126	1.42	.155
MDA*	.168	.090	1.87	.061
FHSA**	.253	.058	4.32	.000
NTMVSA	.046	.198	.23	.817
FBSA**	.275	.056	4.88	.000
CPSA	-.138	.287	-.48	.630
FCLAA**	.287	.070	4.08	.000

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

Number of observations = 229

Pseudo R2 = 0.52

Log Likelihood = -68.15

\*\* statistically significant at the five percent level

\* statistically significant at the ten percent level

Table AX  
**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)  Administration)	}	HMTA (Hazardous Materials Transportation Act) LIA (Locomotive Inspection Act) FBSA (Federal Boat Safety Act) (Coast Guard) NTMVSA (National Traffic and Motor Vehicle Safety Act) FAA (Federal Aviation Act) (Federal Aviation
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