Manufacturers Immunity: The FDA Compliance Defense

*Lars Noah & Michael Greve**

Lars Noah: Thank you for inviting me to participate. I have been intrigued by these issues since writing a seminar paper on this as a student in law school. And they really do continue to attract my attention. I am going to spend my limited time today trying to flesh out some of the more technical issues, if you will, having to do with the interplay between the Michigan statute and federal preemption arguments, because they are terribly important in terms of how those two avenues are going to operate in practice.

I should also say this puts me in a ticklish position. My scholarly publications are generally aligned with the views that Daniel Troy expresses [*see* Author Note in preceding article], but I think it is only fair that I should play Devil's advocate today. As a law professor, I am apt to ask hypothetical questions; so let me start with this one. Imagine the FDA concludes that a drug manufacturer headquartered in the state of Michigan had withheld some material information. To make it even starker, let us assume that the Agency actually succeeds in bringing some sort of enforcement action, criminal charges, if you will, against a company. The question is: Could a person injured by that drug—and we will assume that the FDA would not have approved the drug had it been aware of the information withheld by the company—could an injured victim bring a product liability suit against the company?

Let me answer my own question—it is a trick question. The first part is: it all depends on where the lost suit is filed. If it is filed in any other state than Michigan, I dare say that the choice of law analysis would not respect the Michigan compliance statute as a defense. If filed in Michigan—and there is some case law for this proposition—choice of law defaults to forum, and the state has an interest by virtue of its legislative enactment in this case. So, the statute would, in fact, apply.

But there is another trick to this question. There is a clear exception—in fact, two exceptions—in the Michigan compliance statute, as there are exceptions in comparable state statutes that prevent punitive damage actions against drug companies in a few other states, for either fraud or bribery. In a case called *Garcia v. Wyeth Ayerst*, a couple of years ago, involving withdrawing the drug Duract, the U.S. Court of Appeals for the Sixth Circuit concluded that the fraud exception was impliedly preempted by virtue of a 2001 decision by the Supreme Court in *Buckman*. Not only that, it was severable and therefore removed from operation from the Michigan statute.

The punch line is that the plaintiff would not be able to successfully sue because the Michigan compliance statute remains in place, minus the fraud exception. And by the way, this is not entirely a hypothetical question. There are instances in which important information has been withheld from the Agency during the approval process. In fact, Dexfenfluramine—the drug at issue in the Michigan litigation I think, where the state supreme court rejected a constitutional challenge on impermissible delegation grounds to this statute—there were strong suspicions that there had been some undisclosed adverse effects reported in Europe before approval in this country that could have made a difference in the FDA's decision. But those issues now become inconsequential, for purposes of operation of the Michigan Shield Statute. The same thing is true of the bribery exception, which appears to be a dead letter—(again not entirely hypothetical, although you have to go back to the generic drug scandal in the FDA many years ago for an example).

Now, understand, this broad reading of the Supreme Court's directive in *Buckman*, calling for an implied preemption of fraud on the FDA claims, is hardly required. In fact, there are some real serious flaws in the Court's analysis in *Buckman*, as I have written. And the decision to sever itself, I think, is somewhat controversial. There is narrow construction that would have saved the statute from running afoul of the Court's preemption directive, but lower courts have in fact read *Buckman* for all it is worth. And so, let me pose another hypothetical. There is no finding now where a plaintiff, in allegation of fraud or bribery against the Agency (not that they matter anymore), argues that the manufacturer failed to comply with FDA requirements.

Just to make it even more concrete and starker, let us assume that the Agency itself thought there was some sort of failure of compliance or other regulatory infraction by the company. Would the Michigan Shield Statute shield the company from a lawsuit in such a case? You would think so—otherwise, why would it be a called a compliance statute? But there is at least a strong argument to be made that the same analysis that bars fraud and bribery claims in tort litigation involving FDA regulated products would also bar negligence or defectiveness per se claims against these very same products.

I will hasten to add that no lower court has yet decided that *Buckman* reaches that far. In fact, there was an interesting case here in the Western District of Michigan federal court involving claims against BioPort, the anthrax vaccine manufacturer, where the court declined to dismiss by virtue of operation of the Michigan statute because there were a variety of questions of fact about whether the company was in fact in compliance.

But put aside the possibility that negligence or defectiveness per se claims might face preemption. Let us just say that a drug company need not fear tort liability, at least in the state of Michigan, in cases of fraud or bribery. What will motivate a drug company to act responsibly in such cases? Are FDA sanctions alone enough to keep the industry honest? Will we trade what Dan refers to, and I have referred to previously, as 'defensive labeling' for what you might call 'offensive labeling'? As Dan noted, and I tend to agree, Merck probably overreacted with Vioxx in terms of withdrawing the product from the market. But that very argument suggests that the post-approval dynamics would differ if there were not a threat of tort liability in place. And that might operate for better or for worse.

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How quickly would a company seek FDA approval of a Black Box warning instead? How long would that go on until both the industry and the Agency realized that the warnings were not doing the trick? I mean, this has happened time and again where the regulatory response is slow and moderate. Perhaps it is the right response. But when that does not work, the issue becomes more dramatic. So, instead of a compliance statute or a patchwork of such state statutes, I would say that the onus is on Congress to design sensible tort limitations for products that are deemed essential. In fact, it has done so in a couple of instances—twenty years ago in the National Childhood Vaccine Injury Act, which Dan mentioned, for example; ten years ago, in the Biomaterials Access Assurance Act, which Dan did not mention. In point of fact, all of those cases have been sent to the claims court, because federal judges and state judges have realized that such claims are in fact covered by the Act and excluded from tort litigation. And notice, by doing it this way instead of relying on different states to adopt compliance defenses, we have the benefit both of uniformity and of the opportunity to close this loophole that implied preemption under *Buckman* has created with regard to fraud or bribery exceptions.

But there is no reason to think the Congress is eager to get into this fight. The courts can find implied federal preemption on grounds of actual conflict or frustration of purpose. A few have done so recently, sometimes on the strength of FDA input, provided through amicus briefs. In fact, preemption of this sort may operate in a more refined way in the Michigan compliance statute, which bars all tort (though not other claims) once a drug is approved and in compliance, whether or not the FDA has focused on the particular risk at issue and whether or not you have a conflict between the operation of state common law and federal requirements.

The decisions that Dan highlights, though, like the *Dowhal* case from California, are not traditional tort claims involving requests for monetary damages. Indeed, *Dowhal* would not be affected by a statute like the one in Michigan. And the others, like the SSRI cases, are, at least as the courts explain them, peculiar cases because the issue was not just a one-time FDA approval of a product and rejection of a stronger label warning about suicide. In most cases it was the repeated, very public and very clear FDA review of that question that persuaded at least a few courts that a jury really had nothing to add.

A simple approval decision, however—those focused more clearly on risks and benefits of a particular product—passes through a much less public and, you might say, less accountable process. Indeed, here I think the Michigan legislature may have had too simplistic a view of the FDA's processes. Approval, compliance, and withdrawal are not static, dramatic, distinct, regulatory stages. There is more of a spectrum. Initial product approval is just one point in the ongoing learning process of the Agency and the medical community. With compliance, it is often hard to tell; often it is accomplished by indirection. There is a lot of negotiation going on, with several regulatory agencies. Withdrawal: the FDA almost never actually withdraws the drug. That is left to the nominally voluntary decisions made by the industry, whereas the Michigan statute assumes that the withdrawal process is something distinct, coming from FDA headquarters.

Let me illustrate. Dan mentioned that there were six enumerated examples of the preamble. Several things strike me as curious about that. First: only one of the six is squarely within the scope of the FDA's rule revising format and content of prescription drug labeling. One of the others is curious because it says that where companies comply with a non-final, non-binding draft guidance document, they should not have to fear tort liability. Now if you tell that to a federal or state judge, they would be scratching their heads, quite appropriately, trying to figure out how that is a measure of compliance and where there is any sort of conflict with federal purposes. Even the one example he provided where there is clear content and format directives from the Agency does not always point in the direction of preemption. For example, there was much discussion in this rulemaking process about the appropriate minimal font size: eight-point, six-point, ten-point, etc. The FDA finally announced a minimum of six to eight, depending on the type of labeling. But that does not set a ceiling; that is explicitly a floor. Now it is unlikely that the plaintiff would be able to base a case solely on a lack of visibility argument, suggesting that a drug company should have used a certain size font, as some others in the industry have done, but it would be hard to say whether there is any conflict that might fit with the minimum federal font size requirement and also allow a jury to conclude that a larger font size may in fact have been the reasonable thing to do.

My last, and most serious, objection to the FDA's recently published implied preemption analysis—apart from the argument that it is largely dicta, a failure to engage in express administrative preemption—is that it misses on legal analysis. It entirely ignores a critical U.S. Supreme Court decision issued just nine months earlier in a case called *Bates v. Dow AgroSciences*. That involved FIFRA and the operations of the EPA. Plaintiffs' lawyers have announced that it signals the death knell of implied preemption in tort claims. It is not that strong, but it is fair to say that implied preemption arguments in the tort arena are going to be much harder to pursue under this regime. If *Bates* suggests something broader, as it seems to, about the way conflict preemption should operate in these sorts of cases, the Court makes it sound like, unless there is an unmistakable and direct conflict between not just a jury verdict but a common law duty—(and it uses a very high level of generality in defining that duty)—and the federal obligation to find either in statute or in regulation (but not otherwise) the mere possibility that an occasional jury verdict holding the manufacturer of a product who appears to be in compliance with federal requirements, a verdict against such a manufacturer the Court thinks is not a sufficient threat to uniformity to displace state tort law. If the Court is serious about that—and it is hard to tell because these preemption decisions are constantly going back and forth—that could put a real damper on implied preemption of tort claims, and it is never even decided in the FDA's implied preemption analysis in its preamble.

Michael Greve: I was asked to give an over-flight version of today's topic, and this naturally implies statesmanlike, judicious presentation. Those of you that know me know that is not possible: contentiousness is my only mode of discourse.

The entire preemption debate, involving both the FDA and other important agencies in Washington, is overlaid with issues of federalism. On the one hand, the corporate community says, "Yes, federalism is fine, but sooner or later it runs up against the needs of capitalists, economy, and then states' rights and all the rest of it has to stop." On the other hand, the trial lawyers and the state attorneys general say, "Look, our tort system, the operation of the tort system, in addition to centralized legal regimes, is a valuable form of state experimentation and error correction."

Whatever the general argument is for sustaining a state-based private liability system in addition to federal regulation, it cannot be defended on federalist grounds. If you value federalism, you have to favor preemption and all of its forms at the FDA, and in many other contexts. Experimentation is just dandy. State experimentation is great. All this is fine so long as states experiment, as Justice Brandeis said, without risk to the rest of the country. That is the end of an oft-quoted phrase that is often omitted. What the Justice meant was, the costs and benefits of state experimentation have to fall on the state's own citizens. If that could be done, if corporations could price the litigation risk in accordance with state boundaries, experimentation would be easy to support.

Instead, you can have, for example, two Vioxxes. There would be the New Jersey Vioxx, with a picture on the side that says, "If you got a problem, you've got a lawyer. And even if you don't have a problem, you still have a lawyer." And then the Michigan Vioxx. It has a picture of Dan Troy and next to it the words: "Trust me." And it costs what the New Jersey Vioxx costs. Better yet, you could ship both products throughout the country and let people make their own decision about the risks they are willing to bear and the price they are willing to pay for all of these good things—deterrence, insurance, compensation—at the front and that way, we would have at least their ex ante judgment, which is the only judgment that counts.

Of course, the world does not work this way. As in the case of drugs, you cannot modify the product. You can roll the cross-border arbitrage that drugs will make it from one state into another, one way or the other, and then under our fabulous source of law rules, you are stuck with whatever forum the plaintiffs attorneys may choose. And so, at the end of the day the litigation risk from the separate states aggregates and is priced into the product, across the country. Which means that the costs for consumers, shareholders, and workers will accrue everywhere in unknown proportion. It means that the states who want less liability and the benefits thereof—including lower prices—can no longer have their choice. Whatever effect Michigan's liability shield has on the price of drugs will be redistributed nationwide, and so therefore only a very small chunk of the benefits will accrue in Michigan. And it seems to me, especially if you insist on state integrity, you have to allow states to experiment with their own rules, but not allow them to experiment on each other. You need a rule of nonaggression, and the means to enforce it.

I use the term "aggression" advisedly because it was Alexander Hamilton's term. He was talking about New York's import tax, not the Food and Drug Administration; but the economic analysis is just about the same. New York, at the time of the Founding, had an import tax; a portion of which fell on citizens in Connecticut and New Jersey, both states lacking a deep-sea port. Hamilton said, "Look, this import tax is illegitimate. New York could say (what the states now say), that this tax is needed to pay and provide for the health and welfare of our citizens." In fact, New York said just that. Nonetheless, the tax was exploitative, Hamilton thought, because at the end of the day its incidence in Connecticut and New Jersey was intolerable to the citizens of those states. And a rule that has that effect, Hamilton argued, is neither welfare-enhancing nor stable. The State right to that form of aggression is like comparable to saying, "Our mutual welfare and our rights would be benefited by my right to stick my fist in your face;" and, therefore, the only solution to this problem, Hamilton thought, would be to monopolize the decision-making process. The federal government—which under the Constitution obviously has a monopoly over tariffs, import duties, and so forth with respect to foreign trade—is not any smarter. We do not monopolize these decisions because we think the feds are automatically smarter. We have decision-making processes that respect the states—all states, not just those with deep sea ports or trigger-happy juries.

That brings me to my second point: the error correction and safety-valve function. It is, of course, true that the FDA can make mistakes. But the crucial recognition is that it can err on both sides: on the side of excessive caution and on the side of excessive risk-taking. There are ample reasons to believe that this FDA, for at least the last several decades, for political reasons, is excessively cautious, and lots of empirical evidence to back that up. What is the tort system doing, then, in addition to FDA? I think the only serious argument for the tort system has to be that it provides a more adequate deterrence level; because if you want compensation or assurance, no economist I know of would provide that sort of thing through the tort system. The system that chews up 50-60% of transaction costs is not a very good insurance system and not a very good compensation mechanism, except for the consumers. The glitch in the tort system, however, is that it can operate and correct FDA errors only in one direction. It cannot correct FDA errors on the side of excessive caution. And so what are left with, under present circumstances, is tort law systematically increasing systemic error in only one direction. And that is exacerbated by the fact that, given the realities of the pharmaceutical markets, automatically the strictest tort rules in the country dominate the entire, nationwide market.

I am not speaking to the fact that you could have redundant systems, redundant tort and regulatory systems that could work optimally together better than regulation or torts alone. Maybe you can. But the only premise on which the current coordination mechanisms make any sense of all is: more regulations, *ipso facto* better regulations.

There are, in fact, serious law professors who believe that. Erwin Chemerinsky is one of them. "More regulation is *ipso facto* better regulation" is what the trial bar and the

National Association of Attorneys General mean when they say state regulation and state experimentation. Because when Michigan experiments with a tort shield law that drives you "to the floor" of FDA standards, the trial lawyers do not scream, "Hallelujah! Let's hear it for state experimentation." They say, "It's an outrageous infringement on states rights!"—even though the state did it itself. It seems to me the only backstop in a system like this is preemption, and that is the critical argument for it. It is the only backstop to an otherwise out-of-control, one-dimensional process. Without comprehensive implied preemption—and I unfortunately agreed with the *Dow v. Bates* analysis; though I disagreed with the decision for that reason—without implied preemption, you freeze a pro-regulatory bias into the institutional structure.

That brings me to my last, final point. Once you think through the economics of the stuff, it is actually very hard to see when Michigan or any other state will opt out of the "More liability is *ipso facto* better liability" race. What companies in Michigan would get out of the shield laws, as I understand them, is a little more protection against in-state consumer class actions. That is worth something. It's quite probably worth a lot to them. (Ask what it would be worth to them not to have a consumer class action in this state of New Jersey where they can get into federal court because they are headquartered here.) But, by and large, those types of actions are too small a part of the overall litigation risk to really influence corporate location decisions.

So that brings us back to the question: Why are states, occasionally at least, reforming in the right direction? I think the answer—and this is pure speculation—is that the total local wealth effect from the tort system is too small to be worth the very, very large risk to states' reputations. There are many, many states now that have enacted meaningful tort reforms, both in pharmaceuticals and in other areas, and it is most likely, to me, that they care about their reputation as regards being a favorable business climate. That is at least one reason for both.