
ADMINISTRATIVE LAW & REGULATION:

AGENCY PREEMPTION: SPEAK SOFTLY, BUT CARRY A BIG STICK?

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DIARMUID F. O'SCANNLAIN: It is a great pleasure for me to welcome you to our panel today, entitled "Agency Preemption: Speak Softly, but Carry a Big Stick?" As moderator, my task is twofold. First, I hope to frame the panel discussion by reference to preemption law generally, as well as recent events and developments in agency preemption. Secondly, I hope to convince you of the enormous importance of this otherwise arcane topic, because, while it may sound esoteric, it goes to the heart of the constitutional order, in my view. As one scholar explained, the extent to which a federal statute displaces state law affects both the substantive legal rules under which we live and the distribution of authority between the states and the federal government.

Speaking generally, there are three types of preemption: expressive preemption, applied field preemption, and implied conflict preemption. This panel will focus on implied conflict preemption, which courts find either where it is impossible for a private party to comply with both state and federal requirements or where state law stands as an obstacle to the accomplishment and execution of the federal purposes and objectives of Congress. Given that we have a former official of the Food and Drug Administration on a panel today, I thought I would set the stage for today's panel debate by discussing a recent state court case dealing with agency preemption.

The case is *Levine v. Wyeth*, by decision of the Vermont Supreme Court. The facts of the case are simple, yet sympathetic. Levine brought a tort action alleging negligence and failure to warn against the drug company, and was awarded \$6.8 million in damages by a jury. Her claim was that the warning accompanying the drug was insufficient to alert her and her doctors to the dangers of intravenous injection. The primary question on appeal was whether Levine's failure to warn claims was preempted by the FDA's approval of the particular label that accompanied the drug.

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The Vermont Supreme Court essentially held that the FDA's approval of the drug label constituted a warning floor and not a ceiling. In other words, the court thought Wyeth could have, and should have, done more to warn Levine of the dangers associated with intravenous injection of Phenergan. In dissent, the Vermont Chief Justice argued that, by approving Phenergan for marketing and distribution, the FDA concluded that the drug, with its approved methods of administration label, was both safe and effective. He continued, "In finding defendant liable for failure to warn, a Vermont jury concluded that the same drug, with its FDA-approved methods of administration and as labeled, was unreasonably dangerous. These two conclusions are in direct conflict." In the Chief Justice's view, the FDA's approval of the warning label constituted both a floor and a ceiling, and Levine's claims were preempted.

Such competing views raise important legal questions. In *Levine*, the drug company's position was bolstered by a statement of the FDA that cases rejecting preemption of failure to warn claims pose an obstacle to the Agency's enforcement of the labeling requirements. So, what sort of deference, if any, is due to an agency statement about the preemptive scope of its regulations? Most broadly, in promulgating preemptive regulations and adopting statements regarding preemption, can and do agencies adequately protect the values of federalism? How should the traditional presumption against preemption operate in this realm? Finally, what is the best way to protect citizens like Ms. Levine?

The U.S. Supreme Court has the opportunity to enlighten us on the proper resolution of some of these difficult questions when it considers the case *Waters v. Wachovia Bank* later this month. At issue in that case is a regulation promulgated by the Office of the Comptroller of the Currency, which states that, unless otherwise provided by federal law or OCC regulation, state laws apply to national bank operating subsidiaries to the same extent that they apply to the parent national bank. The Sixth Circuit, following both the Second Circuit and my court, the Ninth Circuit, applying *Chevron* deference,

took the view that the Commissioner's regulations preempted Michigan banking laws in their entirety, as applied to the operating subsidiaries. Perhaps one of the panelists will comment on why it is that the Supreme Court took *Waters*, given the fact that the three prominent cases all came out the same way.

In any event, to help us think about the many important issues and lead-up to *Waters* and beyond, the Federalist Society has gathered a distinguished group of scholars who will speak with us today. We will be hearing first from Daniel Troy, who is a partner in the Washington office of Sidley Austin, and immediately prior to that served as the Chief Counsel of the Food and Drug Administration, after being appointed to the position by President George W. Bush. In that role, Mr. Troy was an active player in the FDA's generally successful assertion of preemption in selected product liability cases. Mr. Troy is a graduate of Columbia Law school and served as a clerk for D.C. Circuit Judge Robert Bork from 1983 to 1984.

Next, we'll be hearing from Ronald Cass, who currently serves as the President of Cass & Associates. He previously served as the Dean of the Boston University School of Law, from 1990 to 2004, and was a commissioner, and then later vice chairman, of the U.S. International Trade Commission under Presidents Reagan and Bush I. Dean Cass is a graduate of the University of Virginia and of the University of Chicago Law Review, with honors. After graduation, he served as law clerk to the Honorable Collins Seitz, Chief Judge of the U.S. Court of Appeals for the Third Circuit.

We will then hear from Professor Catherine Sharkey, newly minted professor of law at Columbia Law School and currently visiting professor at NYU Law School. Since joining the Columbia faculty, professors Sharkey has come to be recognized as a leading voice in the legal academy on both punitive damages and products liability preemption. Professor Sharkey is a graduate of Yale University, as well as Oxford, which she attended as a Rhodes Scholar. She is a graduate of Yale Law School and served as law clerk for Judge Guido Calabrese of the Second Circuit and Justice David Souter of the Supreme Court.

Finally, we will hear from Professor Thomas Merrill, the Charles Keller Beekman Professor of Law, also at Columbia Law School. Professor Merrill recently filed an *amicus* brief on behalf of the Center

for State Enforcement of Antitrust and Consumer Protection Laws in the *Waters* case that will be argued shortly. He is a graduate of Brunel College and also attended Oxford as a Rhodes Scholar. After graduation from the University of Chicago Law School, he served as law clerk to Judge David Bazelon of the U.S. Court of Appeals for the D.C. Circuit and to Justice Harry Blackman of the Supreme Court of the United States.

We will hear first from Mr. Troy.

DANIEL TROY: Thank you, Judge for the introduction. It's a pleasure to be here. Often those of us who are members of this Society and in favor of preemption in appropriate circumstances are accused of being hypocrites. Everybody says, "Well, it's the Federalist Society," confusing Federalists and federalism. I want to make clear that there is difference between the Federalist Society and being reflexively in favor of federalism. Madison was selected as the icon for our group not because of his much later states right's positions but because he was the father of the Constitution. Sometimes I think we should have selected both Madison and Hamilton, because it is, of course, the Federalist Papers after which the Society is named, and those Papers are in favor of a strong, albeit limited, central government.

It's important in the context of this conference, which is about limited government, to focus on the importance of preemption to limiting government. What do I mean? Well, in the case of food and drugs, if you have very strong federal regulation, but not preemption, you end up with perhaps 51 levels of government, 51 different systems that people need to navigate. Now, one can imagine a world with no federal regulation of drugs at all, with every state regulating. You might have competitive federalism, in that case, and you might not. But when you have the system that we have, at least in the realm of drugs and medical products, you cannot begin to test a product in humans without getting the federal government to approve it in advance, you cannot market the product without the federal government approving it in advance, you cannot manufacture the product without the government approving it in advance. People hear the words "new drug application" and think, "Oh, college application." In fact, a new drug application normally has as much data, as many boxes of documents, as would literally fill this room.

These applications are delivered to the Agency by the truckload. The Agency looks at that data and, for the purposes of this panel, comprehensively determines what may and may not be said about the drug product through labeling. Labeling is not merely a floor, notwithstanding what the Vermont Supreme Court said.

What the FDA said in its most recent preemption preamble is that it is a floor and a ceiling. I want to illustrate that by talking about some specific cases, because the devil is in the details and, on the one hand, this stuff can be esoteric and arcane, but on the other, if you really look at the public health of the matter—and, I'd like to suggest, the common sense of the matter—I think the case for preemption becomes very powerful.

Let me talk about the case called *Dowhal*, the California Supreme Court case. As many of you know, California has something called Proposition 65, which requires warnings if there's any substance in a product that can either be carcinogenic or can cause harm in a pregnancy. The issue in the case involved nicotine replacement therapy products. These are products that somebody takes if they're trying to quit smoking. The FDA said, "We want the warning to say, 'Try to stop smoking without this product, This product can be useful, but talk to your doctor. Nicotine can have adverse impacts.'" There was a lawsuit filed under Prop 65--which, to his credit, the California Attorney General did not join. The gravaman was that they wanted the nicotine replacement therapy product to say "Nicotine can harm your baby." That was all. But the FDA rejected this warning in a series of letters and in more formal responses to citizens' petitions. It said, "We don't want that warning." That warning might cause a woman to misunderstand that, actually, nicotine replacement products are a good thing."

Well, the California Court of Appeals said, as the Vermont Supreme Court did, that it's always better to have more warnings, and the FDA got involved. One thing the federal career officials believe is that when they decide a matter, when they have, in the language of *Chevron*, directly spoken to the precise question at issue, they should get to win. So they thought in this case. Fortunately, we went to the California Supreme Court, and the California Supreme Court." Actually, more warnings are not always better."

Perhaps the most controversial case involved something called SSRIs (antidepressants). It is a tragic fact that people who are depressed tend to commit suicide. So, it's hard to tease out whether there's a connection between antidepressants and suicide. At the time these products were first approved, the question to the FDA Expert Advisory Committee was: Should there be a warning that these products might cause suicide? They said no because they didn't think there was data to support that. Secondly, they thought it might dissuade people who were depressed from taking the drug. There are many people concerned about antidepressants. So, for example, the Scientologists and Public Citizen came back to the FDA time and again asking the Agency to put this warning on, and the FDA kept saying, "We're sorry, but we don't think that's the right thing to do. It will over-warn. It's not just a floor; more warnings are not always better."

Well, a lawsuit was brought in the Ninth Circuit, the thrust of which was that, in this case, Pfizer should have labeled its antidepressant product Zoloft to say, "This product can cause suicide." It was brought by someone who survived a relative who had taken the product and six days later committed suicide, tragically. The district court said that more warnings are always better, the suit can go forward. Again, the FDA got involved, and said, "Excuse me, we think that would have misbranded the product."

So, in talking about conflict preemption, it certainly begs the question, if the FDA thinks a product would be misbranded, how a state law requirement can compel product labeling that would be technically misbranded and illegal under federal law? If that's not an implied conflict preemption, I don't know what is.

FDA has continued to intervene, but it's important to note that the Agency itself does not have litigating authority. The FDA does intervene through the HHS General Counsel's Office and the Justice Department. It is the final backstop. This is, I think, one of the things that has caused this controversy and caused this panel. Instead of intervening with individual *amicus* briefs, the FDA issued this broad statement on preemption that basically said, "Our regulations are not just a floor, they're also a ceiling. More warnings are not always better. And when we make a decision, we are not looking at the benefits

and risks of a product in the context of an individual. We're making a societal decision. We understand that all drugs have risks. There are no drugs that are risk-free; people often forget this. And so, we understand when we put the product on the market that there will be some adverse events. That is an unhappy fact that comes from having therapeutic products. But we're making a broad risk-benefit calculation, and so that calculation must necessarily displace state suits that would have the effect of undercutting the FDA's definitive determination about the warning label."

And so, to close, this is part of what is sometimes called the "stealth tort reform" by the Bush administration. But it seems to me that if you're going to have a very powerful regulatory scheme that there is naturally going to be some state regulation imposed through the product liability system that has to be set aside. Thank you.

RONALD A. CASS: Before I start, I have to say I had a phone conversation with my colleagues here, and I misunderstood the topic. I thought that they said talk softly and do shtick. So I'm going to begin with a brief anecdote. This is actually a story my wife told me, involving a friend of hers who one day saw a funeral procession in the suburbs of Washington. It was a very unusual procession. In New Orleans, you're used to seeing that but not in Washington. It consisted of a Hearse followed by a second Hearse, followed by a woman dressed in black walking a dog, followed by a thousand women in single file. My wife's friend went up to the woman walking the dog and said, "You know, I have to ask you. This is the most unusual funeral procession I've seen. Who's in the Hearse?" The woman said, "It's my husband." "How did he die?" The woman pointed and said, "My dog attacked him. We were having an argument. The dog took it seriously, went berserk, and killed my husband." Her friend apologized and said, "Who's in the second Hearse?" And the woman said, "It's my mother-in-law. She tried to intervene and the dog killed her too." Susie's friend thought for a minute and said, "Can I borrow your dog?" At which point, the woman said, "Get in line."

There are some ideas that seem like good ideas, and appeal to a lot of people. We're really not dealing with one idea here but three: the idea of limited government, the question of the level of government appropriate to make a particular decision, and the

question of which organ of government should make that decision. What's the right competence? Is it the courts? Is it the agencies? Is it the Legislature?

For me, the ultimate test is not: Do these get us a particular amount of government? It's a combination of quantity and quality of government. If you look to the Framing, the concern wasn't just to limit government. After all, the Constitution expanded the national government in very significant ways over the Articles of Confederation. The goal was to preserve and protect liberty and security, which is done by having not the minimal government but the right sort of government, delivered in the right way.

The Constitution gives the national government control over interstate commerce. It also has a provision decreeing that the national government should not tax or lay particular impediments to the trade coming out of any one state. It says to the states that they shouldn't lay taxes on the trade coming out of their states unless they're so directed by Congress; and the tax goes to the Treasury. What the Framers were quite clearly trying to do was to facilitate the free flow of goods among states. They were cognizant of the fact that if you don't give the national government the control over the flow of goods within states, you will have a lot of impediments to trade, because states have an incentive to internalize benefits and externalize costs.

We see this all the time when you look at how state attorneys general deal with companies doing business in their state. They try to impose special burdens on the business that can bring benefits into their state; they try to localize regulation of what is a national or international enterprise; and they frequently do this using very ham-handed means, because if they were more transparent about what they were doing, it would be more difficult to get where they want to go.

The distinction Dan Troy drew between those who are Federalists, believing in a system with different levels of government, and those who believe this automatically means that all decisions should be made by the state or local level, is a very important one. There are certain decisions that should be made at the state or local level because they deal with state and local problems. That is most congruent with protecting the liberty and the values of the people in those states or localities. When you deal with something that has national or international

scope, giving states the right to speak to those issues can be counterproductive to liberty, security, and efficiency.

When we are trying to determine who ought to be making these decisions, we are often dealing with statutes that most of us might not like. We think the area of regulation may not be a good thing. We think the national government is excessively regulating. But to then say that the way to deal with this problem is to allow states to also regulate may impose additional duplicative and conflicting burdens on businesses. Those are the things we ought to disfavor and avoid whenever possible.

A lot of the cases we're dealing with here deal with the question, When an agency is regulating, what presumption should attach? Should the presumption be that an agency regulation ousts state regulation? Should we be relatively inclined or relatively disinclined to find conflicts? Historically, the rule has been that we are relatively disinclined to find conflicts.

The next level of argument is: Who ought to be making that determination? Here is where things have gotten more contentious. The courts have said that the agencies at the national level issuing regulations are given deference in interpreting the law because Congress intended, in creating this particular regulatory scheme, to authorize the agency to be the first place ambiguities are resolved. This is a matter of statutory interpretation. That interpretation logically extends to the interference or noninterference with the schemes of state and local governments.

Judge O'Scannlain asked, "Why, when all of the courts—the Ninth Circuit, the Second Circuit, the Sixth Circuit—came out the same way on this, did the Supreme Court take *cert*?" I think they were confused. They saw the six upside down and thought it was a nine. You know, the Supreme Court took cases from the Ninth Circuit to reverse your colleagues, not you. I also noticed that at the dinner the other night that there was a place for Judge O'Scannlain, but they did not put the usual "reserved" sign. They were afraid he would think it said "reversed".

CATHERINE SHARKEY: Good afternoon. I want to talk about what I call an "agency reference" model—as distinct from an "agency deference" model—to be used in a court's determination of implied preemption, particularly in the products liability context.

First, to set the stage, consider that the FDA and other agencies have recently enacted "preemption preambles"—statements included in preambles to final regulatory rules indicating the agency's belief that the federal regulatory standard preempts common law tort actions. As Dan Troy has pointed out, the FDA included a statement of preemptive intent in its recent rule governing the format and content of prescription drug labels. NHTSA's preemption preamble appears in a recent notice of proposed rulemaking about roof safety standards. The Consumer Products Safety Commission, for the first time in its thirty-three-year history, proposed a preemption preamble in a 2006 regulation addressing flammability standards for mattresses. (The FDA and NHTSA had done so previously.) Given the flurry of recent federal agency activity here in Washington, D.C., this topic has real currency.

The agency reference model is a middle course approach to guide courts in making implied preemption determinations. Were Congress clear about its intent to preempt or displace state law, its intent would govern. It turns out, however, that when Congress enacts piecemeal legislation concerning specific products, such as the Motor Vehicle Safety Act or the Federal Boat Safety Act, Congress has been anything but clear. Typically, these product statutes include very broad preemption clauses that expressly preempt any conflicting state requirement. Congress usually says that state "requirements" or "standards" are preempted, using broad language that has been read to include common law state tort actions. These broad preemption clauses are coupled with very broad savings clauses that purport to leave common law actions intact. In these instances, Congress seems to be saying everything. In other instances, such as the Food Drug and Cosmetic Act, it is all but silent. In the provisions that deal with medical products, there is a preemption clause, but in the provisions dealing with drugs there is not. As Congress does not expressly answer the preemption questions that products liability cases implicate, there is ample room for other decision-makers—namely, courts and agencies—to step in.

Congress' failure to weigh in on the issue of preemption of common law actions, which cannot realistically be ascribed to inadvertent omission, is puzzling. For example, associated with the Federal Insecticide, Fungicide and Rodenticide Act, at issue

in the recent Supreme Court case of *Bates v. Dow Agrosciences, LLC*, there are over a thousand pages of legislative history and yet not a word about the fate of state common law tort actions. But when this Act was amended in 1972, such actions were quite common. The interesting question is an institutional one: Does Congress punt the preemption determination to courts or to agencies? How should this interplay work? The agency reference model that I advocate would leave the decision-making power in courts but not allow them either to give mandatory deference to the agency position or to ignore the agency's position.

Contrast the present situation where courts are taking extreme positions when faced with the issue of whether the FDCA and regulations promulgated thereunder by the FDA preempt common law failure to warn claims. In his remarks today, Judge O'Scannlain mentioned the *Levine v. Wyeth* case, which exemplifies one extreme pole, where courts say that there's a presumption against preemption and that the purpose of the FDCA is to protect health and safety, so how could any state tort action ever be preempted? The idea that more regulation is always better seems clearly wrong in the context of drugs or any product situation where the determination rests upon risk-risk tradeoffs. If you add warnings, you're not just warning consumers of certain risks, you are inevitably creating alternative risks insofar as individuals, or their physicians, are scared off from these drugs. That's one extreme.

At the other extreme lie courts that defer unconditionally to the FDA's "misbranding" argument in favor of preemption of common law claims: that a manufacturer can never unilaterally strengthen or alter a label warning, lest it risk being prosecuted by the FDA for misbranding the drug. The upshot is that the FDA's pre-market new drug approval process would grant the drug manufacturers immunity from state common law tort actions (most often failure to warn claims). And this safe harbor would protect drug manufacturers even in situations where new risks (or which the manufacturer was aware) come to light in the post-approval period.

But between these extreme positions lies a middle course approach, whereby courts would be able to look specifically at the risk-risk determination by the Agency—not just at the time of approval, but during the post-approval period, too. Most of these

cases deal with situations where new risks allegedly came to light in the post-approval process. The manufacturer then has an opportunity to go back to the FDA.

In *Levine*, the manufacturer went back to the FDA (during the post-approval period) to try to strengthen a warning for a different variety of the drug and was told to keep the current verbiage in the warning label. The court nonetheless held—erroneously, in my view—that a state law failure to warn claim was not impliedly preempted by the FDA's regulatory action pursuant to the FDCA.

Perry v. Novartis embodies the middle course approach that I am advocating here. The federal district court starts with the idea that the FDA's preemption preamble should neither be rejected nor accorded mandatory *Chevron* deference. Instead, the court decides that the preamble should get *Skidmore*, or "power to persuade," deference. I think that's actually the right approach.

Moreover, it comports with the U.S. Supreme Court's jurisprudence. I unearthed an interesting positive empirical observation when doing a study of products liability preemption. If you look at the U.S. Supreme Court's product liability preemption cases, which span from *Cipollone v. Liggett Group, Inc.* to *Bates*, in every case (save *Bates*), the Court's ultimate decision, whether pro-preemption or anti-preemption, aligns with the position urged by the relevant agency. Thus, the FDA had argued in favor of preemption in *Buckman v. Plaintiffs' Legal Committee*, and the Court went that way; it argued against preemption in *Medtronic v. Lohr*, and the Court went that way. NHTSA argued in favor of preemption in *Geir v. American Honda Motor Company* and against in *Freightliner Corp. v. Myrick*, and the Court followed suit. The Court's anti-preemption holding in *Sprietsma v. Mercury Marine* likewise follows the agency's position. The Coast Guard, having done a risk-risk analysis, came to the conclusion that no uniform propeller guard design was suitable, given the variety of recreational boats and motors in existence; and thus, a state law design defect claim in no way interfered with any federal policy reflected in its decision not to regulate.

The Supreme Court has been very cryptic. It has never said, "We are applying *Chevron* (or *Skidmore*) deference here." Most often in dissent, Justices try to force the issue by saying, "Look, the majority is giving

deference by saying things like ‘We give significant weight to the Agency’s determination,’ but they never come out and say they’re giving *Chevron* deference.” If you look carefully at what the majorities in those cases do, though, I think they apply something that looks like *Skidmore* deference, and in general provide a model for courts to follow.

One last observation: if you look at the dozen or so cases that post-date the issuance of the FDA’s preemption preamble, some have been decided by federal courts, some by state courts. The state courts have, over the past quarter century, consistently rebuffed the regulatory compliance defense to state common law tort actions; it is hardly surprising, then, to find that state courts, on the whole, seem predisposed to resist the idea of federal preemption of state law, which after all, is essentially an even more forceful immunity-conferring mechanism. The federal courts seem more likely to listen to what the FDA says, and the FDA is much more likely to intervene in federal cases, either on its own or when the Court asks for its views. That will be a very interesting dynamic to observe over time.

Thank you.

THOMAS MERRILL: Thank you very much. I notice that the room’s a little crowded in the back, so in the effort to clear things out, let me announce in advance that I’m going to be talking about administrative law doctrine for the next eight minutes. In case you want leave quickly, now’s your chance to do that.

I’m going to approach this from the perspective of ad law rather than tort law or ordinary preemption law. I think when you approach it from a perspective of ad law, you discover that the range of disagreement here is actually quite narrow; that a number of propositions which you might think would be contestable in fact have been resolved, more or less, by express holdings of the Supreme Court or by settled propositions (or at least what I regard as several propositions, of administrative law). So, let me mention three things that I at least regard as settled propositions, which have the effect, I think, of compressing the area of disagreement down to a fairly small point.

First, it’s well established that agency legislative regulations have preemptive effects. If an agency has been delegated power to act with the force of law, to issue legislative regulations, where those

legislative regulation are deemed inconsistent with state law—by the court, at least—there’s no question that the federal regulation trumps or preempts state law. This was held back in 1961 in *United States v. Scheimer* and reaffirmed in the *De la Questa* case in 1982. The issue is off the table.

Second, if Congress expressly delegates authority to an agency to issue preemptive regulations—not just legislative regulations but regulations that say, “We deem state law in Area X to be preempted”—that is permissible as well. There are a number of examples in federal law where Congress has given express preemptive authority to agencies, whose exercise of that authority have been upheld by courts. The Supreme Court’s authority at this point is a little sketchier. If I had my way, the Court would insist a bit more on the need for express delegated authority to preempt, rather than finding it in some kind of clearly implied fashion. There’s a case called *New York v. FCC* from 1988, in which the Supreme Court found express authority to issue preemptive regulations based on congressional ratification of prior practice by the agency, which I think is pushing it a little far. But the basic proposition that Congress can express expressly delegate preemptive authority to an agency, I think, is off the table as well.

Thirdly, an agency’s statement of its opinion about the preemptive effect of either the federal statutory scheme or a combination of the federal statutes and federal regulations is not entitled to *Chevron* deference. The reason for this follows from recently established principles about when *Chevron* does and does not apply. The infamous *Mead* case that Ron tried to make me promise not to mention, holds, well, who knows exactly what it holds? I think it holds that agencies are entitled to *Chevron* deference only if they act with the force of law; meaning that they’re issuing something like a legislative regulation which is within their delegated jurisdiction. If they issue an interpretive of rule or some kind of opinion letter, that’s not entitled to *Chevron* deference.

Now, with respect to these preambles, the issue is a little bit trickier. I take it that a statement in a preamble about the preemptive effect of a federal regulation being adopted pursuant to whatever perambulatory statement does not itself have the force of law. Administrative lawyers distinguish all the time between what’s called the Statement of Basis and Purpose required by Section 553 of the APA

and the regulation itself. The regulation itself is a thing that goes into the Code of Federal Regulations. That's what has the force of law. The statement in the preamble is the explanation for the regulation. It does not of its own effect have the force of law.

If an agency has to interpret federal statutory authority in order to reach a particular legislative regulation, and the explanation for its statutory authority is in the preamble, it is entitled to *Chevron* deference, because the explanation is the condition precedent for the regulation itself. But if you have something like a regulation dealing with drug labeling and the FDA says in the preamble, "By the way, it's our opinion that any state court action inconsistent with this labeling would be preempted," that's just a statement of agency opinion; it's not a necessary condition of finding authority on the part of the agency to issue that regulation. It would not be entitled to *Chevron* deference.

So, I think those propositions are pretty much settled. What is not settled is the issue presented by the *Waters* case, which is going to be argued on November 29. The issue is: What happens if an agency that has legislative rulemaking authority but has not been given express authority to issue preemptive regulations uses its general rulemaking authority to issue what purports to be a legislative regulation, which regulation then states if the agency's determination that state law in a particular area is preempted? Is that sort of legislative regulation pursuant to a general delegation of authority rather than to an authority to preempt, also entitled to *Chevron* deference or to some lesser degree of deference (presumably *Skidmore*)?

In answering this question, I think we have to revert to more general principles, not simple case law and settled principles of administrative law. Several propositions are relevant here in sorting things out. First of all, I do not agree with Ron's statement that determinations of preemption are simply a species of statutory interpretation. In preemption cases, there are three determinations to be made, not just one. The first determination is that somebody, be it a court or an agency, has to decide what the federal law means or requires. That's an exercise in straightforward interpretation. Then, the decision-maker, be it a court or agency, has to decide what the state law means or requires. That's another exercise in interpretation. The third step is critically different;

that is, the decision-maker has to decide how much tension there is between the federal and the state law, if any; and, given the degree of tension, whether it's necessary to displace or nullify state law in order to effectuate the general purposes of the federal statutory regime.

Now, in some instances that third step is not necessary. You've got an express preemption clause which is squarely on point; that would not be a contested case. In all other cases, if there's a dispute about the scope of an express preemption clause, something about obstacle or frustration of purpose preemption or field preemption—even, in most cases, of conflict preemption where there's not a square X or -X type of conflict—somebody has to decide whether a displacement of state law is necessary. So, the question is really one of institutional choice, as several of the other speakers mentioned. Who is going to make this determination of displacement? I think an argument can be made that the agencies ought to be given significant say-so in this exercise. The agencies, after all, have great expertise about the nature of the statutory scheme. They probably have unique understanding about how state law is or is not going to interfere with the way the federal statutory scheme is carried out. But let me give you some quick reasons why I think strong *Chevron* deference probably is not the way to go in making this displacement determination. I'll just mention these quickly.

First of all, and Cathy mentioned this briefly, preemption is an issue that comes up in state court almost as often as it comes up in federal court. I have trouble imagining exactly how the U.S. Supreme Court is going to enforce a duty upon state courts to give *Chevron* deference to federal administrative agencies on the question of preemption. The Supreme Court just does not have the institutional capacity, I think, to change state court behavior in that radical direction. Something like a *Skidmore* doctrine, which allows agencies to submit their views in various ways and instructs courts to give them effect insofar as they are persuasive, would I think be something more reasonably workable in the state court system.

Secondly, I think there are systemic considerations here. Most of our panelists are interested in explaining how Madison was really in favor of powerful federal government. But there are systemic interests here in terms of maintaining

a balance between the federal government and the states; that is, not having the federal regulatory juggernaut completely take over our system. I'm concerned that if each federal agency which has a little individual regulatory slice of the world is given *Chevron* deference for its determinations, we're going to see a lot more displacement of state law. There will be a tendency for each agency individual to push the limits of federal law in isolation. We need some kind of judicial counterweight to that. I think the federal judiciary, the Supreme Court in particular, which has a broad-brush picture about the need for state and federal balance in the system, is a better institution to maintain that balance than are individual agencies.

Lastly, and I'll close with this point, the question of whether agencies can preempt or be given strong *Chevron* deference for preempting state law is another one of these issues that implicate the scope of an agency's authority. All sorts of scope issues come up about whether agencies can regulate with the force of law or not. But there are reasons to be concerned about giving that issue to states to decide under a strong deference doctrine like *Chevron*. Agencies would have a tendency to view state regulators as rivals, to see state courts as rivals and try to expand their authority. We need federal courts to discipline the boundaries of agency action. *Skidmore* is better suited to doing that than *Chevron*.

Thank you.

