

# NEW YORK UNIVERSITY JOURNAL OF LAW & LIBERTY

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## LITIGATION: THE FUTURE OF FEDERAL PREEMPTION\*

### *MINUTES FROM A CONVENTION OF THE FEDERALIST SOCIETY*

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**HON. WILLIAM H. PRYOR JR.**, Moderator, U.S. Court of Appeals, Eleventh Circuit

11-13-09

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State Ballroom

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\* Editor's Note: This transcript has been slightly modified from its original format to correct obvious grammatical errors.

**JUDGE PRYOR:** Welcome to this luncheon panel that has been organized by the Litigation Section and will address the future of federal preemption.

Federal preemption of course is a recurring concern of the Supreme Court of the United States in cases about a wide variety of economic regulations, including regulations of financial services, product safety, environmental protection, and the labeling of food and drugs.

Our panel will discuss whether there is a discernable pattern in the decisions of the Supreme Court about preemption, whether and how recent changes in the membership of the Supreme Court will affect any pattern of those decisions, and whether there is a principled and coherent framework that the Court should employ in this vital area of constitutional law. To discuss these matters, the Society has assembled a distinguished panel of experts. Each panelist will make an opening statement of eight to 10 minutes. I will make sure they adhere to it.

I will now introduce our first panelist, and later we'll introduce the remaining panelists after each panelist speaks. Our first panelist is Dr. Michael Greve, the John Searle Scholar at the American Enterprise Institute. Dr. Greve cofounded, and from 1989 to 2000 directed, the Center for Individual Rights, a public interest law firm. He has written extensively on many aspects of the American legal system, and his publications include *Real Federalism: Why it Matters, How it Could Happen*.<sup>1</sup> He is the co-author with Richard Epstein of *Federal Preemption: States' Powers, National Interests*.<sup>2</sup> He is an adjunct professor at Boston College, has been since 2004. He holds a Masters and Ph.D. in Government from Cornell University and a diploma from the University of Hamburg, Germany.

Please join me in welcoming Michael Greve.

**DR. GREVE:** Thank you, Judge. I'm very honored to be here.

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<sup>1</sup> MICHAEL S. GREVE, *REAL FEDERALISM: WHY IT MATTERS, HOW IT COULD HAPPEN* (1999).

<sup>2</sup> *FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS* (Richard A. Epstein & Michael S. Greve eds., 2007) [hereinafter *Federal Preemption*].

**JUDGE PRYOR:** I should have mentioned that he also once introduced me in the *New York Times* as being the “key to the puzzle,” and I’m still trying to figure out what that was about.

**DR. GREVE:** In a quiet moment.

I hope this works here with the technology. I should say thanks for the invitation. I haven’t done one of these Federalist Society panels at an annual convention in a while. That’s because I really never have any strong opinions about anything, and so that makes it boring. But we’ve concluded that I can be trusted with empirics, and so that’s what I’ll do for 10 minutes, the empirics on federal preemption.

Much of this is based on an article I wrote an article a while ago with John Klick, which was published in the *Supreme Court Economic Review*. We’ve recently updated the data and added some variables that we collected earlier. I should say that work was done principally by Mike Petrino, who is here, who is, as of this coming Monday, at Kirkland and Ellis. It’s no slight to him if I say that much of what comes now you have to take with Jimmy Buffet’s lost shaker of salt.

We haven’t done much of the analysis yet. You’re dealing with a very small, and the coding is very, very small—I mean, starting with what is or is not a preemption case. It’s not difficult because we can’t read cases, but it’s difficult because the justices themselves can’t agree on that. But I am a believer in Richard Posner’s position that in an information-free environment even a questionable data point is valuable information. And so I’ll give you a few data points. I hope they’re useful, and we’ll see what the panelists make of them.

This is my first chart. It shows you the preemption votes by court. We divided the Rehnquist Court into two periods: the first Rehnquist Court and the second Rehnquist Court. That follows a widely followed distinction originally made by Thomas Merrill in a celebrated article.<sup>3</sup> Basically, the second Rehnquist Court starts after

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<sup>3</sup> Thomas W. Merrill, *The Making of the Second Rehnquist Court: A Preliminary Analysis*, 47 *ST. LOUIS U. L.J.* 569 (2003).

Justice Breyer's appointment. After that, the Court remained in the same position.

You'll see some half cases. That's because some cases had split rulings.

There's a total of 118 cases in this set—58 for the first Rehnquist Court; 48 for the second Rehnquist Court; 12 so far for the Roberts Court. That works out to roughly four to four and a half cases per term. There are a few more in the first Rehnquist Court, but that reflects basically the miraculously shrinking docket.<sup>4</sup>

This chart illustrates cases broken down into unanimous cases, cases with one or two dissents, and then contested cases, that is cases with a vote differential of three or less. What this illustrates or suggests is a loss of unanimity on preemption questions on the court. If you look at the Rehnquist Courts, over half of the opinions were unanimous. Only 20 percent, roughly, were contested. On the Roberts Court that is obviously different, although you have to remember the small number of cases there are.

My second chart—preemption votes by Court. The outcome is binary; it's either pro-preemption or anti-preemption. You can't learn very much from this because there are too few Roberts Court cases, but I will flag one question that bears watching I think. If you look at the first Rehnquist Court and the second Rehnquist Court, the outcomes in these cases pro/anti-preemption were basically 50-50, and it's also true so far of the Roberts Court.

Here's what's different so far. On the Rehnquist Courts, preemption was somewhat more likely when the case was contested, and that hasn't held so far in the Roberts Court. There's only one contested case with a vote differential of three or less that came out in favor of preemption. That case is *Watters v. Wachovia*.<sup>5</sup> All the other cases, if it's contested, the pro-preemption people lose. We'll

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<sup>4</sup> See, e.g., Adam Liptak, The Case of the Plummeting Supreme Court Docket, N.Y. TIMES at A18, Sept. 29, 2009 available at <http://www.nytimes.com/2009/9/29/us/29bar.html>; see also David M. O'Brien, *The Rehnquist Court's Shrinking Plenary Docket*, 81 JUDICATURE 58 (1997).

<sup>5</sup> 550 U.S. 1 (2007).

see whether that holds up. As I said, this is not a finding; this is something to watch.

I'll go straight to this. This is the first of three charts on the justices' votes. So the height of the graphs reflects the number of cases that the justices participated in, and then the red bars indicate the number of times they voted in favor of preemption. The most pro-preemption justices on the Rehnquist Courts were Justice Scalia and Justice Kennedy. Chief Justice Rehnquist and Justice O'Connor, not shown here, were very similar. At the other end of the spectrum are Justices Stevens, Ginsburg, and Breyer. Justice Souter, also not shown here, is virtually identical to Justice Stevens.

What has changed is that Chief Justice Roberts and Justice Alito are much more pro-preemption than their predecessors. Of course, Justice Alito's perfect record of 100 percent pro-preemption votes won't hold up. But what will hold up, I think, is that Chief Justice Roberts and Justice Alito will be the anchor votes for the pro-preemption side. If and when their percentages go down, as they will, it will be unanimous cases that find no preemption.

This is somewhat more illustrative – Justices' votes in contested preemption cases. This, of course, dramatizes the vote differentials, which obviously don't come into play in unanimous cases, so two quick observations on this.

If you look at Justice Breyer's vote, 26 percent pro-preemption in contested cases – I think corporate lawyers have every reason to rethink their intuitive assessment of Justice Breyer. There is a tendency to view him through the lens of *Geier v. American Honda Motor Co.*<sup>6</sup> That is, of course, a foundational case for corporate attorneys.<sup>7</sup> It was a five-to-four case. Justice Breyer wrote the opinion for the majority, and so there's a lot of distress; at least that's the vibes I picked up over votes in *Wyeth v. Levine*<sup>8</sup> and in *Cuomo v.*

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<sup>6</sup> 529 U.S. 861 (2000).

<sup>7</sup> See, e.g., Joseph Mulherin, *Geier v. American Honda Motor Company, Inc.: Has the Supreme Court Extended the Pre-emption Doctrine Too Far?*, 21 J. NAALJ 173, 173 (2001).

<sup>8</sup> 129 S. Ct. 1187 (2009).

Clearinghouse<sup>9</sup> because if you put those things together, it turns out that it looks like Justice Breyer may no longer believe what he said in *Geier*. Given his overall record over time, that shouldn't have come as a surprise I think.

The second thing about this is that this suggests why corporate litigants are having so much trouble in preemption cases. If you remember the last chart, you'd think that if you have four justices with you 60 percent of the time and Justice Thomas half of the time, you ought to be fine most of the time, but that's not true, and here's why. The anti-preemption justices are much more reliably against preemption than the pro-preemption justices are pro-preemption. This was also true of Justice Souter. So Justice Kennedy gets barely a bounce from dropping the non-unanimous cases. Justice Thomas isn't far from it, 50-50, 57 percent, and that's not good news if you need his vote.

So one way of reading this is if the Chief keeps up his average, he'll barely compensate for Justice Ginsburg, who bats .810 the other way. Justice Alito will have to compensate for two votes that go against preemption, and personally I think that Justice Alito should get two votes in every case.

Is this really true? Express/implied preemption cases – this is sort of a newly added section to the dataset. It's very preliminary, but I included it because both sides to the preemption debate want to reduce or say, look, preemption is at a bottom statutory interpretation. It can be reduced to that. That's Justice Thomas's position in *Wyeth*<sup>10</sup> more or less. It's the position of liberals who want to say there ought to be a clear statement rule for preemption,<sup>11</sup> and an express preemption provision is, of course, not the Rosetta Stone of preemption analysis, but at least it's a start. It gets you out of this netherworld of implied obstacle preemption. Sort of the Rodney

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<sup>9</sup> 129 S. Ct. 2710 (2009).

<sup>10</sup> 129 S. Ct. at 1205.

<sup>11</sup> But see Howard A. Learner, *Restraining Federal Preemption When There is an "Emerging Consensus" of State Environmental Law and Policies*, 102 N.W. U. L. REV. 649, 651 n.9 (2008) (noting that support for a clear statement rule cuts across ideological lines).

King of preemption theory: If Congress could speak clearly, we'd all get along.

The result here, I think, is suggestive. Express preemption provisions have some effect, apparently, on conservative justices because they're now more likely to find preemption, and that's intelligible even if it's not totally straightforward. In contrast, if you look at the bars of the liberal justices, it's the reverse. If there is an express preemption provision, they're somewhat less likely to find preemption, and that's not so straightforward.

I have two guesses why that might be so. One is that express preemption provisions frequently come with a savings clause,<sup>12</sup> and so you'd have to go through the numbers and see whether that made a difference. The second and more important guess, I think, is that express preemption provisions don't define their own scope.<sup>13</sup> They tell you that Congress wanted to preempt something, but not how much it wanted to preempt. So if Congress tells you expressly that it wants to preempt any state law relating to ERISA-covered health insurance, it really hasn't told you very much.

And so maybe the intuition runs as follows: The conservatives are impressed that Congress has muttered some magic words, 'We want to preempt,' and they cut Congress some slack. And the liberals then go the other way and say, 'We know that Congress paid attention to the preemption provision, and so we have to make sure that we go no further than Congress itself wanted us to go, or maybe we should read the preemption provisions with a presumption against preemption.' Again, this is all just guesswork, but I think it gives you reason to question the rash assumption that express preemption provisions will have any direct and determinate effect on Supreme Court outcomes.

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<sup>12</sup> See, e.g., Sandra B. Zelmer, "When Congress Goes Unheard: Savings Clauses' Rocky Judicial Reception," in *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION* (William Buzbee, ed., Cambridge Press 2008).

<sup>13</sup> See, e.g., Mary J. Davis, *The "New" Presumption Against Preemption*, 61 *HASTINGS L.J.* 1217, 1228 (2010).

The very last chart—are there any swing votes? This chart, by the way, shows how many times in the 10 non-unanimous Roberts Court cases—ten non-unanimous cases—each justice was in the majority and which ways those cases went. The desired score in the rightmost column is zero. Justice Alito got there.

Just two quick observations. One is that Justice Thomas is quite clearly the outlier here. In his estimation, the majority, that is the Court, more often gets it wrong than right, and that is true regardless of which way the majority went, pro- or anti-preemption.<sup>14</sup> The second observation or guesswork from this chart is that there's much less block voting in these cases than, say, in civil rights cases. Notice the absence or rapacity of zeros or ones. You're not, in a civil rights case, going to find Justice Ginsburg cast a conservative vote, and the same is true on the conservative side, but that does happen in preemption cases, and it happens on both sides of the political spectrum.

So consequently, and that's my last point, there is no single Justice Kennedy swing vote, that is to say somebody who routinely throws the five-to-four majority this way or that and is in the majority all the time. The only Justice who was in the majority all the time on the Roberts Court was Justice Souter. And if Justice Sotomayor's inclinations are much different than his, that may have a very large effect in future cases.

Thank you.

**JUDGE PRYOR:** Thank you, Mike. Our next panelist is Alan Morrison. Alan is the Lerner Family Associate Dean for Public Interest and Public Service Law at the George Washington University Law School. In 1972, Alan Morrison teamed up with Ralph Nader to found and direct Public Citizen Litigation Group, the litigation arm of the consumer advocacy group Public Citizen. Over the span of his career, Alan has argued 20 cases before the Supreme Court of

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<sup>14</sup> Compare *Altria Group Inc. v. Good*, 129 S. Ct. 538, 551 (2008) (Thomas, J., dissenting) (arguing in favor of preemption), with *Geier v. American Honda Motor Co.*, 529 U.S. 861, 886 (2000) (Stevens, J., joined by Souter, Thomas, and Ginsburg, J.J., dissenting) (arguing against preemption).



the United States. He received his undergraduate degree from Yale College and his law degree from Harvard Law School, where he graduated magna cum laude and was a member of the law review. In between his studies, he served as a commissioned officer in the United States Navy. His early legal career includes working as an attorney at the Cleary Gottlieb firm in New York and as an assistant U.S. Attorney in the Southern District of New York.

Dean Morrison.

**PROFESSOR MORRISON:** Thank you very much. Thank you all for coming, and I'm not going to talk about very many of these specific cases. I want to step back and try to talk about a few more general principles. I think the only undisputable statement about the law of preemption is that it's a mess. There's plenty of blame to go around, and today I want to try to unbundle the blame and repackage it. I think, as a matter of law, the only thing we agree is that federal law trumps state law.<sup>15</sup> The big question, of course, in every case, is what is the meaning of federal law at issue here, and how does it intersect with state law?

Preemption is a great example of 'where you stand is where you sit'. My best guess is that I've been involved in many, many preemption cases and that about 75 percent of the time I'm opposed to preemption. That's largely because they have been in tort and consumer cases where the effect of the preemption is to wipe out the claim of the individual entirely with no compensation whatsoever, regardless of the merits.

However, when I was a general counsel of Public Citizen, I was much more in favor of preemption with regard to the various state registration requirements for charities. If you engage in interstate solicitation, states require you to file unbelievably onerous and different forms. They're not satisfied with the 990,<sup>16</sup> and they say, you

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<sup>15</sup> U.S. CONST. art. VI, cl. 2.

<sup>16</sup> "Form 990 is an annual reporting return that certain federally tax-exempt organizations must file with the IRS. It provides information on the filing organization's mission, programs, and finances." Form 990 Frequently Asked Questions, available at <http://www2.guidestar.org/rxg/help/faqs/form-990/index.asp>.

can't mail things without getting our approval. I thought the Postal Service decided what went through the mail, not the state Attorneys General. But I was honestly mistaken on that.

I worked on some voter registration matters last year. We passed a statute in 1993 that allows a federal organization to register people throughout the United States by using the federal forms.<sup>17</sup> States have come in and said, wait a second, you have to have your voters register with our state even though you're using a federal form. You have to register them even though they're not coming into our state but just mailing the forms in. You have to comply with the number of days and the number of hours for training for all of these people. It seems to me that undermines the federal form quite substantially.

And then in the Federal Election Campaign Act,<sup>18</sup> I supported others who were supporting the constitutionality of a statute that has federal preemption of contribution limits for state party activities in connection with federal elections.

And finally, and even in the tort area, I agree that when the Food and Drug Administration finally put meaningful labels on tampons to warn women about the dangers of using them, the Agency had made a considered decision that enough was enough and that we should not have states or lawsuits trying to change that regulation, because sometimes more is not better than less.

Looking at the actual cases that are being litigated, the question is always put in terms of legislative intent or, as Justice Scalia put it, the meaning of the words actually used.<sup>19</sup> The biggest problem with legislative intent is, of course, that Congress never thought about these questions at all, or if they thought about them, they thought about them only in the most general sense of the word without thinking through them. In many cases, they never gave it

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<sup>17</sup> National Voter Registration Act of 1993, 42 U.S.C. § 1973gg (2006).

<sup>18</sup> Federal Election Campaign Act of 1971, 2 U.S.C. §§ 431-457 (2006).

<sup>19</sup> See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 548 (1992) (Scalia, J., dissenting) ("[The language of express pre-emption provisions] should be given its ordinary meaning.").

a moment's consideration, and they surely never gave it any consideration except in the context of an alternative regulatory system. That is, they didn't want the states to engage in regulating the very same products in a primary way that Congress had set up an agency to do.

So my first item on my wish list is Congress, please think about these questions. No doubt, the Court will honor them if you make yourself clear and you do not overreach in either direction. There are no more excuses. There was a time when Congress could say, well, we never expected anybody would think that this was preempted as well as that. All of the issues are plainly teed up, and these are both regulatory preemption and what I'll call tort or common law preemption as well. They are not the same, and Congress needs to address them both.

Clarity alone, however, is not sufficient. There is a bill called the Consumer Financial Protection Act,<sup>20</sup> which sets up an independent regulatory agency that will regulate the consumer protection functions in the financial services and products industry. That bill provides that there is complete non-preemption. It is the most anti-preemption provision of all time. It says that the only time it's preempted is when it's inconsistent, but if a state gives greater protection, it is not, by definition, inconsistent.<sup>21</sup> That is a complete and total reversal of what's happened in the law of preemption, and it may be justified given what the banking regulatory agencies did.

I was in the Supreme Court when a case called *Smiley*<sup>22</sup> was being argued. Chief Justice Rehnquist leaned over the bench and spoke to the Solicitor General's representative and said to him, you know, I've been on this court for 23 or 24 years, and I have a question to ask you. Has the Comptroller of the Currency ever not sided

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<sup>20</sup> Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (to be codified in scattered sections of 12 U.S.C.).

<sup>21</sup> 12 U.S.C. § 5551 (2011).

<sup>22</sup> *Smiley v. Citibank*, 517 U.S. 735 (1996).

with the banks?<sup>23</sup> And of course, that's the perception that is driving both the bill and the anti-preemption provision.

As Michael pointed out, even an anti-preemption provision goes too far. There was a savings clause people may not remember in *Geier*. And the Court said, well, it can't really mean what it says because it would completely override everything else, and we don't think Congress meant that.<sup>24</sup> So even that won't be protective. On the other hand, in an ERISA case, when it went the opposite way and said everything was preempted, the Court from time to time would say no, no, they can't really mean it; everything is not really everything. And so you get a situation where the lack of really thinking through and clarity has been a serious problem.

So one alternative Congress could consider is delegating more of the responsibility to regulatory agencies either with a presumption in favor of preemption that can be removed, or presumption against preemption which can be added on if they do it specifically. The Medical Devices Act<sup>25</sup> in the *Medtronic*<sup>26</sup> case had a preemption provision with an option to exclude it.<sup>27</sup> The trouble was it was written in a way that appeared to apply only to affirmative state regulation, and it couldn't work because it was on a per-request basis for tort cases, so it didn't fit together. Congress had thought about one part of the problem and not about the other problem.

The last thing I want to say to Congress is if Congress is going to preempt claims by individuals who have been seriously harmed, somebody has to pay the costs. I'm not an economist, but I understand the costs don't evaporate just because the law says that you can't recover. So if we're going to put these costs onto somebody, if it's not going to be the manufacturer, then somebody else has to absorb it, and Congress is much more likely to get its preemption

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<sup>23</sup> Oral Argument at 46:58, *Smiley*, 517 U.S. 735 (No. 95-860), available at [http://www.oyez.org/cases/1990-1999/1995/1995\\_95\\_860/argument](http://www.oyez.org/cases/1990-1999/1995/1995_95_860/argument).

<sup>24</sup> *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869-871 (2000).

<sup>25</sup> Medical Device Amendments of 1976, 21 U.S.C. §§ 360(c)-(l).

<sup>26</sup> *Riegel v. Medtronic*, 552 U.S. 312 (2008).

<sup>27</sup> 21 U.S.C. § 360(k).

views honored if, in fact, it provides for some kind of alternative compensation system.

Second, what should the agencies do? I assume that agencies have the power, at least in some cases—I agree with Catherine Sharkey, who's going to come on in a minute—regarding the rules and procedures and their attempts to do categorical preemption. Preambles are out. They have to give notice. And there are a couple of very tricky questions about judicial review, which I hope she'll get into, particularly in the context of the tort cases. That, of course, takes care of new rules by having agencies prospectively deal with this problem in a more thoughtful and careful way.

What about existing rules? Well, we could say there's a clear statement requirement, but it's very hard to do that for existing rules. The courts might say, well, they could have expressed it clearly, and they didn't express it clearly, so there's no preemption. The trouble with that, of course, is it's true of every single piece of statutory or rule construction you can imagine. If only they had said it clearly, we wouldn't have a lawsuit. As favorable as that might be in terms of outcomes for me, I don't think that's a very sensible way of analyzing the preemption provision.

So, short of absolute, I think the courts ought to exercise caution, and the agencies ought to exercise caution. They ought to think about the results, and they should not preempt state laws absent significant interference—not some theoretical interference, but significant interference. If the agency tells you metaphorically to put your foot on the accelerator and the brake at the same time, companies have the right to say pick one or the other, but don't make me do both.

Finally, what about the courts? One surprise, which doesn't appear on Michael's charts, is that by and large, the Supreme Court has been less favorable to preemption than the Federal Courts of Appeals. Surprisingly so, certainly in the earlier days and even now today, the Federal Courts of Appeals have been very pro-preemption, and the Supreme Court has been, in my view, more balanced.

The courts purport to follow congressional intent. My own view is that they would do better if, instead of saying what Congress intended, because I don't think Congress intended much of anything, is to say, think about the statute, and what would Congress have done about preemption if they had actually thought about it?

Think about the tobacco cases. We're talking about 1965. Congress is coming in and going to create a new federal scheme on warnings on tobacco.<sup>28</sup> Nobody in the tobacco industry had the temerity to ask Congress for a preemption exemption at the time, and just imagine what would have happened if they did. And yet, a few years later they came in and said, in essence, every one of your tort claims was wiped out by a law that was intended to protect smokers, even from fraud. The courts stepped back and said, clearly that's not what Congress meant at all.<sup>29</sup>

Similarly, I think they went wrong in the Medical Devices Act. Here was a statute that was enacted for the purpose of protecting consumers in an area in which there had been no preemption before because there was no regulation; there was no alternative damages remedy. And the court came in and simply said it's all wiped out as far as new devices. It seems to me, without any substitute, that's a very difficult reason to understand.

Now, if you would acknowledge that there's some uncertainty, and it was not considered, and it was not overcome by a few awards, then what are you going to do? Well, there's a federal judge, who shall remain nameless, who once referred to what the Supreme Court was doing in this area as acting like a bunch of pettifogging grammarians.

It may not be quite that bad, but the attempt to turn around a major issue like this on a word or the absence of a word when nobody thinks that Congress really thought about the topic, let alone the words it was using, seems to me to be absolutely wrong, and the Court should step back and ask, does preemption make sense? Is it

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<sup>28</sup> 15 U.S.C. §§1334-1341.

<sup>29</sup> *Cipollone v. Liggett Group, Inc.*, 505 US 504, 530-531 (1992).

consistent with the purposes of the law? And if the agency comes before it and asks—when did the agency first say preemption? Was it when the case got to the Court or back at an earlier time? It ought to be more skeptical of agencies when they come late and less skeptical when they do it at the time of the initial regulation. I'm not saying that there should be no preemption and that agencies are sometimes not right and that defendants are sometimes not right, but I am very cautious that preemption is often far broader than it needs to be.

Now at this point, this is my take away. If the students were in the classroom, they would take out their pads and pencils or get out their computers and start playing court stenographer. I think we need a fresh start. It's not just the courts but Congress and the administrative agencies. We have to think through preemption in a way that hasn't been thought through in the past.

Thank you.

**JUDGE PRYOR:** Thank you, Dean Morrison. Our next speaker is Professor Cathy Sharkey. Catherine Sharkey is a professor of law at New York University School of Law, where she is one of the nation's leading authorities on federal preemption and products liability law. Her scholarship has been cited by numerous federal appellate and trial courts. Most recently, her work was cited by Justice Ruth Bader Ginsburg in her dissent in *Riegel v. Medtronic*<sup>30</sup> on the issue of the relationship between a product manufacturer's compliance with federal safety regulation and its potential exposure to tort liability. She will join Professor Richard Epstein as co-author of one of the leading torts casebooks and is a co-editor with Professor Saul Levmore of the second edition of *Foundations of Tort Law*.<sup>31</sup>

Professor Sharkey earned her bachelor's degree in economics *summa cum laude* from Yale. She also earned her law degree from Yale and obtained a Masters of Science in economics for development

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<sup>30</sup> *Riegel*, 552 U.S. at 345 citing Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J. LAW & POL'Y 1013, 1024 (2007) [hereinafter Sharkey, *Federalism in Action*].

<sup>31</sup> *Foundations of Tort Law* (Foundation Press 2nd ed., 2009).

with distinction from Oxford. She clerked for Judge Guido Calabresi on the Second Circuit and Justice David Souter on the Supreme Court.

Professor Sharkey.

**PROFESSOR SHARKEY:** Thank you, Judge. You can tell from my short bio, if my talk on preemption were that I stand where I sit, it would be very boring because I sit in the academy, so I don't have a particular client-driven position on this. But I do want to pick up on what both Michael and Alan were saying.

First, preemption, to me, is such a fascinating area because it involves Congress, the courts, and agencies. Unlike Alan, I don't put a lot of faith or stock in Congress. I think Congress has repeatedly punted on the issue of preemption, and federal and state courts face these issues and have to address them. The main drive of my work has been trying to figure out an analytic framework for courts to use in this area that, as Alan pointed out, is a muddle or in chaos.<sup>32</sup>

I think this matters because in the work that I've done, particularly in products liability preemption and with specific focus in the pharmaceutical and medical device area, you can actually see that differences between state and federal courts' analytic models can lead to very different outcomes.<sup>33</sup> For example, the idea that state and federal courts are both interpreting the same federal statute but would follow very different analytic models seems worthy of discussion.

The two factors that I would like to put on the table that maybe I can't say are explanatory factors for Michael's study but they might be worth talking about are, one, the presumption against preemption, and two, the role of the underlying federal agency. So

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<sup>32</sup> Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008) [hereinafter Sharkey, *Products Liability Preemption*]; Catherine M. Sharkey, *Federalism Accountability: "Agency-Forcing" Measures*, 58 DUKE L.J. 2125 (2009) [hereinafter Sharkey, *Federalism Accountability*]; see also Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437 (2009).

<sup>33</sup> See Sharkey, *Federalism in Action*, *supra* note 30.



on the presumption against preemption, what's interesting is that this gets trotted out as a kind of default statutory interpretation canon. One would have thought that maybe judges would need this kind of default presumption in cases of implied preemption as opposed to express preemption.

But in the products area at least, that presumption gets trotted out more often in the express versus implied cases. So, that could be—again, I'm just being speculative and provocative in response to Michael's queries—but that might explain liberals being less likely to find preemption in the express preemption context.

I find the presumption against preemption extremely problematic. It's deployed very haphazardly. It seems to be trotted out in certain cases and mysteriously missing in others. Many scholars and commentators have agreed with this assessment and then said, "so what?" I like the agreement; I don't like the "so what?" The presumption against preemption matters because again, in case studies that I've done, you could see how the presumption is often outcome-determinative. And in particular, I discerned at least some slight differences between state and federal courts in the area of drug preemption, with state courts more likely to deploy a presumption against preemption and more likely to give it definitive weight.<sup>34</sup>

And so, we should decide whether or not this presumption against preemption should exist, what kind of weight it should have, and it shouldn't differ between, say, state and federal court judges. My own normative view is that I don't see any reason why we should have a presumption against preemption. There are certain arguments about political process. For example, if you have a strong anti-preemption default rule, this would lead to better discussion putting the issue before Congress.<sup>35</sup>

I started my remarks with my lack of faith in Congress solving these particular issues, but, in general, my response to that

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<sup>34</sup> *Id.* at 1017-18.

<sup>35</sup> See Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. REV. 1 (2007).

argument is that you could likewise have a very strong default rule in a pro-preemption direction, and likewise, you would energize various actors to come out of the woodwork and debate the issue if that were your main desire.<sup>36</sup> So I think that the presumption against preemption does not help us that much.

The second factor I want to mention is the position taken by the underlying federal agency. In the products liability cases, this has turned out to be a significant factor. In fact, in every products liability case starting with *Cipollone* up to the present, with a couple of exceptions I'll mention, the end position of the Supreme Court, whether it found in favor of preemption or against preemption, aligned with the underlying view urged before it by the federal agency.<sup>37</sup>

In some of the cases, there was cryptic reference by the U.S. Supreme Court to input from the federal agency. The U.S. Supreme Court has repeatedly ducked the issue about whether or not an agency's position on preemption should get *Chevron*<sup>38</sup> or mandatory deference or something more akin to *Skidmore*<sup>39</sup> power of persuasion. They alluded to the latter in *Wyeth*,<sup>40</sup> but in *Cuomo*,<sup>41</sup> for example, the banking case where they could have addressed this

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<sup>36</sup> See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 254-56 (2007).

<sup>37</sup> Sharkey, *Products Liability Preemption*, *supra* note 32, at 471-72; Sharkey, *What Riegel Portends*, *supra* note 32, at 441 & n.20

<sup>38</sup> *Chevron, U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

<sup>39</sup> *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). In *Skidmore*, the Court enunciated a standard for deferring to agency interpretations of statutes. Justice Jackson, writing for a unanimous Court, stated that "rulings, interpretations and opinions . . . while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." He emphasized that, when considering how much deference to give an interpretation, courts should weigh "the thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Id.* at 140.

<sup>40</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009) ("The weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness.") (comparing *United States v. Mead Corp.*, 533 U.S. 218, 234-35 (2001) with *Skidmore* at 140).

issue, they decided not to.<sup>42</sup> In *Watters v. Wachovia*,<sup>43</sup> a previous banking case, they decided not to address it.<sup>44</sup> I think the fractured nature of this factor, of what level of deference individual justices would accord to agency preemption, may possibly explain some of the variation among justices in Michael's findings. In other words, this is an issue on which those justices are very, very divided.

My own normative view is that these questions of preemption are going to fall in the hands of court. I think that paeans for Congress to solve these problems aren't going to get us anywhere. While it's true that Congress may not have originally, in the '60s and '70s when enacting some of these statutes, thought about these issues, as Congress has amended these statutes and as they are on the table today with rife tort litigation in the background, Congress is still not addressing the regulatory interplay.

So courts are going to have to handle these kinds of issues. I think they shouldn't rely on a presumption against preemption. I think courts should look squarely at the issue of whether the regulating federal agency has regulated the precise risk that the state tort law would be trying to regulate as well. And in those instances, there should be preemption.

So I think courts should take seriously the information that comes before them from the agency. By this, I don't mean just a litigation position, whatever the agency says. Courts should look into the record of the regulating agency and should look to the regulatory review. And in those instances, again, where basically the state tort law claim would be duplicating the agency's effort, you would have preemption. And otherwise, you would not.

I would argue that *Wyeth* leaves that kind of review open, and in fact maybe encourages it to some extent.<sup>45</sup> I think if this were

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<sup>41</sup> *Cuomo v. Clearing House Ass'n, L.L.C.*, 129 S. Ct. 2710 (2009).

<sup>42</sup> Catherine M. Sharkey, *Against Freewheeling, Extratextual Obstacle Preemption: Is Justice Thomas the Lone Principled Federalist?*, 5 N.Y.U. J. L. & LIBERTY 63, 106-07 n.230 (2010).

<sup>43</sup> *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1 (2007).

<sup>44</sup> Sharkey, *supra* note 42, at 105 n.226 (citing *Watters*, 550 U.S. at 20).

<sup>45</sup> Sharkey, *Federalism Accountability*, *supra* note 32, at 2180 n. 222.

followed as a kind of framework, it would lead to a kind of rationality being imposed on both state and federal courts as they are doing this kind of statutory interpretation.

Thank you.

**JUDGE PRYOR:** Our final panelist is Daniel Troy. Dan is the Senior Vice President and General Counsel at GlaxoSmithKline. He was previously a partner of the Life Sciences Practice and Appellate Litigation Group at Sidley Austin, where he regularly represented pharmaceutical and biotechnology companies before the Food and Drug Administration and other federal agencies. He is the former chief counsel of the Food and Drug Administration. Before serving as chief counsel, he was a partner at Wiley, Rein & Fielding here in DC. He has argued more than a score of cases in federal and state courts of appeals and has had a successful argument in the Supreme Court of the United States. He is published widely. He is a graduate of Cornell University School of Industrial and Labor Relations and has his law degree from Columbia Law School. And from 1983 until 1984, Mr. Troy clerked for circuit Judge Robert Bork of United States Court of Appeals for the DC Circuit.

Mr. Troy.

**MR. TROY:** Thank you. It is an honor to be back here at the Federalist Society. It's an honor to be on the panel with such deep thinkers who think such deep thoughts. I'm now just a practical lawyer trying to muddle through deciding what cases to fight and what cases to settle, so I want to be very clear: I'm speaking on my own behalf, not on behalf of GlaxoSmithKline. I want to basically make just a few comments and then throw open a couple of hypotheticals. Since I've got free expertise here, I really want to take advantage of it.

Let me be very clear, my expertise is in the pharmaceutical sector, so I'm going to be approaching preemption particularly from that perspective.

Some people often ask what my thoughts are on *Wyeth v. Levine*. I view it, at least particularly from now where I sit as a missed opportunity for the pharmaceutical sector in the sense that before the debate about preemption, preemption was not a tool that the

sector really had to fight off product liability. It relied on causation and a wide variety of other arguments. And I'm not sure we're completely back to where we were from the start. In fact, I think Catherine's ending remarks are very hopeful to me, so I think there's maybe a little bit more room. But obviously, the opportunity that *Wyeth v. Levine* or the effort presented is one that did not come to fruition.

So where I find myself, for any of you who are expecting fireworks here at the Federalist Society, is in incredible agreement. I mean, who can disagree with Alan Morrison? There's not a word that he said that I disagree with. He made a plea for clarity with respect to Congress; well, amen to that. I also agree with Catherine that I wouldn't hold my breath waiting for that. I completely agree with Alan that the kind of anti-preemption urge in Congress has gone way too far.

I agree that I'd like to see this delegated to the agencies. I do think that they should exercise caution and should not necessarily preempt unless there is significant interference by the state regime with their decisions. I am delighted to hear, and wish it were the law, that companies have a right to say, don't make us put our foot both on the accelerator and the brake at the same time because we feel as if we're asked to do that all the time. I'm delighted for the call for a fresh start, although again, I'm not holding my breath about that.

I agree almost entirely with everything that Catherine said. I think that the presumption against preemption is deployed really haphazardly and is cited really as a post-hoc justification rather than as an analytic framework. And, normatively, I agree that we shouldn't have one. I mean, it doesn't really make any sense. If you have federal agencies, then you have very invasive federal regimes like the Food and Drug Administration, where you cannot test a drug, sell the drug, or say anything about the drug without getting the Agency's approval, then why we should have duplicative state regulation through the tort system has always been a mystery to me. And why you should have a presumption against preemption,

if you have the Supremacy Clause and if you have Congress exercising power in that arena, has always been a mystery to me.

And Dr. Greve has a fabulous analysis that I won't even hope to repeat but I will invite him to share, about how you end up with what is basically duplicative regulation rather than one regime or the other.

Catherine and I have even agreed that agencies should get *Skidmore*, not *Chevron*, deference on these issues. I do think that courts should take seriously the regulatory review that the agencies have done and not allow duplicative state law. And again, I'm delighted to hear that she thinks that *Wyeth* does leave open a variety of these preemption questions, especially whether or not the state tort law is duplicating the federal regime.

And I do think that there is still some room in the fact that the Court asked for the SG's [Surgeon General's] views in the vaccine injury compensation case, which I'll come to in a moment. It is a hope to me that at least there is still some room for preemption in what I'll call my space, or the pharmaceutical space.

And the last point—and I've always thought this—is that the rational approach, which is not to say that Congress is going to adopt it in my lifetime, would be to have some kind of alternative injury compensation fund. Why? We have this in vaccines, and we'll talk about this in a second. But when the FDA puts a product on the market, it knows to a virtual certainty that there are certain people who are going to be harmed by that product through no fault of theirs or ours.

So let's take statins. GSK does not market one, so I'm not marketing anything.

When the FDA approved statins, which, according to Bob Temple, the architect of the new drug approval regime in FDA, was the most remarkable public health advance in the United States or indeed in the public health arena over the last generation or so—(If you're not on a statin, you should talk to your doctor about being on one; again, we don't market one. That's what Bob Temple says: I'm not a doctor; I don't play one on TV.) the FDA knew that a certain number of people would get a

pretty debilitating and potentially almost fatal condition called rhabdomyolysis, a terrible condition. The number of people who would get that would be in the scores. The number of people who would be benefiting from statins is in the tens of millions. So the question is, is it fair for those 50 people who bear that cost, that burden, that injury through, no fault of anybody's—it's just a natural consequence of the product—for them to have to bear those injuries for the benefit of the tens of millions of people? I guess I would argue no. You can really see why, as a public policy matter, they would be entitled to some measure of compensation, or at least their healthcare costs (we'll leave aside the health care reform debate) should be covered.

Instead, what we do is we rely on the lottery called the tort system, which does not operate in a fair or science-based manner. So to turn to my sort of hypotheticals to ask the group for help, I have two situations, and one of them—I'll be generic if I may use that word—we have a drug, which is a very useful drug. There's a controversy about it with respect to a safety issue. We have proposed a supplement. We want to disseminate information about its safe use. There is a fight, a struggle between two parts of the federal agency, and this is a prior approval supplement, so unlike a "changes being effected" supplement where we can do it and then wait for the FDA to say yes or no, in fact we are out there. We are not allowed to change the labeling without the FDA's prior approval.<sup>46</sup>

We went to the agency a long time ago and said here's what we think should be out there. We have asked them a number of times, please, can you give us an answer? Can you let us at least disseminate this? Well, one part of the agency thinks this is the right response, and another part of the agency thinks, no, you need something much more draconian, and the agency is completely in deadlock. We have been waiting months and months and months and months and months for an answer.

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<sup>46</sup> See 21 C.F.R. 601.12(f) (2011).

Now, when I was outside counsel, the advice I would give was, well, make sure you get the agency in writing on that. Well, guess what. They won't put it in writing either. All they'll say is do not do it. So what do I do? And if I follow what the agency is telling me, should I really be able to be sued during this interregnum when we've proposed labeling to the agency, and they've just told us not to do it? Now, I'm going to have records that say the agency told us not to do it, but do I have a letter from the agency telling me that they'll sue me and they'll destroy me if we don't do what they told me to do? No, I don't have that.

Okay, so I'm put to a Hobson's choice. Do I directly contradict, A, the law because it's a prior approval supplement and, B, the FDA telling me not to do this? Or I am open to product liability claims for this for the presumed interregnum period. I mean, obviously, we will argue against that quite strongly, and I think we'll win, but you get the point. So what do I do? That's question one.

Question two is, let's take the problem many of us are dealing with, the issue now of vaccines. We do market a swine flu vaccine, but not here in the United States. And one of the reasons why there have been some delays, let's just say, in the swine flu production is because if you use a 10-vial dose or a five-vial dose, you have to put in a preservative. The preservative that everybody uses is called thimerosal. Thimerosal has been used in vaccines since at least the '50s; maybe the '30s. It has a little bit of mercury in it. The National Academy of Sciences has said there is no connection between the mercury in thimerosal and autism, and so has a court, a tribunal in HHS, issuing a many-hundred-page decision.<sup>47</sup>

That said, there is controversy out there in the arena on whether or not thimerosal does cause autism. And so we could take the most restrictive approach or the most risk-adverse approach and only have single-unit dose vials. Well, guess what? More expensive;

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<sup>47</sup> See *Cedillo v. Sec'y of Health and Human Servs.*, Case No. 98-916V,, 2009 WL 331968 (Fed. Cl. Feb 12, 2009); *Hazlehurst v. Sec'y of Health and Human Servs.*, Case No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb 12, 2009); *Snyder v. Sec'y of Health and Human Servs.*, Case No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb 12, 2009).



more costly; takes a lot more time to fill. You go to five-dose vials, ten-dose vials, you need thimerosal. The government has ordered this product. We deliver the product to the government; they are the ones who disseminate it.

So the second question: Should we be able to be sued when and if someone gets a swine flu vaccine and later—God forbid it shouldn't happen—but if they happen to contract autism? So with that, I will close and ask guest panelists for free legal advice, which I love.

**JUDGE PRYOR:** Well, it sounds like we have unanimity on at least a couple of different points. There's unanimity that the law of preemption is a mess. There's unanimity, I think, that we need a fresh start. There may even be unanimity that the presumption against preemption is not very workable or useful. But what do our panelists have to offer—and Dr. Greve, this is your opportunity to be provocative—in terms of what a fresh start should look like? And do you want to answer Mr. Troy's questions as a useful framework for that?

I'll start with you, Dr. Greve.

**DR. GREVE:** Actually, I've written a little bit about what a fresh start looks like, the conclusion to the book<sup>48</sup> Richard Epstein and I did on federal preemption, the conclusion obviously written by Richard and myself. I stand by every word he thought. That is a sort of reasonable start. There are other contributions in that volume that I think are very, very helpful in thinking about these questions, including the contribution by Sam Issacharoff and Cathy;<sup>49</sup> another one by Ashley Parrish and Rob Gasaway,<sup>50</sup> who's in the audience. It would take a long time to sort of try and lay it out in any great detail.

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<sup>48</sup> Federal Preemption, *supra* note 2.

<sup>49</sup> Catherine Sharkey and Samuel Issacharoff, *Supreme Court Preemption: The Contested Middle Ground of Products Liability*, in Federal Preemption, *supra* note 2.

<sup>50</sup> Robert R. Gasaway and Ashley C. Parrish, *The Problem of Federal Preemption: Toward a Formal Solution*, in Federal Preemption, *supra* note 2.

I will say by way of sort of trying to spark controversy, maybe not on the panel but with the audience, I will say this. I share the sense of, wow, I have now found brothers and sisters in arms because I entirely agree that this search for magic words, as Alan rightly calls it, has gotten out of hand. I totally agree that the standard refrain, "Let's get clarity from Congress," is childish beyond belief.

What is significant and demoralizing in this context is that so far, and I'd be interested in people's reaction to this, so far as I can see, the Supreme Court is moving in exactly the opposite direction. There's ever more attention to magic words, indefinite articles, express preemption provisions, and a pretense that no, no, no, if we could just get rid of any purpose in law, if we could just talk about preemption as if Congress had no purpose, we just analyze and pettifog over the precise phrases it uses, we're going to get the questions right. That is so dangerously wrong that I can't believe it's happening.

But it is happening. It is coming from Justice Thomas. It is coming from Justice Scalia, it is coming from some other unlucky quarters. It is making an even bigger mess of things, I'm afraid. And the frightening thing is that those justices think that they are making theoretical progress, whereas I think what you really have to do is step back and ask what this is actually about? This is a form. At the end of the day, this isn't statutory interpretation, that is a large part of it. It's not about agency deference, although that is, too, and part of it.

At the end of the day, this is preemption law. To make any sense of the world at all, it has to be sort of a form of federal common law if you will. That's not a popular thing to say in these hallways, but it's the truth of the matter. And so what you want to do is come to grips with that insight and then try to get the analytics right. A lot of people on the panel here have worked on that, and I wish us all success.

Just one more thing. Speaking of which, I think your second problem is not a preemption problem. I think it's a *United States v.*

Boyle<sup>51</sup> problem, and I hope it falls under that, and I hope that case is still good law.

**PROFESSOR MORRISON:** If the Government buys it, especially, yes.

You know, I'm actually rather disappointed in this program because I come to the Federalist Society programs and expect to have a big fight, and everybody disagrees with everything I say, and I come out saying, well, that's a good fight; we got some people energized. This agreement is no fun. I mean, it's just not any fun anymore. So let me just try.

**JUDGE PRYOR:** Well, there still is an opportunity.

**PROFESSOR MORRISON:** All right, so let me just try.

The presumption against preemption is actually used in two ways. When they've already reached a conclusion, they put it in there, or they put it in there and say there is a presumption against preemption, but . . . ["dot dot dot"] it doesn't apply in this case because it's Tuesday, or it's December, or any other similarly persuasive reason. Or there's a strong federal interest, as if that isn't the argument in every case. Not the answer to the question. I guess I would say, the rest of the panel may be right, that it's too much to ask Congress to do anything about any of this, but at least we ought to recognize that Congress isn't doing anything about it and, as Michael just said, stop pretending that they're actually deciding these questions and look more broadly.

However, when we get to the agency level, I think we can expect the agencies to focus on this because it can be an important part of the regulatory function, whether we're talking about specific product approvals or we're talking about rules or standards as a general matter. So I would go a long way toward saying I would give the agencies lots of deference, provided they had adequate notice and a clear statement of what is preempted and what is not preempted, not simply coming out and saying everything in the world is preempted because that's essentially what Congress has done.

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<sup>51</sup> 469 U.S. 241 (1985).

Now, the last point—I want to turn to the request from Dan. I have an academic colleague who has at the bottom of his email, “If this were legal advice, it would be accompanied by a bill.” So this is not legal advice, Dan, but the first thing I would do is, if they won’t write you a letter, write them a letter. Say to them, we are specifically abjuring from doing this because you have told us ‘you can’t do it.’

Second question on that is—

**MR. TROY:** Done that.

**PROFESSOR MORRISON:**— well, then you have something, and to send it certified mail/return receipt requested.

The Second question I ask is, are you forbearing from sending “Dear Doctor” letters out about that? That is not labeling, and one of the points that’s been made in all of these prescription drugs cases where the issue was one of warning is that there’s nothing, I think, that forbids you, even in those cases where you have to get prior approval, from sending a letter to the doctor that says, by the way, you at least ought to think about this; some people think it ought to be more than that, but you ought to at least think about that.

After all, the FDA can’t regulate doctors. They don’t regulate doctors when they do off-label prescriptions. I can’t imagine—maybe they can. They can tell you that you can’t send a letter to the doctor, and maybe that’s a free speech case that you take up, Dan.

**PROFESSOR SHARKEY:** So, one quick recap just on the presumption against preemption and whether it matters because I think I do disagree. Let me give another provocative example.

In the hands of state courts, one thing we have to remember is that in every single state, save one, Michigan, the regulatory compliance defense, which is the state-based affirmative defense in these kinds of areas, is not dispositive. So if you show that you complied with the FDA regulations, it’s merely some evidence of non-negligence. So state courts that regularly encounter this kind of regulatory compliance defense will often perceive preemption as a blunter form of the compliance defense. And the presumption against preemption is an enormously powerful weapon for them to

wield in these kinds of cases to then determine, without doing any further analysis, that there's no preemption. And that's why I disagree with Alan's position on the presumption that says, well, it's there, but it never does any particular work.

Particularly when you look at state court cases, it's really revealing. Many of these cases will invoke the presumption against preemption, and then they'll cite all the regulatory compliance defense state law tort cases supporting their view against preemption. So I think it does matter.

In terms of how I look at these things with a fresh start, I've come up with what I call an agency reference model, and this relates to Dan's first question because in this model, what it requires is that courts scrutinize the agency regulatory record.<sup>52</sup> Dan provided a provocative example where the defendant manufacturers might be in an uncomfortable limbo period. Another example just to put forward: this same issue arose when the notice and comment period went out on the "change being effected" rule for drug labeling.

Johnson and Johnson submitted a comment to the FDA at the time saying, when you weigh in on our change being effected when we want to change the label, please respond in writing what your reasoning is as to whether you're accepting this or not. The FDA just blew it off. In their response, they said, no, and we don't really see why that is relevant.<sup>53</sup> Well, that's pretty shocking to me, because I think that's sort of the name of the game going forward.

So likewise, this isn't going to be very good legal advice. I think you're in a bit of a bind. I think you need to make the best record possible. My sense is post *Wyeth*, these agency regulatory record issues are being litigated in a way that they weren't as much before. So you know, you push that forward and then make new law.

**MR. TROY:** Just what I'm here to do. That's what my CEO wants to hear: But we'll make new law.

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<sup>52</sup> Sharkey, Products Liability Preemption, *supra* note 32, at 452; Sharkey, Federalism Accountability, *supra* note 32, at 2189.

<sup>53</sup> Sharkey, Federalism Accountability, *supra* note 32, at *id.*

**PROFESSOR SHARKEY:** Cite my article. That'll get you really far.

**MR. TROY:** Putting on my former FDA hat for a moment, the reason why the agency—to poke Catherine—blew off the suggestion that it respond is they get about 3,000 “changes being effected” supplements per year. That's a different number than the prior approval supplement where change is being effected, I do it, I tell the agency, and they have to object. With prior approval, they have to tell me before I can move forward.

You have an agency that is 10,000 people regulating 25 percent of the American economy, completely overwhelmed, besieged, beleaguered, attacked all the time, and on top of that, was just given the responsibility for regulating tobacco. (That made a lot of sense.) And so the people we're talking about are the scientists who are in charge of ensuring that the drugs are properly labeled, keeping up on the science, et cetera. The reality is that the lawyers and the legal system and *Wyeth v. Levine* and their discussion about the agencies and their expectations of the agencies are a complete disconnect from the reality of the agency.

So maybe the lawyers might think about preemption, but if you're a scientist, all you care about is making sure that the labeling is in accordance with the state of the art in terms of the science. You don't care at all about, and you don't even know what, preemption is by and large.

These are brilliant people, Ph.D. scientists. The FDA has more MD/PhDs per capita than any other agency in the federal government, but they think as scientists. They don't sit there and think, oh, well, I need to respond in order to give them a preemption argument.

So when Justice Breyer or Catherine or Alan says, well, I will give the agencies lots of deference if they provide notice and comment, and they really make a formal legal finding. Well, that's just not the way the interactions between the companies and the agencies work on a day-by-day, product-by-product basis, and it would absolutely paralyze the agency if every time they made a decision on a product-specific basis, they needed to promulgate a rule. It's a

paradigm that the device law kind of tried to flirt with, but it's totally impossible and nonoperational on a day-by-day basis.

So we certainly have written them letters. And you make an interesting point, Alan, about your doctor letters, but guess what. The FDA's definition of legally includes "Dear Doctor" letters, Power-Point slides, anything that has a textual connection to the product under the *United States v. Kordell*<sup>54</sup> case from the 1940s.

Now, there is a free speech challenge that Allergan has teed up, a very broad First Amendment challenge that Allergan has again teed up against the agency, literally taking issue with the agency's ability to prohibit off-label uses.<sup>55</sup> That's pretty broad.

**PROFESSOR MORRISON:** That wasn't my challenge. I was talking about sending "Dear Doctor" letters.

**MR. TROY:** Right. Okay, but you should understand that—again, the horns of the dilemma. The agency says that "Dear Doctor" letters are labeling and within their jurisdiction. And indeed, everybody thinks that the Bush FDA was the first one to assert preemption, even in courts. The first preemption brief that we looked at was actually filed by the Clinton administration, the Clinton Justice Department, in a case called *Pfizer v. Bernhardt*.<sup>56</sup> And what happened was the plaintiffs in that case sought the remedy of forcing the company to send out a "Dear Doctor" letter. And guess what. The Clinton Justice Department came in on behalf of the FDA and said, that's our province; sorry, no.<sup>57</sup> You may not go to a court and ask a court for that, and that issue is preemptive.

So again, although many people think that it was the Bush FDA that started these targeted interventions, that was —

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<sup>54</sup> 335 U.S. 345 (1948).

<sup>55</sup> Allergan dropped their First amendment lawsuit against the FDA in September 2010 as part of their settlement negotiations with the Department of Justice concerning off-label uses of Botox. See Press Release, Allergan Resolves United States Government Investigation of Past Sales and Marketing Practices Relating to Certain Therapeutic Uses of BOTOX(R) (Sept. 1, 2010) available at <http://agn.client.shareholder.com/releasedetail.cfm?ReleaseID=503974>.

<sup>56</sup> 2000 WL 1738645 (S.D.N.Y. 2000).

<sup>57</sup> See Statement of Interest Of the United States, *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645 (S.D.N.Y., filed Nov. 13, 2000) (Nos. 00 Civ. 4042 LMM).

**PROFESSOR MORRISON:** That, of course, is the line between regulatory preemption and tort preemption.

**MR. TROY:** Yes.

**PROFESSOR MORRISON:** And I did not intend to suggest that.

**MR. TROY:** Okay.

**PROFESSOR MORRISON:** That is an important line, and I view the issues rather differently in that context.

**MR. TROY:** Okay. So, the last point. You suggested, Alan, that, well, if the agency has come lately to it, then maybe we should give the agency less deference. I actually think, in at least my practical experience, the agency, at least the FDA, got a lot more deference—and I would be interested in your views or whether it should—when it came in on a case-by-case basis and said, we have looked at the specific question, and in this case, we believe there should be preemption. Most of those cases, when the FDA got involved on a targeted case-by-case basis, the federal courts, or in one case the California Supreme Court,<sup>58</sup> ended up giving the agency deference.

It was when the strategy was tried—By the way, the preemption preamble came out 2006.<sup>59</sup> I left in 2004.

When the preemption preamble came out, that was an attempt to, instead of going on a case-by-case basis, which was very resource intensive, to deal with it in a broader way, and we know what the fate of that was in *Wyeth v. Levine*.<sup>60</sup> So I guess I'd be interested in your views. I mean, it would seem to me that if the agency has made a specific decision in a specific case and explains

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<sup>58</sup> *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004).

<sup>59</sup> See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

<sup>60</sup> The Court in *Wyeth* refused to give deference to the preemption preamble because of perceived procedural defects. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009) (“Under [the *Skidmore*] standard, the FDA’s 2006 preamble does not merit deference. . . . In 2006, the agency finalized the rule and, without offering States or other interested parties notice or opportunity for comment, articulated a sweeping position on the FDCA’s pre-emptive effect in the regulatory preamble. The agency’s views on state law are inherently suspect in light of this procedural failure.”).



why in a particular case they think their ox is gored by the state regime, I would think that would get more deference, not less.

**PROFESSOR MORRISON:** Well, I think the problem is that it looks—especially when they come in at the very end of the case like they’re results-oriented, and the early aspect is explaining what they’re doing and why they’re doing it, at the beginning, to indicate, as in the tampon labeling case for example, that more is not necessarily better.

It seems to me that’s the problem, that you have them coming in and saying—well, take *Geier*, for example. I would have had no trouble with the outcome in *Geier* if the agency had thought about preemption and said, you know, we don’t want anybody to force anybody to do it. This is important. It said, even in the rule, instead of making it up 25 years after the fact, that the reason we gave people an option was because we wanted compliance on all the things they ultimately said in the Supreme Court, which they completely made up. I think they should have to say it at the time they make a decision, whether they use preemption magic words or not. But the rationale at least has to be there. And then you don’t think that they’re deciding it based on who they want to win a particular case.

**PROFESSOR SHARKEY:** Yes, I agree with Dan that the case-by-case intervention, at least empirically, seems to hold. Actually, this is where there also is a difference between state versus federal court. The FDA is more likely to intervene in federal court versus state court. Also, federal courts are more likely to call for the views of the federal agency versus state courts. Federal courts are more used to seeing federal agencies before them on a whole host of issues.<sup>61</sup> Informally, various judges have also confirmed this kind of difference that comes out empirically in the cases.

Maybe you two are talking past each other. I think it’s a slightly different question with respect to when, in that case-by-case intervention, the court is reviewing what the agency is saying. What is it based on? Is the agency just coming up with some “litigating” position, or

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<sup>61</sup> See Sharkey, *Federalism in Action*, *supra* note 30, at 1037.

can they show a regulatory record to say this is a risk that we really looked into, et cetera.

Very interesting to me is the post *Wyeth* case involving SSRI antidepressants, *Colacicco*. It was decided by the Third Circuit,<sup>62</sup> got remanded back to the Third Circuit after *Wyeth*,<sup>63</sup> when the U.S. Government then withdrew its amicus brief in favor of preemption.<sup>64</sup> I think that the withdrawal of the U.S. position is part of what made the Third Circuit just remand it back to the district court.<sup>65</sup> The position of the United States, representing the FDA, in that kind of case, on how closely they were looking at the risks in the SSRI context would be very, very important.

**MR. TROY:** That is one of our cases. That is a GSK case. Again, the tension is the agency makes this decision not in a formal rule-making context. The reviewers make these decisions on a day-by-day basis. Then there's the litigation. And the question at what point should the—I guess I'm struggling with at what point does the agency need to get involved in order to get this level of deference? By definition, if it's getting involved after the litigation has commenced, then you could, Alan, accuse it of picking winners and losers, but before the litigation there isn't really a preemptive action to take.

Now, the SSRI case that Cathy mentions, the FDA, time and time again, including in public fora and in the rejection of citizen petitions, including some by Public Citizen, said we do not believe

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<sup>62</sup> *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3rd Cir. 2008).

<sup>63</sup> 129 S.Ct. 1578 (2009) (“Judgment vacated, and case remanded to the United States Court of Appeals for the Third Circuit for further consideration in light of *Wyeth v. Levine*.” (citations omitted)).

<sup>64</sup> See Letter from Sharon Swingle, Appellate Staff Attorney, Department of Justice, Marcia M. Waldron, Clerk, Third Circuit Court of Appeals, Apr. 28, 2009 available at <http://www.ahrp.org/cms/content/view/583/1>; see also posting of Frommer Lawrence & Haug to FDA Lawyers Blog, Generic Drug Labeling – Are Generic Drug Manufacturers Responsible for Petitioning for New Warnings? <http://www.fdalawyersblog.com/2010/11/generic-drug-labeling--are-gen.html> (Nov. 30, 2010).

<sup>65</sup> *Colacicco v. Apotex*, 2009 WL 4729883 (E.D.Pa. 2009) (On remand, the Third Circuit vacated its judgment, and remanded the case back to this Court for further proceedings consistent with *Wyeth*.” *Id.* at 2).

you should have a suicidality warning on these antidepressants. And the argument was that the agency, to use the language of *Chevron*, has directly spoken to the precise question at issue, and where that is true, there should be preemption.<sup>66</sup> The Third Circuit had said yes post *Wyeth*.<sup>67</sup> I guess we're at a fresh start.

**JUDGE PRYOR:** One question, and then we're going to start inviting questions from the audience. There is a microphone in the center of the room. I'm stunned that Roger Pilon is the first to approach it.

**DR. PILON:** I'll try not to disappoint.

**JUDGE PRYOR:** But I will ask that those who approach have a question in mind, as opposed to a speech.

The question I was going to ask first, Dean Morrison, is you mentioned that federal courts of appeals are, in your experience, more likely to favor preemption to the Supreme Court. Do you have an—maybe I have a personal interest in this—do you have an explanation for that? And could it be that the reason is just the mix of cases the federal courts of appeals are more likely to see, which I guess would be more likely, actually, to involve the agency as a litigant, whereas the Supreme Court is exercising jurisdiction over cases not only from the federal courts of appeals where agencies are involved but from state supreme courts and from the state court system, and therefore, there's just the result of a different mix of cases? Or is there some other explanation?

**PROFESSOR MORRISON:** Well, I actually probably should have qualified my statement because I haven't looked at in the last few years. Certainly, it was very true in the tobacco area, where state courts rarely found the kind of preemption, they found some sort of

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<sup>66</sup> See, e.g., *Colacicco*, 521 F.3d at 269 (“Not only has the FDA filed an amicus brief in the *Colacicco* action but it has repeatedly rejected the scientific basis for the warnings that *Colacicco* and McNellis argue should have been included in the labeling. The FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.” (internal citations omitted)).

<sup>67</sup> See *Colacicco*, 2009 WL 4729883 (E.D.Pa. 2009).

mixed preemption. And in tobacco, the federal courts were essentially unanimous in finding total, complete preemption based upon a statute that was fairly broad but not that broad.

I think one of the explanations may be that what happens in these cases—most of them are tort cases—is they're handled by lawyers who are basically product liability lawyers, who were not used to interplay of federal preemption law and federal agency law. And when they get to the Supreme Court, other people get brought in who are more familiar with them, and they turn the case around in ways that just didn't happen. So I think that's part of the explanation, and I don't have anything more to say on that.

**JUDGE PRYOR:** Dr. Greve, do you have a thought on this?

**DR. GREVE:** Yes. We've tried to look at it or thought about looking at it and done some preliminary work. It's just very, very hard to do because the universe of appellate cases about preemption is a very large and very hard to sort of circumscribe and define.

My impression from sort of just eyeballing this stuff is that Alan is probably right. And the other thing is that I would just warn against the inference from that that the appellate courts are reflexively more pro-preemption. I think it's much more likely that the answer lies in the dynamics at the Supreme Court, the pattern of cert. grants and the factors that Alan mentioned.

**JUDGE PRYOR:** So, I take it, Alan, then, you're on the side of Paul Clement with his recent exchange with Chief Justice Roberts, that advocates make more of a difference in the cases there than maybe the judges.

**PROFESSOR MORRISON:** I think that's a pretty broad statement.

**JUDGE PRYOR:** That's a rhetorical question.

**PROFESSOR MORRISON:** There is another factor. My difficulty in getting any kind of empirical data is, of course, on the Supreme Court, you have nine justices, and in the courts of appeals you have ever-shifting panels and multiple panelists, so it's even harder to get any significant numbers out of that.

**JUDGE PRYOR:** Roger.

**DR. PILON:** Yes. My question is probably for Dan Troy. Given the egregious facts in the *Wyeth* case, it raises a question, what's left

for the FDA? There, the nurse ignored no fewer than six warnings, administered a double dose of the drug, leading Justice Alito to conclude that the majority on the Court had bootstrapped an ordinary medical malpractice case into a frontal assault on FDA warning labels. And it leads to the conclusion that no matter what untoward result eventuates, the warning will be found wanting. And so what is there left for the FDA after *Wyeth*?

**MR. TROY:** Well, it's a reasonable question, and it gets to the point I was trying to make. The Court talks about two things, right? It talks about, that the manufacturers are in full control of their product labeling.<sup>68</sup> It would be interesting to ask an FDA reviewer, off the record, what they really thought of that because I don't think they would agree with that. They view the labeling as essentially their real estate. We propose; they dispose. And if they want us to say something, guess what. We say it. And if we don't, then they can come after us for misbranding. So there's that point.

And again, lawyers and the Court, Justice Breyer in particular, both talk about the FDA as if it's making—I mean, of course, because it's an agency that operates under law, the decisions it's making are legal, but the day-to-day scientific interaction between scientists at the agency and scientists in the company, to expect that to have the kind of process that is going to be, A, open and transparent and, B, lead to free regulatory and preemptive effect is unrealistic and never going to happen.

So as Catherine said, we find ourselves on the horns of a dilemma. I do hope that post *Wyeth* we can win cases like *Colacicco*, like the generic hypothetical that I posed, where the agency tells us exactly what to do and what not to do. But there was actually some debate within the pro-preemption-pro-innovator community about whether or not *Wyeth* should go up or they should wait for *Colacicco* because they thought that *Wyeth* was just too easy a case. Maybe that's the rebuttal to what Paul Clement said about Supreme Court advocates.

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<sup>68</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1196–1199 (2009)

**JUDGE PRYOR:** Okay. Mike Rosman.

**MR. ROSMAN:** I have a quick question for Dr. Greve. Did you try in your analysis to ever break down the preemption cases between conflict and field preemption? Are there any justices who are more predisposed to one rather than the other?

**DR. GREVE:** We toyed with the idea and decided against it because you're dealing with a very small number of cases; therefore, every coding decision you make has a very big effect. If you try to slice the salami that thin, the potential errors and the debates over which case belongs where will just overwhelm you.

**JUDGE PRYOR:** Michael Wallace.

**MR. WALLACE:** I told Alan before lunch the only thing my clients care about preemption is whether it will get them out of the courts of Mississippi. But standing contrary to where I sit, my question for the panel is, why should it?

If the federal government wants to disable local juries and local voters from making decisions that they've been making for 200 years, shouldn't they have to say so in terms that nobody can misunderstand? You've got a clear statement rule, an 11th Amendment law that says if Congress wants to put a liability on a state enforceable in federal court, they have to say so in absolutely clear terms. Is there any problem with the presumption other than the Supreme Court hasn't said, we really mean it. If you don't say in so many words, "We're preempting," then you're just adding rules. You're not replacing any.

**PROFESSOR MORRISON:** Mike is offering me a great gift, and I shouldn't turn it down. It certainly ought to be true at the regulatory state, but I think we have to be realistic. As much as I would like that, at least in 75 percent of the cases, to have that in the congressional stage, I just don't think it's realistic to expect Congress to make clear statements about a whole range of issues which they can't even reasonably expect to think about in the same ways that are going to arise in the real world, being a very complicated place.

So at the regulatory level, definitely. At the other level, at least you ought to have some indication that they intended not only to effect regulation preemption but also tort and compensatory damage

preemption because in regulatory preemption, you're just simply telling the state agency they can't do it. You're not depriving somebody of compensation to which they would otherwise be entitled, assuming that they had a valid claim.

**JUDGE PRYOR:** Anyone else?

**MR. TROY:** I guess I would make a plea for the realism principle that I agree that Alan is properly applying to Congress and to the state agencies as well. I guess the point I'm trying to make is to expect every regulatory decision that in the real world does have, and I would argue normatively should have, preemptive effect. To expect that to be accompanied by a clear statement rule is as chimerical as expecting that the Congress is going to do it when we'd like it to.

You're simply not going to get regulatory scientists making decisions about what should and shouldn't be in labeling on a product-by-product, day-by-day basis, to make specific findings that this decision should or shouldn't preempt state tort law.

**DR. GREVE:** I just want to add something to this, which is sort of largely agreeing with Michael but for the most part, no. I don't think it's right to describe the sort of run-of-the-mill preemption disputes where they come in contact with state law as displacing the kinds of judgments that Mississippi juries have been making for 200 years. I mean, most of these things are rather more modern and unconventional and untraditional forms of tortious liability.

I mean, you can describe the same actions under two different labels, right? It's tort liability and so, therefore, traditional state power. Or you can say, well, this is a tort substitute for the regulation of national commerce, in which case it's decidedly non-traditional, what they do, and there's no reason for a clear statement at all.

I'll say this much in agreement with you. It is true that preemption doctrine in the modern universe is made to do an awful lot of work for which we formerly had totally different doctrines, right? All those doctrines have gone by the board, and so now, the only thing that's left standing is the preemption doctrine. The courts and theorists and legal scholars crowd all of those sort of federalism

concerns that once upon a time were handled under very, very different labels—“extraterritoriality”, right? You had sort of pre-Erie rules of choice of law and so on and so forth. Under those circumstances, I would be much more open to these kinds of federalism arguments.

Now that all of that is dead and gone and this is the only horizontal federalism doctrine<sup>69</sup> that’s still on the books, with the exception of the dormant Commerce Clause, which is also on its way out, no doubt. I’ll hang onto this doctrine whatever I can.

**JUDGE PRYOR:** Next question.

**AUDIENCE PARTICIPANT:** I appreciate Dr. Greve. You’re leading to my question directly, and I’m just a simple dirt lawyer from Idaho, so many of these complexities escape me, but I do cut my spaghetti. So my polestar is that it seems to me that the Constitution as you allude to preempts Congress. And so my question to Dr. Greve and perhaps to Ms. Sharkey is, to what extent do you find and to what extent do you think that they often find—start with—in the modern cases, they start with a constitution that says, well, this is the power that Congress has, vis-à-vis the states, vis-à-vis the people. In your research of the modern cases, do they do that anymore, or is it all just swept away?

**PROFESSOR SHARKEY:** Certainly in the products liability realm, I agree with Michael, there are seemingly no limits to congressional authority to regulate national products, and Congress has done so in a sort of piecemeal way. The preemption cases do start with the Supremacy Clause, and they talk about the fact that if a statute or regulation is valid federal law, it will preempt state law. In the products area, a lot of the fighting is over whether or not tort law, in

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<sup>69</sup> The discussion of preemption deals with two distinct federalism doctrines: vertical federalism (e.g., federal-state interaction), and horizontal federalism (e.g., state-state interaction). For a discussion of issues that arise out of horizontal federalism, see e.g., Allan Erbsen, *Horizontal Federalism*, 93 MINN. L. REV. 493 (2008); see also Mark D. Rosen, *Extraterritoriality and Political Heterogeneity in American Federalism*, 150 U. PA. L. REV. 855 (2002); Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353 (2006).



other words common law claims, are the same as regulatory or statutory type claims.

But there has been some historical work talking about how displacement in, say, the 19th century, early 20th century was much more about exclusive federal versus state spheres of activity. There's been a dramatic shift in preemption analysis towards focus on the intent of Congress. So there's not much questioning about Congress's authority to displace state tort law in these areas. But all the fighting is now over the reading of congressional intent, which gets into purposes and objectives of the statute, et cetera.

On this particular Supreme Court, Justice Thomas, with his concurrence in *Wyeth*, explicitly says he wants to get out of the business of implied obstacle preemption.<sup>70</sup> But what's interesting to me is that he stands alone, so I don't see much support from other Justices who have allied with him in different preemption contexts for that kind of view.

**DR. GREVE:** I just want to add to the point that Cathy made, and it, too, is about the Justice Thomas position. What is interesting about his position in *Wyeth* is this: He makes the point about enumerated powers, to which you alluded and to which Cathy now alluded. He then seems to think that that goes together with skepticism with respect to preemption, even in areas where Congress undoubtedly has the authority to regulate. And historically, that ain't so.

The way the enumerated powers doctrine worked when it was still in effect was precisely what Cathy says: mutual exclusivity. Or, as Richard Epstein and I say: one problem, one sovereign. There can't be any overlap. And what that means is you need preemption doctrine that makes your teeth rattle. There is no congressional intent, right?

The official doctrine in the same court that gave you *Hammer v. Dagenhart*<sup>71</sup> was—the minute Congress says peep, everything in

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<sup>70</sup> Sharkey, *supra* note 42, at 110.

<sup>71</sup> *Hammer v. Dagenhart*, 247 U.S. 251 (1918). In *Dagenhart*, the Supreme Court struck down a federal law that effectively prohibited children under the age of 16

that entire field is automatically preempted regardless of whether Congress intended that are not, unless Congress tells us otherwise. End of debate. Out of here. I have a lot of sympathy with that baseline. That's probably water over the dam, but what you want by way of making sort of a fresh start is you want to have a sort of common-law-like preemption doctrine that approximates that baseline of mutual exclusivity as closely as you can.

**PROFESSOR MORRISON:** No, no—I'm not going to take you on, on that.

The gentleman from Idaho, I just want to say that the problem, in part, is the way the courts have construed the Commerce Clause. We thought that maybe they were starting down the road in *Lopez*<sup>72</sup> and found out that the road ran into a big roadblock in the *Raich*<sup>73</sup> case, the marijuana case on which I was a co-author of a brief, and also in the partial birth abortion case,<sup>74</sup> where, after all, one is hard-pressed to understand what the "in commerce" aspect of a partial-birth abortion is. And nobody paid any attention to it in any of the courts, including the parties I might say, who are challenging the statute because it was—well, whatever it was, they were not going to challenge it on those grounds.

So, if Congress is doing—if the Court is letting all of those things go by the board, although Thomas did have a footnote saying the Commerce Clause was not directly at issue in the case<sup>75</sup> and

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from working in mines and certain manufacturing facilities. The law operated by banning the shipment of goods in interstate or foreign commerce if they were produced or mined in facilities that permitted child labor. Justice Day, writing for the Court, stated that such a law was "repugnant to the Constitution" in that "it not only transcend[ed] the authority delegated to Congress over commerce but also exert[ed] a power as to a purely local matter to which the federal authority does not extend." *Id.* at 276.

<sup>72</sup> *Lopez v. Gonzales*, 549 U.S. 47 (2006).

<sup>73</sup> *Gonzales v. Raich*, 545 U.S. 1 (2005).

<sup>74</sup> *Gonzales v. Carhart*, 550 U.S. 124 (2007).

<sup>75</sup> In Justice Thomas's concurring opinion in *Carhart*, he stated that "whether the Partial-Birth Abortion Ban Act of 2003 constitutes a permissible exercise of Congress' power under the Commerce Clause is not before the Court. The parties did not raise or brief that issue; it is outside the question presented; and the lower courts did not address it." *Carhart*, 550 U.S. at 169 (Thomas, J., concurring).

even though, of course, it's the underpinning for the statute, he wasn't going to rely on that amicus brief on that count.

**JUDGE PRYOR:** Professor Selman.

**PROFESSOR SELMAN:** I was interested to hear Alan Morrison say that Congress could not and did not consider many of these issues that come up in these cases, and Dan Troy stated that the agency is also often lacking the ability or the incentive to consider them because there are just too many of them or they are too complex. And I wonder, if neither Congress nor the agencies are actually capable of properly considering these issues and giving them the attention they deserve, does that not suggest that maybe the federal government has taken on too large a regulatory sphere for itself in these areas?

It seems that what you have is a classic problem of central planning, where the planners lack the information or the incentive to actually organize the parts of our economic and social life that they've taken upon themselves.

Perhaps in the interest of creating more dissension on the panel, one very small note: In the partial-birth abortion case, Justice Stevens actually did ask about the Commerce Clause underpinnings of this at oral argument, so ironically, he being the author of the *Raich* opinion, maybe the answer would be, well, what you said in *Raich*. But it was brought up. But that's not my question. My question is what I said before.

Thank you.

**MR. TROY:** Let me take it on in a potentially controversial manner with the audience, perhaps, and not necessarily with the panel. As libertarian as some of my instincts are, I think that there's a pretty good argument for a federal Food and Drug Administration as, to pick up on what Michael said, one problem, one solution. I don't think we would be better off as a country if we had 50 state FDAs.

The point I was making is not that the FDA lacks the ability to address the question it is really supposed to address, which is, is the labeling of the product effective? Is the product safe and effective for the purpose for which it is intended? Is the labeling adequate?

What I suggested was, just like to expect Congress to come up with a clear statement on preemption is unrealistic, to expect the scientists who are doing their very important day jobs of assuring that these products are safe and effective for the purposes for which they are intended, under the conditions in use on the labeling, that they're also going to sit there and say, "Oh, is this decision preemptive," that's probably expecting a little bit too much.

If you asked me to live in a world of 50 state FDAs plus the courts or one federal FDA with or without the courts, I want the one federal FDA because at least we can go to one place where we can get one marketing authorization to market the product on a country-by-country basis.

**PROFESSOR MORRISON:** Can I just be clear about one thing? I don't expect scientists to use the magic word "preemption". That's not what I was asking for. What I was asking for is if there's a dispute about what ought to go on the label, it ought to be clear in whatever the communications are back and forth what evidence was presented. That is, what types of risks were presented? And the agency has to say, we think that those are not significant, or they are significant, or more information is not necessarily good or not. They don't have to use any legal words or other kinds of words.

The whole point is to see that the agency addressed the actual issues in the case and not somebody claiming that everything is preempted because the agency only insisted upon A and B and never thought about C, D and E.

**PROFESSOR SHARKEY:** Just one quick note, because I agree in part. At the time that the agency is deciding whether to regulate an issue or not, they have all sorts of task forces that get together their findings. I've looked at a lot of these kinds of documents. I do think, though—Dan didn't put this fine a point on it—but I do think there is, then, a strategic danger that if you got this world to shift to this great "agency reference" model or model that I think would be pretty good, then there is this strategic element that the FDA contemporaneously, at the time that it's reviewing its risk information, is going to know that down the road there's potentially court review with preemptive effect. So I do think that it is a real concern.

**JUDGE PRYOR:** Where I thought Professor Selman was, given the gaps and failures that Alan has discussed in the Congressional process and the gaps and failures that Dan has identified in the regulatory process, how is it that all of our panelists expect something different from the judicial process?

**MR. TROY:** Because we know how good judges are.

**PROFESSOR MORRISON:** Are we supposed to say because we have confidence in judges like you, Judge Pryor? Is that the answer we're supposed to give?

**JUDGE PRYOR:** It's a good start. Do we have any other questions from the audience?

(No response.)

**JUDGE PRYOR:** I was going to allow each of the panelists to wrap up and give some final comments before we break.

**DR. GREVE:** I have a question maybe to all the rest of the panelists. Should there be any difference in the degree of deference that courts give to agency statements that say, our intent is non-preemption? That is to say, suppose there's this anti-Troy preemption preamble. Should the Court then all of a sudden say, oh, that's an admission against interest, and therefore, it's particularly credible?

(Simultaneous conversation.)

**MR. TROY:** Now you know why we both favor *Skidmore* deference.

**PROFESSOR MORRISON:** Are you talking about as a general proposition?

**DR. GREVE:** As a general proposition, and it's a serious question.

**PROFESSOR MORRISON:** A rule, or—yeah.

**DR. GREVE:** I don't care whether it's—I suppose the preamble stuff is settled now, but let's say rule, litigation positions, AG positions and so forth. In fact, you can empirically show that it does make a difference with respect to the SG's position in ongoing litigation.

**PROFESSOR SHARKEY:** Right. I was going to start by saying, empirically, Eskridge's study also shows significance there too.

Namely, the anti-preemption positions are given stronger *Chevron* deference in the courts of appeals.<sup>76</sup> As a normative matter, I don't think that's right. And also, I'm not sure that I would buy the premise that it's against the interest of the agency. There's certainly a political valence, although it doesn't hold in all of the cases. There's a case called *Sprietsma*,<sup>77</sup> and under a conservative administration, the Coast Guard took an anti-preemption position in that particular case.<sup>78</sup>

There does otherwise seem to be a pretty strong prevailing wind of politics in this type of area, but it's not altogether clear to me. In particular, people lose sight of the fact, for example, that there were a few academics, Lars Noah in particular, who argued under the Clinton administration when the FDA took a very strong anti-preemption position and would say the final word on safety is not up to us, the buck doesn't stop here, that there could be an accountability loophole strongly in that direction as well.<sup>79</sup>

That would be my worry. We should not assume that the agency's interests will always be pro-preemption. And I fail to see why an agency's anti-preemption position should get stronger deference.

**PROFESSOR MORRISON:** As I tell my students in coaching them for moot courts, don't get up on rebuttal unless you have something to say. I think I've said enough, thank you.

**JUDGE PRYOR:** Well said.

Do you have anything else?

**MR. TROY:** Yes, I'll end very quickly because I'm not smart enough to follow Alan's advice.

I just want to again—Well, first of all, as a normative matter, again, I agree with Catherine that an anti-preemption statement by

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<sup>76</sup> William N. Eskridge, Jr., *Vetogates, Chevron, Preemption*, 83 NOTRE DAME L. REV. 4, 1478 (2008).

<sup>77</sup> *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002).

<sup>78</sup> Sharkey, *Products Liability Preemption*, *supra* note 32, at 488-90 & n. 190.

<sup>79</sup> Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L. J. 2147, 2158 (2000).

the agency shouldn't necessarily be outcome-determinative. She's also right that if you observe the cases, it certainly is.

Again, I want to take us back as a practical matter. What ends up happening, again, using the FDA as a paradigm, but it's somewhat representative, if you look at the total NDA—a new drug application sounds like a college application, but actually it's enough documents to fill this room. That's how much data is submitted to the agency—in the back, if you look at the sum total of the correspondence back and forth, by and large the company has told the agency everything that it knows about it, then the agency responds.

But again, to expect that the agency's response back, "Here's what we think you should say in the labeling," is going to have a written decision that is going to go on for pages and pages of, well, we considered a study and decided not to put this one in, we considered it. They do decide what the labeling is, and it is footnoted, and there is a scientific discussion. But inevitably, what happens is the plaintiff's bar comes in and says, well, we found these three Croatian studies that you didn't submit to the agency, so you didn't tell them everything. And then in the back-and-forth between the agency, there is no document that explicitly discusses this French study, so therefore, it wasn't an adequate discussion or the agency didn't consider it, so therefore, we can litigate about that. And that's what ends up happening.

So on top of having to decide the scientific causation, basically, you're asking the federal courts—and I'd rather trust the federal courts than the state courts—but you're asking the judges and ultimately, God help us, juries to decide whether the back-and-forth of the agency was sufficient to give it preemptive effect. And that's kind of, you know, where we are.

I just hope that when we've got a good enough case where the agency has told us to do something or not do something, that we'll be able to get preemption.

**JUDGE PRYOR:** Please join me in thanking our panelists for their discussion.

(Panel concluded.)