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**THE CASE FOR PREEMPTION:
WHY THE U.S. SUPREME COURT AND THE
ADMINISTRATION ARE WRONG TO CURTAIL
IMPLIED CONFLICT PREEMPTION**

Malcolm E. Wheeler*

TRANSCRIPT OF PROCEEDINGS¹

Because you in the audience today are torts scholars interested in preemption and I am no longer in academia, but have been litigating preemption issues for more than a quarter-century, I'm going to provide some remarks about the practical development, rather than the theory, of preemption law. I argued *Geier v. American Honda*² in the Supreme Court for Honda on Pearl Harbor Day in 1999. The court decided it in May 2000, five to four in my favor. I'll first describe how we got there and then comment on some of the subsequent developments in conflict preemption.

The "no-airbag" lawsuits that culminated with the Supreme Court's decision in *Geier* in 2000 began in 1983. Hundreds of them and related "no-passive-restraints" lawsuits were filed in succeeding years. The plaintiffs in the latter group claimed that all cars made without passive restraints—restraint systems designed to provide second-collision protection³ to vehicle occupants in crashes without the occupants' taking any affirmative action, such as buckling their seatbelts—were defectively designed. The two categories of passive restraints at the heart of those cases were airbag systems and passive seatbelt systems (seatbelts that automatically moved into place around the occupant of a particular seat when the occupant closed the door adjacent to that seat).⁴

When the "no-airbag" litigation began, no manufacturer was making vehicles with airbags, and only a tiny fraction of vehicles had passive seatbelt systems. Plaintiffs who had failed to buckle their seatbelts in vehicles with manual seatbelts and no airbags and had been injured in accidents gen-

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1. Revised and annotated by author for publication.

2. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

3. A "second collision" is the collision that occurs between a vehicle occupant and some part of the vehicle interior, such as the steering wheel or the instrument panel, after the vehicle first collides with another vehicle or some other object.

4. Airbag systems and passive-seatbelt systems also usually included a knee bolster, a padded protrusion below the instrument panel that was intended to limit the forward movement of the occupant's knees, thighs, and lower torso in a frontal crash, thereby reducing the risk that the occupant would slide forward under the shoulder harness if the seatbelt system did not include a lap belt.

erally made “no-passive-restraint” claims. Plaintiffs who had buckled their manual seatbelts and had been injured in accidents made “no-airbag” claims.

As I looked at the litigation in its infancy on behalf of my automotive clients, I thought:

The auto companies can’t litigate these on a case-by-case basis. If they litigate these on a cases-by-case basis, every single frontal crash that occurs, and every side-impact crash that occurs, throughout the United States is going to be a “no-airbag” claim or a “no-passive-restraint” claim. There will be not just thousands, but millions, of these cases over the years because there are more than 150 million motor vehicles without airbags on the roads and more than six million police-reported motor-vehicle crashes annually.⁵ The defense costs for litigating the cases in courts throughout the country will exceed the manufacturing cost of some cars.

The problem was that there were twenty-four reported decisions that were unrelated to “no-passive-restraint” claims but that, broadly read, could be read to say, and had been widely viewed as saying, that there could be no preemption of state-law tort claims under the National Traffic and Motor Vehicle Safety Act of 1966⁶ (the “Safety Act”) and its implementing regulations promulgated by the National Highway Traffic Safety Administration (the “Safety Administration”). But when I examined those cases closely, I concluded that none of them actually said, “There is no preemption under the Safety Act.” Instead, each of them found no preemption because of the particular facts of the case; addressed only field preemption, not express preemption or conflict preemption; or addressed not a preemption argument at all, but an argument that the vehicle was not defectively designed because it complied with an applicable federal motor vehicle safety standard promulgated by the Safety Administration.⁷ Because of the extensive regulatory history regarding passive restraints, and airbags in particular, I thought the most compelling argument in the “no-airbag” cases would be an implied preemption argument focused on the federal agency’s stated pur-

5. See, e.g., United States Department of Transportation, Traffic Safety Facts 1994, pp. 14-15 (Aug. 1995) (showing number of reported crashes for each year in 1988 through 1994 and number of registered motor vehicles for each year in 1966 through 1994).

6. National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-670, 80 Stat. 931 (codified as amended at 49 U.S.C. §§ 30101 *et seq.*).

7. See, e.g., *Dawson v. Chrysler Corp.*, 630 F.2d 950, 958 (3d Cir. 1980), *cert. denied*, 450 U.S. 959 (1981).

poses and on the conflict between those purposes and the state-law tort claims the plaintiffs were asserting.

So from the very beginning we litigated these cases with a narrow approach that focused on the detailed, complex passive-restraint regulatory history that had begun in the late 1960s. We formulated arguments carefully explaining why, given that narrow focus and that unique regulatory history, a finding of preemption in these cases would not mean that a broad swath of automotive product liability claims—for example, claims of defectively designed brakes, steering systems, or fuel systems—would be preempted.

We also carefully chose the cases in which to make the arguments, and we purposefully made the first case in which we chose to make the arguments a case in a federal court in Missouri. We could have made it in any of several other courts, but we wanted to test the arguments in a federal court, not a state court, for a couple of reasons. First, we thought that state courts would be somewhat inclined to think, “I’m not going to dismiss this case brought by a citizen of this state in this court under this state’s tort law simply because some federal agency has promulgated a regulation addressing the issue.” Second, unlike many state trial courts, federal district courts had law clerks who were likely to have time to study the regulatory history and to read the prior preemption cases as closely as they had to be read to see that they had not foreclosed preemption under the Safety Act and its implementing regulations.

We also preferred to test the arguments in a court in the middle of the country, rather than one in, for example, California, Florida, or New Jersey—states that had been leading the expansion of product-liability law for nearly two decades at the time. We certainly did not want to make the argument in one of the courts that in today’s vernacular are called “judicial hellholes.” We wanted a court that we thought would be open to considering in detail why the Safety Administration had regulated the issue as it had, how consumers would be harmed by the premature introduction of airbags before the technology had advanced to a point at which it would not cause severe injuries and fatalities to occupants who otherwise would have escaped such severe injuries, and why the law had to be applied by keeping in mind the safety of the people who were being protected by the Safety Administration’s regulatory stance, not just the individuals who were in court claiming to have been injured because manufacturers had acted in compliance with their understanding of that regulatory stance.

When we won that case,⁸ we made the motion in another federal court and won again.⁹ Soon after that we made the arguments in a state court in

8. *Vanover v. Ford Motor Co.*, 632 F. Supp. 1095 (E.D. Mo. 1986).

9. *Cox v. Baltimore County*, 646 F. Supp. 761 (D. Md. 1986).

Alaska, and we won again.¹⁰ But almost all the auto companies began facing “no-airbag” and “no-passive-restraint” claims, and trial courts throughout the country were deciding preemption motions. When some courts held the claims preempted and other courts held them not preempted, we had to decide which case or cases we wanted to be the first to be decided on appeal, because ultimately our aim was to get to the United States Supreme Court, but with a case having good facts and positioned at the best time within the lengthy regulatory history to show the conflict between the Safety Administration’s regulation and the state-law tort actions. Accordingly, we asked ourselves a variety of questions: Would our arguments be better received in a federal court of appeals or in a state appellate court? Which courts, panels, and judges had a history of being at least somewhat hospitable, and which hostile, to preemption arguments? Which of our cases, or which cases being defended by other firms, had plaintiffs who would generate little judicial sympathy—for example, a plaintiff who had chosen not to buckle the available seatbelt and, in addition, had engaged in reckless conduct by driving at an excessive speed or while drunk and, still further, had not incurred a catastrophic injury? Which of our cases, or which cases being defended by other firms, arose out of crashes in which the vehicle in issue was manufactured at a time in the lengthy regulatory history when the Safety Administration’s rulemaking purposes most clearly were inconsistent with a “no-airbag” tort claim?

Once again, we thought that, all other factors being equal, a federal court of appeals would be somewhat more likely to find preemption than would a state appellate court. For a variety of reasons, the first case that went up on appeal was *Wood v. General Motors*,¹¹ in the United States Court of Appeals for the First Circuit. When that court found preemption and the plaintiff filed a petition for a writ of certiorari in the Supreme Court, however, the time did not yet seem right, so General Motors opposed the petition. The Supreme Court denied the petition.

Over the next few years, the Third Circuit,¹² Ninth Circuit,¹³ Tenth Circuit,¹⁴ and Eleventh Circuit,¹⁵ as well as several state appellate courts,¹⁶ held “no-airbag” claims or “no-passive-restraint” claims preempted, and a

10. *Soboscienski v. Ford Motor Co.*, No. 2NO-85-246 (Alaska Super. Ct. Oct. 18, 1986).

11. *Wood v. General Motors Corp.*, 865 F.2d 395 (1st Cir. 1988), *cert. denied*, 494 U.S. 1065 (1990).

12. *Pokorny v. Ford Motor Co.*, 902 F.2d 1116 (3d Cir.), *cert. denied*, 498 U.S. 853 (1990).

13. *Harris v. Ford Motor Co.*, 110 F.3d 1410 (9th Cir. 1997).

14. *Kitts v. Gen. Motors Corp.*, 875 F.2d 787 (10th Cir. 1989), *cert. denied*, 494 U.S. 1065 (1990).

15. *Taylor v. Gen. Motors Corp.*, 875 F.2d 816 (11th Cir. 1989), *cert. denied*, 494 U.S. 1065 (1989).

16. *E.g.*, *Boyle v. Chrysler Corp.*, 177 Wis. 2d 207, 501 N.W.2d 865 (Ct. App. 1993).

few state appellate courts held claims of the same nature not preempted.¹⁷ By 1995 more than 120 courts, including more than a dozen appellate courts, had ruled on the issue. The case that ultimately reached the Supreme Court was *Geier*, a “no-airbag” case involving a driver who had been wearing the available lap-shoulder seatbelt when she crashed her 1987 Honda. The United States Court of Appeals for the District of Columbia Circuit held the “no-airbag” claim preempted; the plaintiff filed a petition for a writ of certiorari; and the Supreme Court granted the petition and affirmed.

I provide all that as background to show that how the Supreme Court shapes preemption law can depend significantly on how litigants shape the law for presentation to the Supreme Court for decision. I also provide it because I think that, had the same approach been followed to the end with respect to preemption in the pharmaceutical arena, the Supreme Court never would have decided *Wyeth v. Levine*¹⁸ in 2009 and the state of preemption law in the pharmaceutical arena would look quite different than it does today.

In fact, I tried to follow a similar approach in the pharmaceutical arena. I thought I had an excellent medication, an excellent regulatory history, and an excellent case factually in which to establish that, in a narrow category of cases, state-law claims that the labeling for a particular prescription medication provided inadequate warnings of a particular adverse side-effect can be preempted because of a conflict with the Federal Food, Drug, and Cosmetic Act¹⁹ (“FDCA”). The medication was Zoloft®, a member of the class of antidepressants called serotonin selective reuptake inhibitors, or SSRIs.

The SSRI litigation started with another SSRI, Prozac®. After the FDA approved Prozac® in 1987 for the treatment of patients with major depressive disorder, it quickly became the leading medication prescribed for patients with depression, one of the most common and debilitating illnesses in the world and an illness that all too frequently resulted in suicide and other self-injury.²⁰ Over time, the Food and Drug Administration (“FDA”) also approved Prozac® as safe and effective for the treatment of several other psychiatric disorders.

An important advantage of Prozac® was that, unlike previously available antidepressants, it could not readily be used to commit suicide by ingesting an overdose. Nevertheless, and although the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders named

17. *E.g.*, *Gingold v. Audi-NSU-Auto Union A.G.*, 389 Pa. Super. 328, 567 A.2d 312 (1989).

18. *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

19. 21 U.S.C. §§ 301-399 (2009).

20. AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 350-51 (4th ed. text rev. 2000).

recurrent thoughts of death or a suicide attempt as one of the primary criteria for a diagnosis of major depressive disorder,²¹ the manufacturer of Prozac® began to face multiple lawsuits by plaintiffs claiming that they or a family member had become suicidal because of treatment with Prozac®. The plaintiffs claimed that the FDA-mandated suicidality language in the “Precautions” section of Prozac® labeling should have been made stronger and should have been moved to the “Warnings” section of the labeling. Over a period of six years, each of two entities and an individual also filed separate citizen petitions²² with the FDA asking the agency to withdraw its approval for Prozac® or to require that the labeling be changed to strengthen the language addressing suicidality. The FDA rejected the petitions because of the absence of scientific evidence of an association between the antidepressants and suicide.

The FDA also conducted a public meeting in 1991 with its Psychopharmacological Drugs Advisory Committee, a group of expert physicians and scientist from academia and elsewhere,²³ to consider whether the language regarding suicidality in the labeling for Prozac® and other antidepressants should be strengthened. The committee and the FDA concluded that it should not. In that meeting, referring to controlled clinical studies, Dr. Paul Leber, Director of FDA’s Division of Neuropharmacological Drug Products, stated: “[E]valuation by FDA scientists, outside consultants, and by our physicians, have not led us to conclude that there is a differential rate of risk for Prozac related to suicidal thoughts, acts, or other violent behaviors.”²⁴ He cautioned that,

[T]he net effect [of additional suicidality warnings] might be a reduction in the use of antidepressants in the treatment of depression, and that result might cause overall injury to the public health. . . . We all have to remember that the best-intentioned of actions do not necessarily turn out well; they can cause harm.²⁵

Dr. Thomas Laughren, who headed the Psychopharmacology Unit of the FDA’s Division of Neuropharmacological Drug Products, added that the labeling FDA had approved for “suicidal ideation” and “violent behav-

21. *Id.* at 356.

22. *See* 21 C.F.R. § 10.30 (2010) (authorizing citizens’ petitions).

23. *See* 21 U.S.C. § 355(n) (2009) (authorizing the FDA to form and seek advice from advisory committees of experts).

24. Transcript of Proceedings, FDA Psychopharmacological Drugs Advisory Committee, Sept. 20, 1991, p. 126, *available at* http://commons.wikimedia.org/w/index.php?title=File%3A1991_FDA_Psychopharmacological_Drugs_Advisory_Committee.pdf&page=126.

25. *Id.* at 129-30.

iors” “reflects our lack of confidence in a causal link between the taking of the drug and those behaviors.”²⁶

Several other manufacturers developed similar SSRI antidepressants and, after extensive clinical trials and FDA review, received FDA approval to market them. My client, Pfizer, developed the SSRI called Zoloft®. After receiving FDA approval, Pfizer began making Zoloft® available for doctors to prescribe beginning in 1992. Litigation like that against Prozac® followed, and I was asked to defend it.

I found that the FDA-mandated labeling for Zoloft®, like the FDA-mandated labeling for Prozac® and other antidepressants, contained precautionary information about suicidality. Specifically, the “Precautions” section stated:

Suicide - The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Zoloft should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

(Emphasis in original).²⁷ The FDA-mandated labeling also informed physicians of the quantified range of rates at which Zoloft® patients in clinical trials had experienced attempted suicide and suicidal ideation. And FDA-mandated language in the labeling stated: “It is important to emphasize that although the events reported occurred during treatment with Zoloft, they were not necessarily caused by it.”²⁸ When I looked at the Zoloft® regulatory history, its documented developmental history, and the extensive medico-scientific literature analyzing its performance, I concluded that the tort claims should be preempted and that many individuals suffering from depression could otherwise be seriously harmed by the litigation and its attendant publicity. In particular, patients suffering from a disorder that often led to suicide might be induced not to seek treatment at all or might decline to be treated with antidepressants or might be noncompliant with their doctors’ dosage instructions, and some doctors might decline to prescribe the antidepressants because of a fear of malpractice actions. Moreover, I considered it vitally important that it was concerns of this nature that had led the FDA repeatedly to reject any warning language stating that an association between the antidepressants and suicide had appeared in the scientific evidence.

26. *Id.* at 137.

27. PHYSICIAN’S DESK REFERENCE 2001 (48th ed., 1994).

28. *Id.* at 2002.

My legal research indicated that, just as there had never been a case in which a court had held a state-law product-liability claim preempted under the Safety Act when we began asserting conflict preemption in the “no-airbag litigation,” there had never been a case in which a court had held that the FDAC preempted a state-law product-liability claim for inadequate warnings. But in this instance, unlike the typical pharmaceutical inadequate warning case, the FDA had examined SSRI suicidality data for about five years before approving Zoloft® for the treatment of depression, had considered and rejected three citizen petitions addressing Prozac® and other anti-depressants, had repeatedly examined suicidality data for Prozac®, Zoloft®, and other SSRIs throughout the 1990s, was aware of the massive medico-scientific literature examining SSRIs, and repeatedly had found no reasonable evidence of an association between SSRIs and suicidality. By the time the Zoloft® litigation began, the FDA had examined and reexamined multiple times the growing and massive data for treatment of patients with SSRIs generally and for Zoloft® in particular. Between 1987 and 2006, not a year went by in which the FDA did not look at SSRI data for evidence of an association with suicidality, because there were new SSRIs coming out, manufacturers were seeking approval for using SSRIs to treat additional illnesses, and the FDA was monitoring the data closely.

In short, Zoloft®, along with Prozac®, appeared to be the most thoroughly regulated drug in the history of the world, and the possibility of an association between these medications and suicidality appeared to be one of the most thoroughly considered questions in the history of the FDA. Yet the tort cases continued, and I thought wrongly so. So we filed a motion in a case in the United States District Court for the Central District of California seeking summary judgment on alternative grounds of lack of causation and conflict preemption. When the district court granted the motion on the state-law ground and rejected the preemption argument,²⁹ the plaintiff appealed and we cross-appealed. The Department of Justice (“DOJ”) filed an *amicus curiae* brief on behalf of the United States supporting conflict preemption, but the Ninth Circuit affirmed the summary judgment on state-law grounds and never reached the preemption issue.³⁰

We then made the preemption argument in a summary judgment motion in a federal district court in Texas and won it.³¹ We then filed a similar motion in a different federal district court in Texas and again won.³²

After more litigation against SSRI manufacturers in various trial courts, I lost a Zoloft® preemption motion in a case called *McNellis*³³ in the United States District Court for the District of New Jersey. We took an in-

29. *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001).

30. *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004).

31. *Dusek v. Pfizer, Inc.*, 2004 WL 2191804 (S.D. Tex. 2004).

32. *Needleman v. Pfizer, Inc.*, 2004 WL 1773697 (N.D. Tex. 2004).

33. *McNellis v. Pfizer Inc.*, 2005 WL 3752269 (D.N.J. 2005).

terlocutory appeal to the Third Circuit.³⁴ Meanwhile, parallel to that was a case called *Colacicco*,³⁵ in which GlaxoSmithKline (“GSK”), the manufacturer of another SSRI, Paxil®, had won a preemption motion in the United States District Court for the Eastern District of Pennsylvania.

Now, the backdrop to all this is that there was another pharmaceutical case coming up through the judicial system that was completely unrelated, had nothing to do with SSRIs, had nothing to do with antidepressants, and had nothing to do with a claimed association of the drug and suicidality. It had to do with a medication used to treat migraine headaches. That case became *Wyeth v. Levine*.³⁶ When we filed our summary judgment motion in *McNellis*, we were a full year ahead of *Wyeth v. Levine*, and we thought we were going to end up in the Supreme Court. Unfortunately, the judge in our case took months to decide the summary judgment motion. When he denied it, we filed a motion for reconsideration, and he again took months to decide it. The time between our filing of the initial motion and the denial of the motion for reconsideration was sixteen months. Meanwhile, the district court in *Colacicco* granted GSK’s motion for summary judgment on preemption grounds and the plaintiff in that case appealed to the Third Circuit. Even though *McNellis* had fallen behind in the briefing schedule, we asked the Third Circuit to consolidate *McNellis* and *Colacicco* for oral argument, and the court agreed to do so. So we argued those cases together. We won both cases.

The plaintiffs then filed a petition for writ of certiorari, but by this time *Wyeth v. Levine* had reached the Supreme Court. It had not been argued yet, but it had been fully briefed. My view was that it was nowhere nearly as good a case for conflict preemption as were the SSRI cases, either factually or with respect to the regulatory histories. In *Wyeth* a nurse had injected the plaintiff with a medication to alleviate a migraine headache, and what was the trade-off? The plaintiff lost her arm to amputation. In contrast, *McNellis* was a case in which we could say to the United States Supreme Court, if we were to get there,

This drug treats depression, and major depressive disorder is an illness that is associated with suicide. So unlike in *Wyeth v. Levine*, the trade-off here is life versus life. The FDA made a determination in 1991, in a public hearing, that the public could be *harmed* by adding a warning saying that this drug causes suicide. The FDA made that as a scientific, medical finding. The finding was not made by a lawyer, by

34. *McNellis v. Pfizer Inc.*, 2008 WL 927848 (3d Cir. 2008).

35. *Colacicco v. Apotex, Inc.*, 521 F. 3d 253 (3d Cir. 2008), *vacated* in consideration of *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), *Colacicco v. Apotex*, 129 S. Ct. 1578 (2009).

36. *Wyeth*, 129 S. Ct. 1187.

the chief counsel of FDA, or by DOJ, but by doctors and scientists making a medico-scientific judgment about safety.

But Wyeth had decided to pursue the preemption issue in *Wyeth v. Levine*, and that was simply the way it was. So the Supreme Court decided that case before getting to *McNellis* and *Colacicco*. The Court found no preemption in *Wyeth v. Levine*, and our opportunity for a ruling on narrowly focused grounds with an extensive regulatory history similar to the regulatory history in *Geier* in vital respects was gone. So there you have two contrasting examples—*Geier* and *Wyeth*—of how preemption law gets shaped by the Supreme Court.

And here, in my view, is the tragedy. Following massive publicity orchestrated by lawyers representing plaintiffs in SSRI cases, the FDA in 2005 directed antidepressant manufacturers to change their labeling to add a black-box suicidality warning. I predicted that someday, perhaps two or three years after that, the data would show that the suicide rate increased following the implementation of the warning. And in 2007 came the first of what have now been several published studies finding an increase in the suicide rate and a decrease in the rate of SSRI prescriptions.³⁷ A finding of “no preemption” can have terrible adverse safety consequences for the public.

What I also am seeing is that some lower courts are misreading *Wyeth v. Levine* as having dramatically changed the law in an anti-preemption direction. I argued a case in January of last year in the Tenth Circuit,³⁸ and the then-chief judge of the Tenth Circuit, Judge Henry, said to me something like this: “You know, there was a sea change caused by *Wyeth v. Levine*.” I said, “Your Honor, there was not a sea change.” And he said, “Counsel, if you take that position, we’re going to have some trouble.” I stood firm. The district court had found preemption, and the court of appeals remanded the case to the district court for reconsideration in light of the Supreme Court’s decision in *Wyeth v. Levine*. We have not yet received a decision on remand.

The mistake that I think Judge Henry made, and that other courts interpreting *Wyeth v. Levine* have made, is in thinking that Justice Stevens, speaking for the majority, established a “sea change” in the test for conflict preemption by saying that when a drug manufacturer asserts preemption on the ground that the FDA would have rejected a supplemental new drug application seeking approval of the warning advocated by the plaintiff, there must be “clear evidence” that the FDA would have done so. The require-

37. R.D. Gibbons et al., *Early Evidence on the Effects of Regulators’ Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents*, 164 AM. J. PSYCHIATRY 1356 (2007).

38. *Dobbs v. Wyeth Pharmaceuticals*, No. 08-6018 (10th Cir.).

ment of “clear evidence” is not a “sea change” or new at all. Justice Breyer used the very same term, “clear evidence,” in *Geier*.

Perhaps more importantly, I ask you this: What does “clear evidence” mean as used by Justice Stevens? We have, as you know, in the law of evidence, the “preponderance of the evidence” test; we have the “clear and convincing evidence” test; and we have “beyond a reasonable doubt.” What is this “clear evidence” requirement? Is it an evidentiary test? If so, is it somewhere between preponderance and clear and convincing? If it is, where between them is it? Where in the law of evidence has such a test ever been defined and applied? And if “clear evidence” is not an evidentiary test, is it just a directive that judges should be hostile to preemption in some undefined way?

I say that *Wyeth v. Levine* did not change the law. What changed was the tone, the essentially *ad hominem*, attack that Justice Stevens made on the then-chief counsel of FDA and on DOJ personnel who supported his interpretation of preemption law. If you take out the *ad hominem* attack, what you have left is the undefined “clear evidence” requirement, and I again ask, What does that mean? I say it is simply a different formulation of the presumption against preemption. So I next ask you, What is the nature of the presumption against preemption? Is it a “bursting bubble”³⁹ presumption? Or is it a “weight of the evidence” presumption? If it is a “bursting bubble” presumption, it does not mean anything other than that the defendant asserting preemption must come forward with some evidence that there is, in fact, a conflict. And if “clear evidence” simply means that the defendant must come forward with a preponderance of evidence, it doesn’t mean much either. “Clear evidence” simply means that the person asserting preemption ought to prove what the federal statute means, or what the federal regulation means, or what the congressional or regulatory intent was, and that the plaintiff’s state-law claim creates a conflict.

But what has happened is that a number of federal judges and state judges are looking at *Wyeth v. Levine* and saying, “Oh, clear evidence—wow, this is a huge burden to establish preemption,” and making it essentially impossible to find preemption. But not a single court has articulated what “clear evidence” means or how it imposes some huge new burden in some defined way. I think the reason no court has done so is that all “clear evidence” can sensibly mean is that the defendant asserting preemption has the burden of going forward with evidence showing the conflict the defendant claims to exist.

Now, the last thing I want to mention is that there is another preemption case currently before the Supreme Court that my fellow panelists have

39. FED. R. EVID. 301, available at <http://www.law.cornell.edu/rules/fre/ACRule301.htm>.

not mentioned: *Mensing*.⁴⁰ It is important because the issue in the case is whether generic-drug manufacturers have an obligation to change the labeling on the generic drug when they do not hold the new drug application (“NDA”) approved by the FDA for the branded drug. When the pioneer manufacturer continues to hold the NDA, FDA regulations prohibit the generic-drug manufacturers from using any label that is not identical to the label for the branded drug. So the question before the Court is: Even though they can’t change the label for the generic drug unless and until the label for the branded drug is changed, do generic-drug manufacturers nevertheless have an obligation to take steps to get the label changed?⁴¹

Now, what is really fascinating is the government’s brief in support of the petition for a writ of certiorari, because what the government does in that brief, among other things, is argue for a subjective test for preemption. The government says that the test should be whether the generic manufacturer has new information that causes it to believe that the label should be changed; if the plaintiff doesn’t allege such a subjective belief, the claim is preempted. There has never been anything like that as a test for preemption, so it is a very interesting proposition. I’m looking forward to seeing how the government develops that argument in its *amicus curiae* brief on the merits, now that the Court has granted the cert petition.

To me, an important aspect of the current preemption situation overall is that Justice Stevens has retired. After I won *Geier*, Justice Stevens led a campaign to overrule it. If you look at *Bates*,⁴² if you look at *Altria*,⁴³ and if you look at the language he used in those and other post-*Geier* cases, I think you will find that they provide “clear evidence” of an attempt to cabin *Geier*. But *Geier* lives, and preemption lives, just as the Founders intended when they wrote the Supremacy Clause of the Constitution.

40. *Pliva v. Mensing*, 130 S. Ct. 3349 (2010).

41. *Actavis Elizabeth, L.L.C. v. Mensing*, 131 S. Ct. 817 (2010); *Actavis, Inc. v. Demahy*, 131 S. Ct. 817 (2010).

42. *Bates v. Dow Agrosiences, LLC*, 544 U.S. 431 (2005).

43. *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008).