Testimony of

Collyn Peddie

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OF
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HOUSTON, TEXAS
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My name is Collyn Ann Peddie and I am a foot-soldier in the on-going battle over the federal preemption of state pharmaceutical claims. I want to thank Chairman Leahy, Ranking Member Specter and the members of the Committee for the opportunity to speak on this matter.

For most of my career, I have represented corporate defendants, including many Fortune 500 companies and large pharmaceutical companies. In recent years, I have tried a number of lawsuits for pharmaceutical companies and have personally advised senior executives at Pfizer concerning federal preemption issues and strategy involving the diabetes drug Rezulin.

For the last two years, I have practiced trial and appellate law with the firm of Williams Kherkher Hart Boundas, L.L.P. in Houston, Texas, where I currently take the leading role in several key appeals in Texas and Pennsylvania state and federal courts involving federal preemption of prescription drug or vaccine claims. For some time, I have regularly consulted with other counsels around the nation on preemption issues.

In short, I have been on the front lines virtually every day for the last 5 years dealing first-hand with federal preemption of state pharmaceutical claims and the impact of these decisions on the lives of injured Americans.

THE PROBLEM
Increasingly, those injured by prescription drugs are seeing their right to seek compensation in court eliminated entirely by the preemption doctrine. Derived from the Supremacy Clause of the U.S. Constitution, the doctrine means that federal law - even a regulation of a federal agency - may trump a conflicting or parallel state law. Preemption can be express or implied, either because federal law so occupies the field that there is no room left for state regulation, because state law directly conflicts with federal law, or because enforcement of the state law might frustrate federal purposes. Congress has never expressly preempted prescription drug claims and neither Congress nor the FDA has ever asserted that federal law occupies that field.1 Thus, the current dispute over preemption has involved conflict preemption principles and whether permitting state tort claims somehow frustrates federal purposes.

Breaking sharply with express Congressional dictates2 and a century-long policy of claiming no preemption of state-law failure to warn claims,3 the FDA has, in the last few years, aggressively asserted the doctrine of implied preemption of state pharmaceutical claims in a series of amicus briefs filed in private lawsuits. This power grab culminated in the FDA including a Preamble to its 2006 drug labeling regulations, in which it announced its position that state failure to warn claims - based upon the failure to include in proposed warnings information that the FDA considered and rejected - are preempted.4 In 2007, in another amicus brief, the FDA retreated somewhat from the position it took in its Preamble and it now asserts a very strict form of direct conflict preemption.5

Since 2006, a few courts have ignored express Congressional directives and federal law, some relying on the FDA amicus briefs and the Preamble to the 2006 drug labeling regulation instead, to expand the application of the preemption doctrine. Thus, in Colacicco v. Apotex, et al., 432 F. Supp. 2d 514 (E.D. Pa. 2006), Judge Michael Baylson solicited an FDA amicus brief himself, held that it and the FDA's prior amicus briefs' and Preamble's statements on preemption were entitled to Chevron6 or conclusive deference, that the federal courts were powerless to reject them, and, on that basis, dismissed the plaintiffs' failure to warn claims. The number of these cases are approaching a critical mass, and soon it will be difficult, if not impossible, to undo the damage done without significant Congressional intervention.

Ruby Ledbetter's7 case is a good example. At the time she began taking Vioxx, Ruby was a 62-year old Texas grandmother who actively gardened, rode horses, cleaned their stalls as well as her own house, and walked up to a mile three times a week. As the result of taking Vioxx for a year and a half, however, she suffered a severe heart attack that has left her unable to live her previously-active life. She sued Merck, Vioxx's manufacturer, for failure to warn her of its potential cardiovascular effects.

A few months before her scheduled trial date, a Texas trial judge dismissed her failure to warn claim as impliedly preempted. Under a recent Texas law, there is a statutory presumption of no liability for a drug manufacturer if its drug was FDA-approved. There is, however, a statutory exception to that law that would have permitted Ruby to show that Merck had withheld or misrepresented to the FDA material information during the Vioxx approval process. Under those circumstances, Texas law would not have permitted Merck to avail itself of the statutory presumption based upon FDA approval as a defense in her case.

In holding her failure to warn claim impliedly preempted, Judge Wilson conceded that Ms. Ledbetter had made the requisite statutory showing that Merck withheld important information from the FDA. Nevertheless, he dismissed her failure to warn claim because he found that her ability even to make that threshold evidentiary showing was impliedly preempted by the Food Drug and Cosmetic Act under the Supreme Court's decision in Buckman because such a showing was somehow analogous to a preempted affirmative claim of fraud on the FDA and attempt to enforce privately violations of FDA regulations.8 He refused, however, to declare the whole statute, including its rebuttable presumption in favor of drug manufacturers, preempted and return it to the Texas Legislature for reconsideration and amendment, but instead claimed that the exception was not wholly preempted. He opined that the statutory exception could be satisfied by proof that FDA itself had found, under the provisions of the Texas Act, that it had been defrauded during the approval process. This is the same conclusion reached by a Sixth Circuit Court of Appeals panel in interpreting a somewhat similar Michigan statute to find its exception preempted.

When, in a motion for new trial, Judge Wilson was informed that there were no possible circumstances under which the FDA would ever make the requisite findings and, therefore, that no Texas plaintiff would ever be able to file a failure to warn claim under the exception expressly created by the Texas Legislature, he admitted that he would have to declare the entire statute preempted and return it to the Texas Legislature and that, under his interpretation, he was immunizing corporations who lied to the FDA to gain drug approval. Nevertheless, he failed to rule on that motion and let stand his original decision rather than take down the whole statute. As part of multi-district proceedings, his decision potentially affects thousands of Texas Vioxx and pharmaceutical plaintiffs and would bar their claims outright.

Under the guise of furthering perceived Congressional intent then, a Texas judge has immunized from suit in Texas even drug manufacturers who lied to the FDA to gain drug approval and expanded the implied preemption doctrine far beyond even what the FDA claims for itself. In the process, he has potentially locked the courthouse door to thousands of plaintiffs injured by prescription drugs. Is that really what Congress intended?

In Pennsylvania, Hannah Bruesewitz suffered a similar fate. Her personal injury claims have now been dismissed as preempted under the Vaccine Act. While a normal toddler, Hannah Bruesewitz was injected with DPT vaccine. Within 2 hours, she was in convulsions. She is 15 today and has suffered from seizures ever since. Even though she has a normal life expectancy, Hannah's life will never be normal. She will require hundreds of thousands of dollars in medical care for the rest of her life. Before she ever received the vaccine, the VAERS reporting system, created by Congress, had uncovered 2 child deaths and 66 serious injuries associated with the same vaccine lot administered to Hannah; however, no one told Hannah's parents or her doctor about these serious problems with the vaccine.

As required by federal statute, Hannah's parents filed claims seeking compensation for her injuries in the National Vaccine Injury Compensation Program. Because of budget cuts reclassifying her injury, she received no compensation at all through that program. As the result, her parents availed themselves of their express right under the Vaccine Act to sue in state court for her injuries.

Ignoring express Congressional language in the Vaccine Act which preserved suits based on drug side effects that are "avoidable," Judge Baylson, the judge in Colacicco, held that Congress intended to preempt all design defect claims, even those, like Hannah's, that involve vaccines for which there were suitable alternatives, including potentially substituting another lot of the same vaccine. Worse, a second Pennsylvania federal judge, relying in part on the FDA Preamble, would have impliedly preempted Hannah's failure to warn claims too, despite Congress' express reservation of such claims and express preemption of any state law that would stand in their way. In fact, when Judge Baylson specifically solicited an FDA amicus brief to give the FDA an opportunity to state its position on preemption in cases filed after participation in the National Vaccine Program, the FDA stated that it essentially had no dog in the fight at that point.

In short, even though Congress specifically preserved an injured but dissatisfied plaintiff's right to bring state tort claims after exhausting his or her administrative remedies under the Vaccine Act and expressly preempted state laws that would infringe upon that right, two federal court judges have decided that what Congress really meant to do was to limit such plaintiff's remedies, if any, to those afforded under the National Vaccine Program.

These examples reveal an emerging pattern of judicial and executive legislating, and nullification of federal and state laws permitting tort claims against pharmaceutical companies. The FDA and some activist courts are increasingly ignoring Congressional intent and casting aside bedrock legal and constitutional principles that once lent predictability and stability to the law in this area. In Texas and Pennsylvania, this has meant that, while courts have retained the statutory benefits for drug companies, they have removed important checks on those benefits, leaving many injured citizens with no remedy.

The absence of state tort claims also places enormous burdens on the FDA to ensure drug safety, burdens it is increasingly ill-equipped or unwilling to bear. Where private claims are preempted, the FDA becomes the only game in town. According to a recent report to the House Committee on Government Reform,9 however, FDA enforcement actions have declined dramatically in the last 7 years, coincidentally, the period during which the FDA has most vigorously asserted the preemption doctrine. The number of warning letters issued by the FDA for violations of federal requirements, the true measure of enforcement activity, has fallen by over 50%, from 1,154 in 2000 to 535 in 2005, a 15-year low. Id. Internal FDA documents also show at least 138 cases in which FDA field inspectors found violations of FDA safety requirements but the FDA failed to take any enforcement action against the pharmaceutical manufacturer. Id.

In addition, longer term studies indicate that the FDA's response to continual budget cuts and increasing burdens has been to shift from monitoring and pre-approval investigation, actions which are resource-intensive, to product recalls, which are less expensive and time-consuming but make the public unwitting participants in a massive, uncontrolled clinical trial.10 This means that more people will be hurt by prescription drugs in the future. Unfortunately, there is no federal scheme for compensating victims of most prescription drugs.11 Thus, continued preemption holdings by the courts will mean that many victims will simply go uncompensated or the costs of their care will be shifted to American taxpayers through Medicaid or Medicare.

Congress and the courts have traditionally recognized that private tort claims play an important role in ensuring that drugs are safe and that drug companies continue to improve their products. As one federal judge explained: "Rather than working at odds with each other, federal regulations and state common law acting in concert can improve vaccine safety of existing vaccines and spur the development of better safer products."12 The critical role private lawsuits play will be lost if such claims continue to be held preempted.

RECOMMENDED SOLUTIONS

1. Make Congressional intent clear: include in each bill addressing the FDA and other critical safety agencies, language indicating that it is not intended to preempt state law and include such language in its legislative history. When Congress leaves a vacuum, the courts or executive agencies are only too happy to fill it. The Supreme Court

held in its decision in Hillsborough County v. Automated Medical Laboratories Inc.,13 that, in the absence of clearly expressed congressional intent or subsequent developments that reveal a change in that position, the FDA's position on the preemptive scope of its regulatory authority "is dispositive." To avoid usurpation of its powers by the FDA, Congress must speak clearly on the issue of preemption of pharmaceutical claims.

The recent Prescription Drug User Fee Act [PDUFA] is a good example of how Congress can begin to make its intent clear. The House version of the bill includes language seeking to ensure that the Act does not attempt to "occupy the field of drug labeling," thereby giving pharmaceutical companies additional means to argue preemption of state claims. In addition, during debate on the Senate bill, Senator Kennedy, a chief sponsor and floor manager, stated: We do not intend to alter existing State law duties imposed on the holder of an approved drug application to obtain and disclose information regarding drug safety hazards either before or after the drug receives FDA approval or labeling. Nor are we expressing a belief that the regulatory scheme embodied in the bill is comprehensive enough to preempt the field or every aspect of State law. FDA's approved label has always been understood to be the minimum requirement necessary for approval. In providing the FDA with new tools and enhanced authority to determine drug safety, we do not intend to convert this minimum requirement into a maximum. . . Nor are the bill's requirements that holders disclose certain safety information to the Government intended to substitute for the disclosure requirements that may be required under State law. 153 CONG. REC. S5759 (daily ed., May 9, 2007) (statement of Sen. Kennedy). The language in the House bill enhances the ability of practitioners to fight improper assertions of preemption and arms them with the tools they need to succeed in reversing such holdings.

2. Increase Congressional oversight of the FDA and other safety agencies, in particular, in their assertion of the preemption doctrine and enforcement activities. The United States Supreme Court may soon review cases addressing the question of whether to give agency assertions of preemption so-called Chevron or conclusive deference. This could mean that the FDA Preamble, which was issued in violation of applicable notice and comments requirements and in contravention of the FDA's own statement that its proposed rules involved no substantive changes,14 could be considered dispositive of the preemption question. It is, therefore, incumbent upon Congress, in its oversight capacity, to police such statements and assertions that state law is preempted.

3. Consider legislation limiting preemption. Congress should consider limiting the ability of the state and federal courts to find implied preemption or the executive agencies to assert it by defining and restricting the circumstances under which Congress will permit preemption to be implied.

4. Consider passage of uniform statutory interpretation rules, including those addressing preemption. By providing more guidance to the Courts and agencies in interpreting federal statutes, particularly with regard to preemption, Congress can increase the likelihood that state and federal courts will follow established principles in interpreting federal law. Texas has a code construction act as do many states. While it is obviously not always followed, it does direct the state courts in interpreting state law. Even if it is ignored as it was in Ruby Ledbetter's case, however, it provides practitioners with a basis on which to challenge a trial court's idiosyncratic and improper interpretation of a statute and acts as an important check on judges who legislate from the bench.

CONCLUSION

Unless Congress acts by expressly limiting the application of the preemption doctrine, more citizens injured by prescription drugs, like Ruby Ledbetter and Hannah Bruesewitz, will be deprived of any day in court and any remedy for their injuries. Instead, these costs will be shifted to the American taxpayer. In addition, some trial courts and bureaucrats will continue to amend federal and state law at will in a frontal assault on Congressional authority and private rights. For these reasons and because the wide and improper use of federal preemption to supplant state-law claims is fundamentally incompatible with any notion of a limited government, reduced bureaucracy, and states' rights, I urge Congress to adopt the recommendations outlined here.

1Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S.Ct. 2240, 2250, 135 L.Ed.2d 700 (1996), the Supreme Court found no "indication that either Congress or the FDA intended the relevant FDA regulations to occupy any relevant field." Id. at 2261.

2The FDCA provides that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379(e). The Senate Committee Report for the bill enacting that provision similarly noted that "the legislation explicitly provides that it shall not be construed to

modify or otherwise affect the traditional product liability law of any State. Tort liability rules and requirements would remain unchanged and unaffected." S. Rep. No. 105-43, at 66 (1997).

3Hillsborough County v. Automated Med.Labs., Inc., 471 U.S. 707, 714-15, 85 L. Ed. 2d 714, 105 S. Ct. 2371 (1985) (FDA's statement that particular regulations did not preempt state law was "dispositive on the question of implicit intent to pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent, or subsequent developments reveal a change in that position") (emphasis supplied). The position of the FDA as outlined in the Preamble is [o]pposite to the position of the FDA as stated in its December 2000 proposal of the same amendments . . . The 2000 Proposal explicitly stated that its regulations do not have preemptive effect. Rather, the preamble to the 2000 Proposal explained that the FDA did not want its regulations to preempt state tort law, stating that "there should be little, if any, impact from this rule, if finalized, on the States" and that the 'FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.' McNellis v. Pfizer, Inc., 2006 U.S. Dist. LEXIS 70844 *25-26 (D.N.J. 2006) (quoting See 65 Fed. Reg. 81082 (Dec. 22, 2000)). "The Court notes too that the position taken by the FDA in the 2000 Proposal was entirely consistent with the position the Agency took in 1998 in the Preamble to the new regulations regarding consumer medications' guides." Id. at 26, n.6; see 63 Fed. Reg. 66378 (Dec. 1, 1998).

4"FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in [drug] labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." See Preamble, Requirements on Content and Format of Labeling for Humans Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006).

5See, e.g., Amicus Curiae Brief of the United States in Perry v. Novartis, Civ. No. 05-5350, filed Sept. 21, 2006, at 11. In it, the FDA states:

To the extent, therefore, that the defendants argue that federal preemption bars any failure to warn claims premised on a drug manufacturer's failure to provide a warning not contained in the drug's approved labeling, the defendant is incorrect. FDA has not attempted to 'occupy the field' of prescription drug labeling, and state tort liability for failure to warn does not necessarily prevent FDA from carrying out its regulatory goals. Federal regulations explicitly provide for labeling changes to be made to warn of new hazards or cautions relating to a drug without prior FDA approval. Under this regulatory scheme, preemptive conflict does not exist in every instance in which state tort law seeks to impose liability for the failure to provide a warning not affirmatively mandated by FDA. (Emphasis supplied)

6 The Supreme Court's decision in Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), set forth the standard for review of federal agency decisions and stated that if Congressional intent is clear, the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.

7 The Plaintiff, Ruby Ledbetter, in this case should not be confused with Lilly Ledbetter, the Plaintiff in the recent Supreme Court employment discrimination case, Ledbetter v. Goodyear Tire & Rubber, 127 S.Ct. 2162 (May 29, 2007).

8Even the drug industry lawyers in Buckman admitted that the claims Ms. Ledbetter asserts survive preemption analysis. In fact, during the Buckman oral argument, when asked about what remedies an injured plaintiff would have under his theory of the case, the industry attorney responded: "The fraud [on-the-agency] claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available . . ." Id. (quoting Oral Argument Transcript, Buckman, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2000) (emphasis supplied).

9"Prescription for Harm - The Decline of FDA Enforcement Activity," U.S. House Comm. on Government Reform, Minority Staff, Special Investigations Division (June 2006).

10Mary Olson, "Substitution in Regulatory Agencies: FDA Enforcement Alternatives," JOURNAL OF LAW, ECONOMICS, & ORGANIZATION, Vol. 12, No. 2 (Oct., 1996) at 376-407.

11"The bar to finding preemption is raised even higher because the FDCA provides no remedy for an injured consumer. Thus a finding of preemption here will foreclose a remedy that was traditionally available and for which federal law provides no substitute. Courts have been particularly reluctant to find preemption in such a case without an unambiguous signal of Congressional intent." Perry v. Novartis, 456 F. Supp.2d 678, 684 (E.D. Pa. 2006) (emphasis supplied).

12Mazur v. Merck & Co., 742 F. Supp. 239, 248 (E.D. Pa 1990); MacGillivray v. Lederle Labs Div., 667 F.Supp 743, 745 (D.N.M. 1987) (emphasis supplied). 13471 U.S. at 714-15.

14See 65 Fed. Reg. 81082, 81103 (2000).