



August 27, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20851

Re: Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling (Docket No. 2006-N-0515)

Dear Sir or Madam:

The American Association for Justice (AAJ), formerly known as the Association of Trial Lawyers of America (ATLA®), hereby submits comments in response to the Food and Drug Administration's (FDA) proposed rule regarding pregnancy and lactation labeling. *See* 73 Fed. Reg. 30831.

AAJ, with members in the United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, promote injury prevention, and foster the disclosure of information critical to public health and safety. Members of AAJ represent thousands of patients who have suffered serious, life threatening injuries and death where drug manufacturers have failed to properly warn of the risks associated with their products. AAJ's comments pertain to the preemptive effect of the rule. AAJ believes that the FDA must revise its preamble in the final rule to eliminate any reference to the preemption of product liability lawsuits. This language contradicts express Congressional intent. If a court defers to the FDA's opinion on preemption, drug manufacturers will have complete immunity from lawsuits brought by women and families who were injured by dangerous drugs and will prevent them from seeking recourse.

I. The FDA Must Revise the Preamble Language Because it Contradicts Express Congressional Intent

Although AAJ believes that preamble language does not have any substantive effect, the FDA must remove language from the preamble claiming to preempt product liability lawsuits.¹

¹ A federal court evaluated the preemption statements included in a regulatory preamble. *Perry v. Novartis*, Civ. Action No. 05-5330, 2006 U.S. Dist. LEXIS 75319 (E.D. Pa. Oct. 16, 2006). The court explained that preamble language is "not a binding portion of the regulations, but is instead an advisory opinion." *Id.* at *13 (citing 21 C.F.R. § 10.85(d)(1) (identifying as an advisory opinion "[a]ny portion of a Federal Register notice other than the

Congress always had intended to permit consumers to bring state law claims against drug manufacturers, as evidenced by the language in the Food and Drug Administration Amendments of 2007 (FDAAA)² and floor statements. The Supreme Court also has held that the finding of conflict preemption requires the existence of a legal conflict.³ It would be inappropriate to claim that the proposed rule preempts product liability lawsuits without the existence of a direct conflict on the record, as the agency concedes has not been established. Therefore, the FDA must revise the preamble to eliminate any language seeking to preempt state tort law.

A. Congress Recently Reiterated Its Intent Not to Preempt Product Liability Lawsuits Against Drug Manufacturers

Senator Kennedy, the floor manager of the FDAAA in the Senate, made several statements regarding the preemptive effect of FDA regulations including:

Regulation by the Food and Drug Administration and product liability lawsuits against the manufacturers of harmful drugs work together to protect consumers. Both are needed to force drug companies to disclose health risks posed by their products as soon as those risks are discovered. Both are essential to identifying dangerous drugs and getting them off the market quickly. Effective regulation by the federal government and litigation by victims of dangerous drugs work hand-in-hand to keep patients safe and make drug companies more responsible. This legislation improves FDA oversight of postmarket drug safety, and does not undermine or preempt the efforts by injured patients to seek redress under State product liability law. ...Congress has stated very clearly in the legislation that we do not intend the new authority being given to FDA to preempt common law liability for a drug company's failure to warn its customers of health risks. ... Legislation designed to protect consumers from dangerous drugs must not be distorted into a shield protecting drug companies from accountability.⁴

Likewise, Senator Leahy, the Chairman of the Judiciary Committee (which has jurisdiction over preemption issues) stated that in the FDAAA, “Congress has again decided that we are not preempting State law regarding the responsibility of drug manufacturers to immediately notify consumers of dangers without waiting for the FDA to act.”⁵ Because Congress’ intent is the touchstone of preemption,⁶ the FDA cannot unilaterally decide to preempt state product liability lawsuits. When Congress is clear regarding its preemptive intent, as is the case here, a federal agency cannot override Congress’ reasoned decision.

text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation”).

² Pub. Law 110-85, 121 Stat. 823 (2007).

³ See, e.g., *Medtronic v. Lohr*, 518 U.S. 470, 511 (1996).

⁴ 153 Cong. Rec. S11831, 11833 (daily ed. Apr. 20, 2007) (statement of Sen. Kennedy, Floor Manager of bill).

⁵ 153 Cong. Rec. S11831, 11834 (daily ed. Apr. 20, 2007) (statement of Sen. Leahy, Floor Manager of bill).

⁶ See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (explaining that “the purpose of Congress is the ultimate touchstone” of preemption analysis) (internal quotations omitted).

B. The FDA is Incapable of Being the Final Arbiter of Drug Labeling Which Would Impact Millions of Women and Families

The FDA claims that preemption of product liability lawsuits is necessary to maintain the balancing of risks and benefits that the FDA made at the time of the drug approval. But, that rationale does not take into account situations where the full scope of the risks was not known at the time of the FDA's decision or those risks change over time. That is why federal regulations and the civil justice system always worked in tandem to properly protect consumers. Yet, the FDA's preamble language would change the "balance" that had previously existed within the FDA.⁷

The FDA's current balancing of interests also is severely disturbed by the agency's lack of resources. On January 29, 2008, the House Committee on Energy and Commerce (Subcommittee on Oversight and Investigations) held a hearing entitled "Science and Mission at Risk – FDA's Self-Assessment." At that hearing, employees of the FDA's scientific advisory board and Government Accountability Office testified that the agency is hampered by a lack of qualified scientists, poor information technology, and a weak organizational structure.⁸ These factors make it even more difficult for the FDA to engage in an adequate cost-benefit analysis that could result in injured consumers being unable to obtain fair compensation. The FDA is clearly working to remedy some of these shortfalls. That the agency acknowledges these failures is all the more reason that the agency should not place itself between injured patients and negligent or reckless drug manufacturers, who may not release all pertinent safety information under the new labeling regime.

On May 14, 2008, the House Government Reform Committee held a hearing to discuss whether FDA regulation should bar product liability claims.⁹ Again, the testimony was clear that Congress never intended for FDA regulation to preempt claims and afford complete immunity to the manufacturer. The witnesses also reiterated the FDA's dearth of resources. One month later, the Senate Judiciary Committee held a hearing which included an extensive discussion of

⁷ Prior to the current Administration, the FDA made the following statements regarding federal preemption of civil tort liability claims and other labeling requirements:

Federal preemption could unduly interfere with the goals and objectives of existing State programs.... FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations. FDA's regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements. States may authorize additional labeling but they cannot reduce, alter, or eliminate FDA-required labeling.

Prescription Drug Product Labeling; Medication Guide Requirements, Final Rule, 63 Fed. Reg. 66378 (1988).

⁸ See, e.g., Science and Mission at Risk: FDA's Self Assessment, Hearing Before the House Energy and Commerce Committee Subcommittee on Oversight and Investigations, 110th Cong. (testimony of Peter Barton Hutt and Dr. Marcia G. Crosse).

⁹ House Energy & Commerce Committee, Government Reform Subcommittee Hearing, *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?*, 110th Cong. (May 14, 2008).

preemption and even Senate Republicans remarked about the agency's inability to adequately protect the public.¹⁰

The FDA's decision to preempt without testing the new labeling system also will put women and families at risk. Rather than implement the FDA's policy on an interim basis to determine whether it properly warns pregnant or lactating women of potential hazards, the FDA is plowing forward with the brand new labeling system without knowing whether it works properly. There is no guarantee that the FDA's new system will compel manufacturers to disclose product hazards or will better warn women about the dangers associated with drugs ingested during pregnancy. This new policy would hurt patients like those described below and, indirectly, relieve drug manufacturers of the obligation to compensate those who are harmed by their practices. Nothing in the FDCA sanctions this result.

- Jennifer Hayes (Oklahoma) – While Jennifer was pregnant, her doctor prescribed her Paxil to treat her depression based on the warning label issued under the current FDA regulations. Her son, Kade, was born with an irregular heartbeat. He required open-heart surgery within 24 hours of birth and several smaller surgeries afterward. Kade cannot eat or drink on his own and has to rely upon a feeding tube in his stomach. He is not even well enough to play outside with his brothers. Although certain studies have illustrated a link between Paxil and heart defects in infants born to women who took the drug during pregnancy, the drug's label did not indicate a risk. Given that Jennifer's family had no history or genetic markers for this disease, the research indicates that her use of Paxil contributed to or caused her son's birth defects.¹¹
- Kimberly Gueldenzoph (Michigan) – Kimberly also was prescribed Paxil in August 2003, after struggling with depression for years. She remained on Paxil during part of her pregnancy and stopped taking the drug approximately six months before giving birth to her daughter, Kenndyl, on September 26, 2004. Kenndyl was diagnosed with Hypoplastic Left Heart Syndrome (HLHS) one day after birth. She underwent testing which showed multiple heart defects. The next day, she underwent an open heart surgery. One week later, doctors believed that Kenndyl was strong enough to take her off life support. However, they were wrong. She died on October 13, 2004, her mother's birthday.
- Heather Michelle Horne (North Carolina) – Michelle had been prescribed and used Lotensin HCT for control of hypertension for many years. She became pregnant with her first child in October 2003. Her obstetrician kept her on Lotensin HCT until December 16, 2003, when she was switched to Aldomet for the duration of her pregnancy. At the time, she was still within her first trimester. On July 9, 2004, she gave birth to Zachary Horne. Zachary was born with life-threatening heart and kidney defects, which he eventually succumbed to just seventeen days later.

¹⁰ Senate Judiciary Committee Hearing, *Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Law that Protect Americans' Health, Safety, Jobs and Retirement*, 110th Cong. (June 10, 2008) (comments of Ranking Member, Senator Arlen Specter).

¹¹ See, e.g., *Lawsuit forms around anti-depressant* (June 3, 2008) at <http://www.news9.com/Global/story.asp?S+8420531>.

- Lacee Shore (Oklahoma) – Lacee took the anti-depressant, Celexa, which was pregnant with her son, Gavin Shore. Since his birth, Gavin has suffered from persistent pulmonary hypertension (PPHN) and Shone's complex, a form of congenital heart disease, which has required him to spend much of his short life in hospital. He also endures monthly doctor's visits and will require at least one more surgery. The drug first came under suspicion just a few months before Gavin was born, when the February 9, 2006 edition of the New England Journal of Medicine published a study showing higher rates of PPHN in children whose mothers took this type of anti-depressant drug during pregnancy.

If consumers like these do not have the ability to hold the manufacturer accountable for failure to adequately warn of the dangers to pregnant women, they will be left with no choice but to seek aid through state-funded programs and to become a burden on the taxpayer – rather than the company whose negligence caused the injuries.

AAJ appreciates the opportunity to submit these comments in response to the agency's proposed rule regarding pregnancy and lactation labeling. If you have any questions or comments, please contact Gerie Voss, AAJ's Director of Regulatory Affairs at (202) 965-3500 ext. 748.

Sincerely,



Les Weisbrod
President
American Association for Justice

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