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By Hand Delivery

The Honorable William K. Suter
Clerk, Supreme Court of the United States
One First Street, N.E.
Washington, D.C. 20543

Re: *Wyeth* v. *Levine*, No. 06-1249

Dear General Suter:

I write in response to the October 30, 2008 letter from Mr. Frederick, directing the Court's attention to a congressional staff report issued practically on the eve of oral argument in this case, under the imprimatur of one of respondent's congressional amici. If Mr. Frederick's letter is circulated to Chambers, we respectfully request that this response be circulated as well. In accordance with this Court's Rule 32.3, we have not lodged copies of the documents referenced below (all of which are attachments to the report available at the website Mr. Frederick cites); we will do so promptly should the Court request.

Contrary to Mr. Frederick's suggestion, the report and the documents on which it relies do not undermine petitioner Wyeth's position in this case.

As an initial matter, the report is not entitled to any persuasive weight. Even to call it a "Congressional report" (Letter at 1) is a misnomer; it is authored only by the majority committee staff and has not been adopted or endorsed by the Committee, much less a full House of Congress. And the report marshals only selective evidence of allegedly anti-preemption views of FDA staff, without even purporting to reflect all the evidence collected from FDA by the committee staff.

But in any event, the report and underlying documents lend considerable support to Wyeth's position. For example, they leave no doubt that FDA's "CBE" regulation is and always was intended and understood to apply only in cases involving *new* safety information:

- The report and its attachments are suffused with references to the need for a means of allowing prompt incorporation of *new* safety information into drug labeling. *See, e.g.*, Rep. at 1 (FDA has endorsed tort law insofar as it "help[s] to uncover *risks that are unknown to the agency at the time of approval*"); *id.* at 3 (pre-2008 CBE rule "preserved the responsibility of the

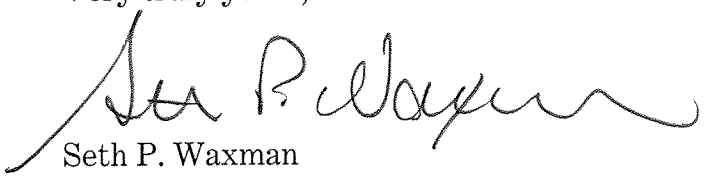
manufacturer to revise the drug label to incorporate *new information* about safety risks"); *id.* at 9 (criticizing proposal to preclude CBE changes to "Highlights" section of drug labeling as inconsistent with FDA's "stated goal of getting *new safety information* out to doctors and patients quickly" and restrictive of manufacturers' ability to "warn about new risks") (emphases added). Notably, although the report (at 13-14) contends that some FDA staff criticized certain of the 2008 changes to the CBE rule, it nowhere suggests that any staff member disagreed with the statement that the 2008 revision codified FDA's "longstanding view" that CBE changes are appropriate only to reflect new safety information. 73 Fed. Reg. 49603 (Aug. 22, 2008).

- The report (at 6) and Mr. Frederick's letter (at 2) selectively quote statements by Dr. John Jenkins, Director of the Office of New Drugs in the Center for Drug Evaluation and Research, suggesting that he disagreed with the proposition that manufacturers generally consult with FDA before making labeling changes. But elsewhere Dr. Jenkins stated: "[T]he CBE pathway does not mean we do not see and comment on the labeling before it is implemented. In many cases we do work with sponsors on the interim labeling to be added via CBE, but we do not approve it since our review is not yet complete." Email from Jenkins to Axelrad et al. (Apr. 25, 2007). This process, he explained, provides "an important pathway to allow important *new safety information* to get to the labeling in a timely manner." *Id.* (emphasis added). The report (at 5) and Mr. Frederick's letter (at 1) likewise cite Dr. Jenkins' supposed disagreement with the characterization of FDA regulations as setting both a "floor" and a "ceiling." But Dr. Jenkins' complete statement—which is not accurately quoted in the report or in Mr. Frederick's letter—makes clear that he objected only on the ground that manufacturers "can and do add *new safety information* without FDA prior approval." Email from Jenkins to Axelrad (May 22, 2003) (emphasis added).

In addition, while the views of individual FDA staff members do not determine whether respondent's claims are preempted, the report (at 5) also implies that Dr. Jenkins questioned whether FDA drug labeling requirements should preempt state law. But the very email that is selectively quoted in the report states: "I agree with the idea that we *should* preempt state requirements for labeling of drugs." Email from Jenkins to Axelrad (June 18, 2003) (emphasis added). He continued: "It makes no sense for us not to have a federal system for labeling approved drugs that is based on a careful scientific review of the available data and a consistent application of labeling policies

across products. I see this as a legitimate FDA area of involvement given our statutory authority over the drug approval process." *Id.* While Dr. Jenkins explored a tentative distinction between positive enactments and common law,[1] he did not purport to be expressing a legal opinion, and this Court has by now made clear that principles of preemption apply equally to common law as to state statutes or regulations. *E.g.*, *Riegel* v. *Medtronic*, 128 S. Ct. 999, 1007-1008 (2008).

Very truly yours,



Seth P. Waxman

Counsel of Record for Petitioner

cc: Counsel of Record for Respondent
Hon. Gregory G. Garre, Solicitor General

[1] Dr. Jenkins pointed out that "we control the text of labeling" and asked "if labeling is the primary way of communicating information about safe and effective use and the labeling is controlled by FDA how can the sponsor be held liable to failure to warn[?]" He acknowledged that the case for preemption would be strongest where FDA has reviewed and rejected a specific warning, but conceded that FDA would be "swamped" if such a requirement were imposed as a precondition for preemption. He also recognized that the case for preemption would be even stronger if the FDA had authority to dictate post-approval labeling changes. The 2007 Amendments give it that power.