CLIENT ALERT

Supreme Court Asked To Consider Congressional Staff Report on Eve of Oral Argument in *Wyeth v. Levine*

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On Monday, November 3, 2008, the United States Supreme Court heard oral arguments in *Wyeth v. Levine* (U.S. No. 06-1249), a potentially landmark tort case regarding federal preemption of state tort suits against the manufacturers of human drugs and biologics. In a surprise move, and just mere days before the scheduled arguments in this case, counsel for the Plaintiff filed a letter with the Supreme Court asking it to consider a just-released report prepared by the House Committee on Oversight and Government Reform, which contained statements by Food and Drug Administration officials that appeared to undermine arguments offered by Wyeth and the Solicitor General in support of their position that FDA approval of drug labels preempts state tort lawsuits.

Both the timing of the release of the report, and its emphasis on the statements of just two FDA officials, have given rise to concerns that the report was a preemptive strike in support of the Plaintiff and other opponents of federal preemption of state tort lawsuits involving pharmaceuticals. A decision in *Wyeth v. Levine* is expected this term. However, yesterday's change in the administration and a new Congress raises a question as to whether new legislation will be proposed which may mute the impact this decision has on future product liability lawsuits.

Contrary Evidence About Internal Agency Support for Preemption

In *Wyeth v. Levine*, the Plaintiff Diana Levine claimed that she was injured by the inappropriate administration of a prescription drug manufactured by Wyeth. On appeal, Wyeth has argued that Levine's suit is preempted because the FDA approved the warning label. The United States Solicitor General filed a brief supporting Wyeth's position.

The October 29, 2008 report issued by Representative Henry A. Waxman (the "Waxman report"), chairman of the House Committee on Oversight and Government Reform, cited to documents the Plaintiff's claim establish that officials within the FDA were opposed to changes to FDA regulations which resulted in the addition of a preemption preamble to the 2006 Physician Labeling Rules. The Waxman report further claims that the Bush Administration resorted to political pressure to ensure that the preemption language was added.

The 2006 Physician Labeling Rule sets forth new regulations governing the content and format of prescription information for human drugs and biologics. Included in the preamble to the rule was the statement that the agency believed that its approval of a drug label preempted conflicting or contrary state law. The 2006 rule also prohibited drug manufacturers from adding additional safety information or warnings to the "Highlights" section of the label without prior FDA approval. Subsequently in August 2008, the FDA issued a final rule which prohibited manufacturers from adding or strengthening a contraindication, warning, precaution or adverse reaction without prior FDA approval. Notice of the proposed rule was provided to the Supreme Court in January 2008 by the Solicitor General in connection with the pending, preemption cases of *Riegel v. Medtronic, Inc*. (No. 06-179) and *Warner-Lambert Co., LLC v. Kent* (No. 06-1498) as well as in *Wyeth v. Levine*. ***See Crowell & Moring Client Alert:*** *U.S.*

Supreme Court Limits Lawsuits Against Medical Device Manufacturers – Products Approved Under FDA's PMA Process Exempt From State Tort Law Claims.

Notably, the brief Waxman report issued last week was a Majority Staff Report and not a report published by the Committee as a whole. The Waxman report describes documents which purport to show the concerns of two FDA officials who questioned the premises of an agency policy of supporting the preemption of state tort lawsuits. It also asserts that under the Bush Administration, the FDA ill-advisedly retreated from its longstanding position that private litigation could "provide an additional layer of protection against unsafe drugs." Reportedly, internal FDA documents showed that "high-ranking career officials repeatedly warned that the central factual justifications for the agency's new positions were false" and that these officials believed that the changes in the labeling rules "would harm patients significantly by delaying the addition of important safety information to the drug labels."

The internal criticisms described in the Waxman report include the charge that the agency's arguments in favor of preemption were "based on a false assumption that the FDA approved labeling is fully accurate and up-to-date in a real-time basis." An FDA official was reportedly also on record contesting the proposition that, without preemption, drug manufacturers would err on the side of adding to much risk information and warnings, noting, "[w]e rarely find ourselves in situations where sponsors want to disclose more risk information than we think necessary." The Waxman report also claims that that the White House pressured the FDA to ignore internal critics and that the FDA Chief Counsel was informed that the 2006 rule changes would "not go forward (this is per the White House)" without the proposed preemption preamble. In further support of its anti-preemption position, the Waxman report concludes that detrimental, public health implications have already flowed from the inability of manufacturers to update drug labels without prior-FDA approval. As an example, it noted the new labeling regulations "delayed by months the addition of important safety information on drug labels" for the drugs Tykerb (Galaxo Smith Kline) and Levaquin (Johnson & Johnson).

On October 31, 2008, Wyeth filed a letter response with the Supreme Court in which it argued that the Waxman report contained cherry-picked statements from all of the evidence collected by the Committee staff and selectively presented the anti-preemption statements of just two agency officials. Further, it claimed, the Waxman report was not entitled to any persuasive weight because it had not been adopted or endorsed by the Committee as a whole.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.