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FDA Proposed Rule About Drug Label Warning Changes Will Lessen Agency's Power To Protect Us powered by BlogBurst

POSTED: Thursday, February 21, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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This January 2008 Rule Issued By FDA Is An Attempt To "End-Run" Congress And Lays The Groundwork For Another Unsafe Drug Debacle Like Vioxx (Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On [January 16, 2008](#) the FDA issued a [proposed rule](#) whereby a drug company would only have to revise the package insert, or label, for its prescription drugs to add an increased warning about a serious side effect where the drug company, itself, was satisfied there was "sufficient evidence of a causal association" between its medication -- *i.e.*, product that it sells for profit -- and the side effect. This is a process which could literally take years (bringing to the mind the recent Vytorin and Zetia "delay" in the release of the ENHANCE clinical study results, albeit that foot-dragging was apparently more about drug efficacy than drug safety).

This new rule proposed by the FDA in January 2008 is wrong for various reasons that we will explore below and, moreover, is such a threat to patient safety that people should contact their members of Congress to express disapproval of this conduct by our FDA.

Let us explore the number of ways in which this FDA proposed rule is not only wrong in theory but actually detrimental to drug safety, also.

To start, the rule proposed by the FDA directly contradicts Congress' expressed intent when it passed the [Food and Drug Administration Amendments Act of 2007 \(FDAAA\)](#) just four months ago. Our Congress included language in FDAAA that confirmed it is the responsibility of a drug company to promptly update a drug label promptly if the company became aware of any new drug safety information, as shown by [remarks made by Senators Durbin, Enzi, Kennedy, and Leahy, as well as others](#), when it passed the FDAAA -- which encompasses the Prescription Drug and User Fee Act (PDUFA).

In more detail, Congress was clear that it intended to keep the burden squarely on drug companies to update their warning labels. Congress explicitly stated that with the passage of this FDAAA law it did not intend to ease the requirements on drug companies to inform doctors and patients about potential drug hazards as soon as

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possible. Rather, as evidenced by the remarks of those several Senators mentioned above, Congress reiterated the need for drug companies to change their labels promptly when they learned of any reasonable information that there was an increased risk of a serious side effect associated with their prescription medications.

Despite this clear Congressional intent, the FDA promulgated this new proposed rule just four months after the FDAAA became law. One might wonder why? Here's a possibility. Lobbyists for the drug companies fought hard to have Congress include in the FDAAA legislation some language to loosen warning label obligations, but failed, *i.e.*, Congress specifically left that language out of the final bill. Following passage of an FDAAA law which is not to their liking, it seems that the drug companies directed their lobbyists to persuade some FDA bureaucrats about this "end-run" on the Congress.

A more important reason that this new rule proposed by the FDA is wrong: It lessens the agency's ability to protect patients from unsafe drugs. Specifically, the FDAAA requires a drug company to update its package insert, or label, to include a warning about an increased risk of a serious drug side effect as soon as there is some reasonable evidence of that risk. By this means, the FDAAA law allows doctors and patients to become aware of a prescription drug's potential risks at the earliest possible time. In turn, this awareness could help prevent the countless injuries and deaths caused by a drug like Vioxx. Recall, Merck fought with FDA and thereby delayed changing the Vioxx label such that it served to sufficiently warn about the risks of heart attacks and strokes -- so that, seemingly, the drug company Merck could continue to sell its so-called "blockbuster" drug Vioxx (this delay, of course, did involve drug safety).

Under the new rule proposed by the FDA in January 2008, a drug company will only need to revise their warning label after the company established "sufficient evidence of a causal association", a process which could take several years (for all kinds of reasons, as one can imagine). To be clear, under the new FDA rule it is the drug company, itself, that has to establish this significantly higher standard before the company is required to inform doctors and patients about a new potential hazard associated with its drug -- leaving doctors and patients in the dark all the while (as the company looks for something it might prefer not to find in the first place, it seems).

In summary, here are the three main things that are wrong with this new proposed rule issued by the FDA:

1. **With this rule FDA has ignored the expressed Congressional intent for FDAAA.** Members of Congress clearly said that FDAAA was not intended to loosen the requirements on drug companies to inform doctors and patients of new serious side effects. This new FDA rule, however, will give drug companies broad discretion to determine whether to revise the drug label to so warn;
2. **This new rule issued by FDA is a step backwards for the agency's purpose of making prescription drug use safer for Americans.** The new FDA rule lessens the agency's power to require that drug companies warn doctors and patients of potential drug safety problems at the earliest possible time. Instead, this proposed rule will give drug companies the ability to choose not to inform doctors and patients even if there is new evidence of a potential serious side effect; and,
3. **The FDA proposed rule makes it more difficult for people injured by an unsafe drug to hold a negligent drug company accountable in court.** By seeking shelter under the FDA's new rule, a drug company will be immunized from accountability -- in terms of legal liability, which currently is available by operation of the FDAAA law -- with the dual contentions that it did not have the "sufficient evidence" such that the company was not required to update its label and warn about a known serious side effect. In turn, if the injured person

does not have recourse for legal compensation from the drug company, costs of care and treatment for that drug injury could become a substantial burden to taxpayers like you and me.

In closing, please urge your respective members of Congress to oppose this proposed rule issued by the FDA in January 2008. Unelected bureaucrats in the FDA should not be allowed to make this end-run on Congress so as to undermine the FDAAA law which our representatives in Washington voted in favor of as being the best way to protect the health and safety of Americans regarding the use of prescription drugs.

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