

August 8, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: FDA Request for Comments on the Draft Guidance entitled, “FDA’s ‘Drug Watch’ for Emerging Drug Safety Information”
70 FR 24606, May 10, 2005, Docket No. 2005D-0062**

Dear Sir or Madam:

I am writing on behalf of the Johnson & Johnson family of companies (“J&J”). We support the fundamental goal of the Drug Watch program to ensure new, important and validated safety information is available in a timely way to health care providers and the public. We fully agree with two of the three categories of information that FDA proposes to post to the website: a) emerging risks that the Agency believes may be associated with the approved use of a drug, and that could potentially be avoided by calling attention to such things as appropriate patient selection or monitoring; and b) information concerning important risk minimization procedures put in the place by the sponsor. These types of information are essential to ensuring appropriate prescribing and disease management decisions.

We are concerned about the public health ramifications of posting the third category of information FDA proposed, that is, information about significant emerging drug safety issues that FDA is still evaluating. Such a step could result in unintended adverse consequences for patients. Publication of emerging safety information that is, in essence, not well enough understood by FDA for the agency to recommend defined actions by healthcare professionals, or patients, could result in widespread confusion. This would be a disservice to the public health.

Such information is likely to frighten patients and cause them to discontinue or modify their drug therapy, despite possibly being treated successfully and safely. Patients will undoubtedly interpret information related to a drug product posted on a government website as an official government-sanctioned statement of truth, notwithstanding any disclaimers FDA may make. It is also unlikely that patients will always consult with their healthcare provider before taking matters into their own hands.

In addition, healthcare professionals are put in what is, at best, an awkward malpractice situation. Regardless of the ultimate determination of safety, physicians will be judged with 20/20 hindsight. Likewise, Drug Watch postings will likely be improperly used as proof that a drug *caused* a particular side effect in product liability lawsuits. Product

labeling should continue to be the authoritative source of information on which healthcare professionals base their prescribing decision. Premature, potentially unreliable information that could potentially endanger patients should not trump labeling.

We agree with PhRMA that the Drug Watch website should be designed with the following principles in mind.

1. Safety-related information published on the website should be robust enough to be useful in guiding prescribing and treatment decisions
2. Safety-related information published on the website should be presented so as to not create undue alarm among patients or encourage patients to alter or discontinue therapy without first consulting with their healthcare professional.
3. FDA should seek timely comment from the sponsor as to the appropriateness of the information prior to its publication on the website.
4. Labeling should continue to be the primary vehicle for communicating safety-related information to the public; the website should complement labeling.

In addition, it is important to consider the impact of the information posted on this website on decisions made by health authorities around the world. If FDA were to put this type of information on its website, it is likely that sponsors would receive numerous, urgent inquiries from other health authorities. However, sponsors will be unable to respond to such inquiries in a responsible and informed manner unless they have advance notice of these postings.. Sponsors would be put in the position of having to respond to emerging risk reports about which the Agency, by its own admission (FDA's proposed disclaimer), has not reached any final conclusions.

We urge FDA to go forward with a Drug Watch website that includes useful, actionable information for healthcare professionals and patients that will enable them to make the best possible decisions with regard to drug therapies. We would also encourage the Agency to consider the potential for confusion, misunderstanding and impulsive and potentially dangerous treatment decisions that the posting of inconclusive safety information is likely to cause.

In closing, we would like to thank the Agency in advance for its thoughtful consideration of our comments/recommendations. If we can provide further assistance, please do not hesitate to contact us at (908) 927-2797.

Sincerely,

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.



Bonnie J. Goldmann, MD

Senior Vice President

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