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August 5, 2005

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

Re: Docket No. 2005D-0062; FDA Request for Comments on the Draft Guidance entitled "FDA's 'Drug Watch' for Emerging Drug Safety Information"; 70 Fed Reg 24606 (May 10, 2005)

Dear Sir or Madam:

Eli Lilly and Company (Lilly) appreciates the opportunity to submit comments to the above-referenced docket regarding FDA's proposed Drug Watch webpage for "emerging" drug safety information.

Lilly fully supports FDA's mission to help the public get the accurate, science-based information they need to use medicines to improve their health. We agree that timely communication of reliable and meaningful drug safety information to healthcare providers and patients is critically important to achieving this mission.

Lilly also endorses the comments to this docket submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA). As detailed in PhRMA's comments, there are parts of the proposed Drug Watch program that can help to achieve the agency's goal of providing timely drug safety information, while other components of the proposal do not support this goal and raise additional concerns.

It is Lilly's intent in these comments to summarize what we view as the most vital components of an approach to providing meaningful drug safety information in a way that is timely but avoids unintended negative consequences to public health. We look forward to working constructively with the agency to build such an approach.

Lilly believes that the product label represents the key source of comprehensive drug safety information for doctors, patients, regulators, sponsors and the public. Drug safety information that is reliable and meaningful to doctors and patients meets the regulatory and scientific standards for labeling. This appears to be the example referred to as "Drug C" on page 3 of the draft guidance, in which case the sponsor and FDA have agreed on the significance of new safety information. Lilly agrees that a Drug Watch website posting should be considered in this type of example if such a posting might result in expediting or broadening communication of this information to doctors and patients.

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Lilly also believes there should be further consideration and discussion of whether a website posting is appropriate in the situation where FDA and the sponsor have sufficiently analyzed and discussed new safety information but have not yet reached agreement, within a reasonable period of time, on appropriate wording or data to include on the label. In such a situation, FDA may have concluded after full input from the sponsor that the safety information meets existing regulatory and scientific standards for inclusion on the product label and should be posted. However, before implementing this approach it would be important that the process, criteria and content for this type of posting be carefully considered defined and disseminated for review and comment.

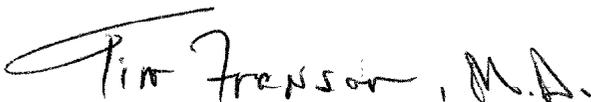
In addition to presuming FDA's careful consideration of the approaches described above, the draft guidance also appears to contemplate an approach to communicating "emerging" drug safety information via the Drug Watch website under a lesser regulatory and scientific standard than exists for product labeling, as described in the example referred to as "Drug A." Lilly believes this approach presents unacceptable public health risks as a result of doctors and patients potentially taking action on inconclusive, premature and unreliable information especially given the absence of precedent or advisement as to what practitioner actions are indicated based on such postings.

Lilly also believes that any communication of important drug safety information must be put into the context of the potential therapeutic benefit. Posting risk information without relevant benefit information is simply misleading. In many cases drug safety information will be misunderstood, and therefore may result in incorrect healthcare decisions, unless it is explained in the context of the offsetting benefits of continued drug use, the comparative risks of discontinuing medication (either with or without a physician's consent), and other possible treatment alternatives. Also, encouraging physician-patient dialogue is paramount, especially to mitigate risks of sudden drug discontinuation and ensure appropriate discussion of therapeutic options. We believe any type of Drug Watch program must take into account these aspects of how doctors and patients are likely to interpret and act on the information provided.

Again, Lilly very much appreciates the opportunity to comment on this draft guidance.

Sincerely,

ELI LILLY AND COMPANY



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