



## Office of the President

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August 8, 2005

Lester Crawford, D.V.M., Ph.D  
FDA Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

### **RE: Draft Guidance for Industry on the Food and Drug Administration's "Drug Watch" for Emerging Drug Safety Information**

Dear Dr. Crawford:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing 49,000 physicians and partners in women's health, we welcome the opportunity to comment on the draft guidance for the Drug Watch web page. ACOG supports the FDA's efforts to provide physicians and consumers with important drug safety information in a timely manner, but we have specific concerns about the content of such a web page, as laid out in the draft guidance.

Obstetricians and gynecologists are committed to providing patients with the most accurate, up-to-date and scientifically valid information about prescribed medications, including a fair assessment of potential risks. However, important questions about the circumstances in which information would be placed on the web page, physician notification and liability must be answered before the system is put into place.

ACOG's overarching and most serious concern with the Drug Watch web page is the increased liability physicians are likely to face when prescribing a drug listed on the web page. Although, according to the draft guidance, efforts will be made to indicate that evidence is preliminary, any drug posted on the Drug Watch will draw consumer, legal, and media questions.

To the extent that incomplete and speculative information on the Drug Watch page differs from known, scientific information on a drug, physicians will be put in an untenable situation and be exposed to exceptional liability in prescribing, continuing to prescribe or not prescribing a drug. And, with no advance notice and incomplete evidence, physicians may be ill-equipped to deal with their patients' concerns about this new information. The liability implications for physicians must be fully addressed before such a system is put in place.

The FDA should also more clearly define what constitutes “sufficiently credible” evidence on drug safety. Would all adverse events, including those associated with incorrect usage by patients, warrant a listing on the Drug Watch page? Use of subjective terminology leaves physicians and their patients guessing about the level and quality of evidence available and how that evidence should affect prescribing decisions.

The discussion of factors the FDA plans to consider when deciding what information to put on the web page appears to indicate that postings may vary in the levels of evidence attached to them, but these distinctions are not clear. For example, preliminary risks still under evaluation will be listed, but also more definitive information, such as “measures to prevent or mitigate harm.” Clarification is needed to guide physician and patient decisions.

While we respect the transparency the FDA is trying to promote, we urge consideration of these concerns, particularly the medical liability for the average physician trying to reconcile known drug information with incomplete and unproven evidence on the Drug Watch website. We look forward to working with you to provide timely drug safety information to both physicians and patients.

Sincerely,

A handwritten signature in black ink that reads "Michael T. Mennuti". The signature is written in a cursive, slightly slanted style.

Michael T. Mennuti, MD, FACOG  
President