



University of  
Washington

CARDIOVASCULAR HEALTH RESEARCH UNIT

Metropolitan Park, East Tower  
1730 Minor Avenue, Suite 1360  
Seattle, Washington 98101-1448  
MR9 Box 358080  
206-287-2777 Telephone  
206-287-2662 FAX



Harborview  
Medical Center

09 81 '03 OCT 16 P1 55

October 9, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852  
Email: [FDADockets@oc.fda.gov](mailto:FDADockets@oc.fda.gov)

Re: Department of Health and Human Services, Food and Drug Administration,  
21 CFR Parts 310, 312, 314, 320, 600, 601 and 606 [Docket No 2000N-1484]  
Safety Reporting Requirements for Human Drug and Biological Products: Proposed  
Rule; 68 FR 12405 to 12497.

Dear Reviewer of Comments,

The proposed rule represent a serious effort to improve safety reporting, and the agency is to be congratulated on proposing some outstanding revisions and important efforts at harmonization.

Several revisions deserve special mention for their merit and for the high likelihood that they will improve safety reporting: (1) the requirement that licensed physicians be responsible for the safety reports (68 FR 12413); (2) the requirement that applications include their "conclusions as to what , if any, safety-related actions should be taken based on the analysis of the safety data" (68 FR 12438); (3) the requirement to comment on the increased frequency even of expected SADR's (68 FR 12437); (4) the requirement to submit serious expected foreign SADR's (68 FR 12442); (5) the increased attention to cumulative reports (68 FR 12440); (6) the requirement that some SADR's are always expedited (68 FR 12414); (7) the use of the "active" query to obtain additional information (68 FR 12433); and (8) the effort to obtain information on denominators (section III.E.2.e 68 FR12439 and III.E.2.k.ix 68FR 12441).

Several additional revisions might improve on the proposed regulations. First, licensed physicians who are responsible for submitting the safety reports should have training in epidemiology. While a knowledge of clinical medicine will help them understand the biologic relations among the components of the SADR, these responsible safety physicians need to be able to understand and interpret patterns in safety data across SADR's. Second, there should be more attention to cumulative reports that summarize safety experience to date. Indeed, cumulative experience of SADR's by type should be part of each of the periodic reports.

00N-1484

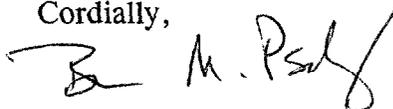
C 44

In section II.A.1, the document indicates: “industry has expressed concern that these [safety] reports, taken out of context and used in a manner for which they were never intended, can create product liability vulnerability” (68 FR 12418). I agree with the FDA that the “credibility and functionality of this critical public health reporting system” is exceedingly important. But the use of spontaneous reports in product liability cases does not necessarily represent a “misuse” of these reports. The current disclaimers are perfectly adequate. Any additional protection for industry might well come at the expense of patient safety.

While these proposed rules represent an important revision, pharmaceutical companies are likely to vary in the degree to which they comply with either the letter or the spirit of these safety reporting requirements. The primary protection for patient safety will therefore be provided by a well-funded safety program at the FDA. The FDA safety program includes not only the spontaneous reporting systems but also the availability of funds to conduct additional safety studies. Congress needs to allocate additional support to the FDA’s important work on safety.

Thanks for the opportunity to comment.

Cordially,

A handwritten signature in black ink, appearing to read "B. M. Psaty". The signature is fluid and cursive, with a large initial "B" and a stylized "M. Psaty".

Bruce M. Psaty, MD, PhD  
Professor, Medicine and Epidemiology  
University of Washington