#1289

MEDICATION/DEVICE REPORTING

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Ralph Nader, Founder

April 12, 1993

Dockets Management Branch (HFA-305)
Food and Drug Administration
Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Docket No. 93N-0072

RE: Proposed "Medication and Device Problem Report"

On behalf of Public Citizen Health Research Group, we offer the following comments regarding the Draft Form for Reporting Suspect Adverse Events and Product Problems With Medications and Devices, Docket No. 93N-0072, published in the Federal Register on February 26, 1993. We are supportive of any method which would improve the reporting of suspect serious adverse events and product problems, because early and consistent reporting practices can help to reduce future similar adverse events leading to serious injuries and death.

Because compliance with reporting regulations is critical in facilitating the FDA's goals of identifying defective and potentially dangerous devices and drugs, the forms provided to various reporters should be designed to elicit accurate and complete information. We do not disagree with the consolidation of drug and device reporting forms. Rather we have several concerns about these specific forms, such as:

THE FORMS HAVE NOT BEEN ADEQUATELY TESTED

Although the proposed reporting forms contain nearly the same required data elements as those they are designed to replace, they differ greatly in structure. Any new reporting form should be field tested among the targeted users, even one with relatively minor changes. But when two types of reporting are consolidated into one form, for use by two types of reporters (mandatory and voluntary), then the reporting system has undergone a complete "overhaul", as evidenced by the increased complexity of the proposed forms. To adopt such a foreign system without adequate testing is particularly imprudent and unscientific. The agency cannot afford to alienate reporters, especially volunteers, and we are not aware that the consolidated forms have been tested among

them. We urge a six-month controlled trial, where proposed forms - in comparison to the old forms - are introduced into various targeted users' facilities. The forms should be adopted only after the agency has sufficient evidence that they will improve compliance among mandatory and voluntary reporters.

IDENTICAL FORMS FOR ALL USERS MAY CONFUSE FDA

As a result of the Safe Medical Devices Act of 1990, medical device user facilities are required to report deaths associated with medical devices to FDA, with a copy sent to the manufacturer. If a device causes a serious injury, the facility must report the incident to the manufacturer, or to the FDA if the manufacturer is not known. Once a report under these provisions is received by a manufacturer, he must investigate and ultimately report to the FDA under MDR regulations. Nurses, doctors and other practitioners (voluntary reporters) also submit reports to FDA.

At present, user facilities submit reports on a different form from that used by manufacturers. Volunteer reporters use yet another form. The proposed forms, being identical for all mandatory reporters (and essentially so for voluntary reporters), could make it difficult for those at FDA to get an accurate count of adverse incidents. According to people in the medical devices division, there would be a danger of duplicate or triplicate reporting of the same incident in the case where a facility submits a report to the FDA and to the manufacturer, a practitioner at the facility submits a report to FDA, and the manufacturer submits its report to FDA, all based upon the same incident. Presently, FDA can readily determine the source of the reports, and account for redundant reporting by comparing forms. If all forms are identical, doing so may be difficult. Accurate numbers are critical in determining the magnitude of problems presented by drugs and devices.

PROPOSED FORMS MAY NOT BE IN COMPLIANCE WITH INTERNATIONAL DRUG REPORTING STANDARDS

Currently, FDA interfaces with other countries in order to learn of their adverse drug experiences. This information is critical, as FDA often utilizes it to determine whether or not to approve a drug for the US, or whether to ban a dangerous drug from the US market. Prior to the adoption of a new reporting form, FDA must determine whether this will adversely affect its ability to continue participating in the international data exchange. FDA cannot afford to jeopardize its continued involvement with other nations in monitoring the safety and efficacy of drugs.

SPECIFIC CONCERNS ABOUT THE PROPOSED FORMS

The consolidated form is an apparent attempt to be "all things to all people". Unfortunately, the end result is more complex and cluttered than any of the existing forms, and the spaces allotted for comments have been reduced. This may cause a reduction in the quality and quantity of information being submitted to FDA.

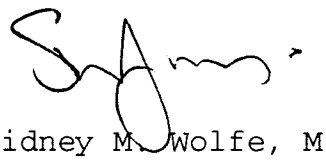
The form contains different blocks to be filled out depending upon whether the incident was caused by a drug or device, but it also requires separate information from "user facility/distributor-devices only", "all manufacturers" and "device manufacturers only". The proposal states that, "[i]f a medication manufacturer is reporting an adverse event in which no suspect medical device is involved, the manufacturer section (section G) on the back side of the form can be completed and reproduced in place of the suspect medical device section (section D) on the front of the form." Obviously, the form requires a measure of scrutiny in order to ensure that it is filled out accurately. The potential for errors is high, perhaps causing a drug to be characterized as a device, or a block of data to be disregarded by a manufacturer.

In addition, we oppose the elimination of manufacturer's data regarding the "method of marketing approval" of a medical device, (510k, PMA, or preamendment exempted) contained in form 3322. Although the FDA already has access to this information, it may facilitate the agency's analysis of the device and appropriate action indicated, if the data is provided by the manufacturer.

We are supportive of the proposed "advice about reporting" contained on the back side of the voluntary report, but would add "unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure" to the list of reportable serious adverse events. Temporary impairments can progress to permanent injury, for example cardiac arrhythmia caused by a drug or device, if not caught, could be life-threatening.

The proposal indicates that "[s]pecific user facility, distributor, and manufacturer reporting guidelines will be developed to provide guidance in the use of the new form." We call your attention to our February 28, 1992 comments to the proposed final rules on Medical Device, User Facility, Distributor, and Manufacturer Reporting, Certification, and Registration regulation (Docket No. 91N-0295, 56 FR 60024, 11/26/91).

Sincerely,



Sidney M. Wolfe, M.D.
Director, Health Research Group
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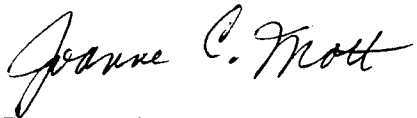

Joanne C. Mott
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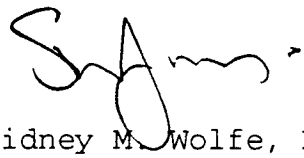

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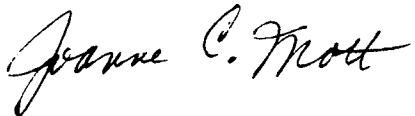

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