1497

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Joan Claybrook, President

October 15, 1999

Deborah Y. Blum
Office of Surveillance and Biometrics (HFZ09520)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: SG2 N31 R1: Proposal for Reporting of Use Errors with Medical Devices

Dear Ms. Blum:

The Global Harmonization Task Force proposal on the reporting of "use errors" associated with medical devices would, if finalized and then adopted as a U.S. regulation, represent a significant weakening of current standards and a fraying of the safety net for U.S. patients.

Under current regulations, manufacturers are required to report to FDA information "that reasonably suggests that a device marketed by the manufacturer:

(1) May have caused or contributed to a death or serious injury; or
(2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." (21 CFR 803.50(a))

The phrase "cause or contribute" is defined under the regulations as an event that may occur as a result of six different factors, one of which is "user error," (21 CFR 803.3(d)) a term that is not further defined in the regulations. Thus, so-called user errors that lead to malfunctions that could cause or contribute to a death or serious injury if the malfunction were to recur are reportable under the current regulations.

The Global Harmonization Task Force proposal, which applies only to user errors (now renamed the equally vague "use errors"), is a significant departure from this regulation. Under the proposal, "events where there is no death or serious injury, should not be reported." This proposal would thus continue to require reports for "use errors" under 21 CFR 803.50(a)(1) (death or serious injury), but not under 21 CFR 803.50(a)(2) (malfunctions that could cause death or serious injury if they recurred).

Continuing to require reporting for this second category of events is critical. The entire purpose of the device reporting requirements is to prevent future adverse events. Yet, under the Task

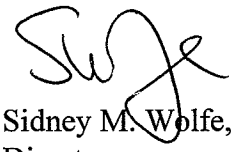
Force proposal, important adverse events deemed by the manufacturer to be due to "use error" could continue to accumulate and not be reported to the FDA as long as in the manufacturer's judgment they would not be likely to cause death or serious injury were they to recur. The proposal does not even deign to provide a justification for this radical departure from current practices; its purpose instead seems to be to appease the device industry.

"Use errors" are the most subjective of the six reporting areas and thus the most susceptible to abuse by manufacturers. The manufacturer would decide whether the user is responsible for the malfunction, and can then decide not to report unless the event involves a death or serious injury. Clearly, it would be in the manufacturer's narrow self-interest to ascribe the event to improper behavior on the user's part. But adverse events are frequently not simply the result of improper use, but may also result from improper training, a mismatch between the user and the device, improper device labeling, etc. None of these should be considered "use error," but the proposed changes would create an incentive for device manufacturers to assign them to the nebulous category of "use error" and thereby evade certain reporting responsibilities. The determination of who or what caused the malfunction is too important to be left to the manufacturer.

The Global Harmonization Task Force proposal thus creates a loophole by excluding one entire category of now-reportable events and then compounds the problem because that category is the one most susceptible to abuse. We urge you to ensure that this pernicious proposal, which substitutes a blame-the-victim mentality for the current regulatory approach, is rejected.

Yours sincerely,

Peter Lurie, MD, MPH
Deputy Director



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