Federation of
American
Hospitals™

Charles N. Kahn III
President

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Dockets Managements Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1484; Safety Reporting Requirements for Human Drug and Biological Products; Proposed Rule (68 Fed. Reg. 12406, March 14, 2003).

Dear Sir or Madam:

In the Federal Register of March 14, 2003, the Food and Drug Administration (FDA) proposed to dramatically revise its regulations concerning pre- and post-marketing safety reporting for human drug and biological products. In the Federal Register of June 18, 2003, 68 Fed. Reg. 36527, the comment period was extended until October 14, 2003.

These comments are submitted by the Federation of American Hospitals (the Federation), the national representative of privately owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, and provide a wide range of acute and non-acute services. The principle objective of the Federation is to foster the public good through the creation and delivery of quality health care for all people; our members share a common philosophy of providing high quality, affordable health care, through free enterprise.

FDA has characterized the rationale of the proposed changes as furthering worldwide consistency in collection of safety information and the submission of safety reports; increasing the quality of safety reports; expediting FDA review of critical safety information; and enabling the agency to protect and promote the public health. The Federation fully supports the rationale of the proposed changes; as professionals involved in health care delivery, Federation members are continually seeking to develop methods and best practices to protect and improve public health. Our members have grave concerns, however, that aspects of FDA's proposal will prove to be so onerous that the reporting of adverse drug experiences will be discouraged, rather than encouraged, thus lessening the amount of information available to FDA. Because of our commitment to improving health care delivery, the Federation favors a more global approach to

801 Pennsylvania Ave., NW, Suite 245 • Washington, DC 20004-2604 • 202-624-1500 • Fax: 202-737-6832

medical error reporting, such as those contained in pending legislation in the House and the Senate.

Three aspects of FDA's proposal are particularly troublesome to the Federation:

- The requirement that drug companies engage in "active query" to collect information about suspected adverse drug reactions;
- The potential for increased liability lawsuits that may flow from these new requirements; and
- The expansion of the concept of adverse reaction to a more broadly defined concept of "medication error" that exceeds the authority and the expertise of the FDA to remedy.

Despite its worthy intentions, FDA must recognize that its legal authority is defined by statute. Thus, while the agency can impose a variety of requirements on those who require FDA permission to market or distribute drugs, it cannot require that the consumers of prescription drugs – patients and medical professionals – file the reports that trigger the reporting obligations of manufacturers and distributors. To that extent, the nation's adverse drug reaction reporting system for marketed products remains, in many ways, both "spontaneous" and voluntary. The Federation believes that aspects of FDA's proposal will impose disincentives on the voluntary reporting of adverse reactions and may result in reporting of "medication errors" which FDA has no legal ability to resolve. These points are discussed in more detail below.

Active Query May Discourage Hospital Reporting

It is understandable that FDA wishes to obtain as much information as possible about a suspected adverse drug reaction (SADR). Thus, under proposed sections 310.305(a), 314.80(a), and 600.80(a), FDA would amend its postmarketing safety reporting regulations to define the term "active query" to mean:

> Direct verbal contact (i.e., in person or by telephone or other interactive means such as a videoconference) with the initial reporter of a suspected adverse drug reaction (SADR) or medication error by a health care professional (e.g., physician, physician assistant, pharmacist, dentist, nurse, any individual with some form of health care training) representing the manufacturer (applicant for proposed §§ 314.80(a) and 600.80(a)). For SADRs, active query entails, at a minimum, a focused line of questioning designed to capture clinically relevant information associated with the drug product (licensed biological product for proposed § 600.80(a)) and the SADR, including, but not limited to, information such as baseline data, patient history, physical exam, diagnostic results, and supportive lab results.

The agency would define this term to describe the process that manufacturers and applicants would be required to use to acquire safety information expeditiously. Active query would be used to:

- Determine whether an SADR is serious or nonserious if the manufacturer or applicant is not able to immediately make this determination . . . ,

- Obtain at least the minimum data set for all SADRs and the minimum information for medication errors that do not result in an SADR if the manufacturer or applicant is not able to immediately obtain this information . . . ,

- Obtain a full data set for individual case safety reports of serious SADRs, always expedited reports, and medication error reports if a full data set is not available for the report, and

- Obtain supporting documentation for a report of a death or hospitalization (e.g., autopsy report, hospital discharge summary) . . . .

Active query would entail direct verbal contact either in person or by telephone or other interactive means (e.g., a videoconference) with the initial reporter of an SADR or medication error. FDA believes that, in many cases, use of active query during initial contact with these reporters would provide manufacturers and applicants with adequate safety information and could eliminate or decrease follow-up time expended by manufacturers, applicants, and the agency. The agency does not believe that it is sufficient for manufacturers and applicants just to send a letter to reporters of SADRs and medication errors requesting further information. These reporters could, however, submit written materials to manufacturers and applicants to clarify or provide support for verbal discussions.

[Citation: 68 Fed. Reg. at 11266]

The Federation understands FDA's desire to require a regulated industry to collect as much information as possible about SADRs, but the requirement of "active query" does not appear to recognize that the recipients of those queries will be already over-worked medical professionals, who may well have to choose between providing patient care and responding to potentially very time consuming information and document production requests. It seems inevitable that those who provide the spontaneous reports to drug companies will, consciously or otherwise, consider whether they are prepared to devote the time and effort that responding to active queries will entail. It is no insult to health care providers to suggest that they may choose to use their limited time to provide care to current patients rather than collect the data that active query may require. Reporting of adverse drug experiences may actually be discouraged given these pressures.

FDA's analysis of the burden in time and money for complying with the new rule does not break out the additional costs of the new "active query" requirement. Yet the magnitude of the costs of complying with the proposed rule is truly dramatic: an annual additional cost of approximately $106 million and 4.5 million hours. As dramatic as these numbers are, they *do not* include the costs or man hours that will be incurred by hospitals, physicians, and others who voluntarily report to FDA or are on the receiving end of "active inquiries."

Potential for Increased Liability

In addition to the burdensome time commitment being asked of hospitals regarding the active query process, there continues to be valid concerns regarding their liability in responding to such queries. As FDA noted in the preamble to the proposed rule:

> Some members of the public have maintained that submission of voluntary SADR reports by health care professionals or consumers to manufacturers or to FDA might be discouraged because of concern that a person or entity might be implicated in a product liability action. In addition, industry has expressed its concern that these reports, taken out of context and used in a manner for which they were never intended, can create a product liability vulnerability. FDA is concerned that such liability misuse of these reports could imperil the credibility and functionality of this critical public health reporting system.
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> Our current safety reporting regulations at §§ 310.305(g), 312.32(e), 314.80(k), and 600.80(l) provide manufacturers, applicants, and sponsors with a disclaimer that permits them to deny that the safety report or other information required to be submitted to FDA under these regulatory provisions constitutes an admission that the drug or biological product caused or contributed to an adverse effect . . . .
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> FDA seeks comment as to whether these "disclaimers" are sufficient to protect manufacturers, applicants, and sponsors, from the use of SADR reports in product liability actions. For instance, perhaps the agency should consider also prohibiting use of SADR reports the agency receives in product liability actions. Accordingly, FDA seeks comment on the need for any further action to promote submission of SADR reports to the agency and guard against their misuse, as well as FDA's legal authority to take any such action.
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> [Citation: 68 Fed. Reg. at 12418]

There is a clear tension between the desire to provide information that could help prevent patient injury (whether by medication or treatment "error" or SADR) and the fear that such information will trigger a lawsuit in a society that increasingly believes that any adverse outcome must be the result of culpable behavior. The additional information FDA seeks to capture through the use of active query can only heighten this tension. We strongly recommend that the use of SADR information be prohibited in product liability actions. However, it is not clear that

FDA has the legal authority to take this action. The Federation would prefer to see clear legislative action in this area. Congress clearly has the authority to bar the use of these reports in lawsuits. Such legislation would eliminate a significant barrier to voluntary hospital reporting.

Medication Errors Definition Too Broad to be Effective

The Federation fully supports FDA's goal of reducing medical errors related to drugs. No national effort to improve patient safety can ignore the major cause of medical errors. However, we believe that FDA's proposed definition of a medication error extends beyond the limits of what the FDA can do to address the problem. Again, the Federation would prefer to see a more comprehensive framework for capturing and resolving a wide range of medication errors as proposed in the pending bills in the Congress.

Proposed § 310.305(a) would amend FDA's postmarketing safety reporting regulations to define the term "medication error" as:

> Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: Prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.
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> [Citation: 68 Fed. Reg. at 12421]

The goal of preventing medication errors is shared by everyone involved in health care delivery. However, by this definition FDA seeks to collect data about actual and potential medication errors it has neither the expertise nor the authority to remedy. Because FDA's authority extends to drug manufacturers, but not physicians and health care facilities, its information collection activities should extend only to those areas in which it could remedy a problem: drug packaging, nomenclature and labeling. The other issues identified in the proposed definition of medication error simply do not fall within FDA's jurisdiction and it cannot, therefore, help remedy any issues that might be identified.

Coupled with issues discussed above - - the burdensome active query process and very legitimate liability concerns - - encouraging the reporting of medication errors outside of FDA's jurisdiction may well add yet another disincentive to the generation of the spontaneous reports that are the trigger for the entire current and proposed system.

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), a body comprised of 24 organizations, including the FDA, has created a "Taxonomy of Medication Errors" that may provide a consensus-based approach for determining the categories of medication errors the FDA can help resolve. The taxonomy establishes a standard language and structure of medication error-related data for use in developing databases that analyze

medication error reports. Based on the taxonomy, we recommend that the FDA confine its reporting requirements to the type of error called "packaging/design" and confine its determination of the causes of medication errors to those called "name confusion" and "labeling". For a complete copy of the taxonomy, refer to www.nccmerp.org.

The Federation wholly supports the goals of the proposed FDA regulation. However, it is our judgment that, as currently proposed, this approach will not be effective in meeting these goals. We look forward to working with FDA and other stakeholders to develop a workable and useful mechanism for the reporting and prevention of adverse drug reactions and medical errors.

Respectfully submitted,