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FDA PUBLIC HEARING ON PROPOSED
MANDATORY DEVICE EXPERIENCE REPORTING RULE

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We have heard a great deal today from industry interests about how FDA's proposal[1] to require manufacturers and distributors of medical devices to report device-associated deaths, injuries, and other problems constitutes "over-regulation." It is necessary to put these industry complaints into historical perspective in order to appreciate just how self-serving, and threatening to conscientious protection of the public's health, they are.

The Nixon Administration has never had a reputation as a special champion of consumer protection, or an advocate of unnecessary burdens on American industry. Let us go back to September 14, 1973, and recall what President Nixon's Assistant Secretary for Health, Dr. Charles C. Edwards, had to say about today's topic. Dr. Edwards was testifying before the Senate Health Subcommittee on proposed medical device legislation. He stated:

> Precise data on the number of injuries caused by faulty medical devices . . . is difficult to obtain partly because these devices are commonly used in critical situations in which a cause-and-effect relationship between defect and patient condition cannot be definitively determined. A more important reason for our lack of data, however, is that, unlike adverse reaction experience from new drugs, adverse reaction experience with medical devices is not ordinarily brought to the attention of the Food and Drug Administration because there is no legal requirement that this be done.[2]

Dr. Edwards went on to endorse Nixon Administration legislation providing "for the maintenance of records and the submission of reports on clinical experience with devices."[3]

Over seven years has passed, and the situation is virtually unchanged as a practical matter. Despite the enactment of the Medical Device Amendments, and despite large numbers of device-associated deaths and injuries during those years, FDA still lacks the power to require submission of information about deaths, injuries, and other potential health hazards. The agency has now proposed reporting rules that are relatively weak in many respects, compared with those applicable to the drug industry--failing to require submission of new studies reflecting on a device's safety or effectiveness, for example, and failing to require submission of promotional materials and changed labelling. And today, industry

interests are asking FDA to scale back drastically, or even withdraw, this belated and relatively weak attempt to obtain the information the agency clearly needs to do a conscientious regulatory job.

I. THE NEED FOR POSTMARKETING INFORMATION ABOUT MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS

The FDA's Bureau of Medical Devices very often fails in its legal obligation to protect the public health because it keeps itself in the dark. The Bureau allows the overwhelming majority of medical devices to go on the market without even requiring, much less adequately evaluating, submissions of information about products' safety and effectiveness. The Bureau has not systematically kept track of what happens once products are being widely marketed. Even when the products are recalled because of defects, the agency usually finds out about it late or not at all.

A. Need for Information About Products Subject to Premarket Testing Requirements

FDA requires premarket safety and effectiveness testing for a limited group of "Class III" devices--a category that accounts for less than 10% of all types of medical devices and diagnostic products. In theory, the requirement of premarket testing would at least partially obviate the need for postmarket reporting, since unsafe and ineffective devices would be kept off the market. But in practice, FDA's premarket review of Class III products has often been grievously superficial--a fact that is clear from the large number of these products that have been recalled. For example, there have been over 50 separate recalls of defective and potentially defective pacemakers and components since the Medical Device Amendments were passed in 1976, involving over 50,000 units. No one knows how many deaths and injuries have resulted from pacemaker defects.

Even conscientious premarket review--and FDA has some very capable scientists performing them--cannot prevent injuries resulting from quality control breakdowns at the plant. Nor does premarket review, as it is presently carried out, detect adverse health effects that occur infrequently.

B. Imperative Need for Information About Products Not Subject to Premarket Testing Requirements

If postmarket reporting is essential for the small minority of products subject to premarket testing, it is an absolute necessity for those products to which the public is subjected without any FDA-reviewed premarket testing at all. We have previously pointed out how FDA has abused the "grandfather clause" of the Medical Device Amendments by clearing 98% of new products that the manufacturers claim are "substantially equivalent" to pre-enactment products, with-

out subjecting the applications to more than superficial scientific review.[4] Many of the recalled cardiac pacemakers were cleared for marketing through this loophole. So was the Rely tampon. Moreover, the great majority of medical devices are totally exempt from premarket testing requirements because as Class II medical devices their safety and effectiveness is supposedly assured by adherence to mandatory performance standards. But there is not a single performance standard in effect, so there is no assurance of safety or effectiveness for these products either. FDA has no systematic information about the hazards of any of these products, as they are being used in medical and laboratory practice. Reporting requirements are essential for all medical products.

C. Need for Comprehensive Reporting

Some industry interests are contending that only deaths and significant injuries that are definitively linked to the use of devices need to be reported. These arguments misconceive both the law and the purpose of FDA's regulatory mission. Under § 519 of the statute, FDA is to establish recordkeeping and reporting requirements that provide four kinds of assurances for each device: (1) that it it safe, (2) that it is effective, (3) that it is not "adulterated," and (4) that it is not "misbranded." Industry-proposed limitations on this regulation would seriously undercut FDA's obligations in these four respects. For example, a device or diagnostic product may be flagrantly hazardous, ineffective or mislabelled and yet not have resulted in any injury at the time the defect was discovered. But under many of these industry-proposed limitations, the product defect would not have to be reported--even though prompt reporting and FDA action would protect the lives and health of many other patients.

We recognize the importance of not glutting the data-gathering system with trivial observations. This can best be accomplished by limiting the amount of information initially required to be submitted to the elements essential for immediate evaluation of the report: name, source, and lot or serial number of the product, an accurate but abbreviated summary of the circumstances of the death, injury, or device deficiency, and an outline of the plan for remedial action. Further information could be obtained by FDA followup, where necessary. We stress, however, that all deaths or injuries that may be caused by a device and all deficiencies that may result in death, injury, or improper or ineffective treatment must be reported. As the FDA itself has recognized, if only confirmed deficiencies were subject to the reporting requirements,

> few device problems would be characterized as confirmed deficiencies and few reports would be submitted, thereby compromising FDA's ability to protect the public from potentially hazardous devices. Moreover, . . . submission of reports of confirmed device deficiencies would be delayed pending the determination by the manufacturer or distributor that such a deficiency actually exists.[5]

The drug regulations similarly require reporting of adverse reactions "whether or not determined to be attributed to the drug."6/

D. Need for Information About Corrective Actions

Victor Zafra, Acting Director of the Bureau of Medical Devices, is reported to have told a Food and Drug Law Institute meeting on December 10, 1980 that "only 15% of recalls come to FDA's attention."7/ Many of the recalls the agency does find out about are brought to the agency's attention long after the fact. Other corrective actions besides recalls are even less likely to be reported to FDA. It is impossible for the agency to carry out its responsibilities to the public in such circumstances. We strongly support the proposed requirement that manufacturers and distributors promptly submit reports of all remedial actions taken.

II. WAYS IN WHICH THE PROPOSAL SHOULD BE STRENGTHENED

The FDA proposal fails to require submission of a number of categories of information necessary to carry out adequate oversight of the performance of medical devices and diagnostic products. FDA should require experience reporting from hospitals, clinics, and clinical laboratories. It should require the submission of changed labelling for any device, and of promotional materials for all restricted devices. It should require the submission of new studies reflecting on a device's safety or effectiveness. And it should provide for prompt telephone reporting not only of deaths, but also of life-threatening injuries and injuries threatening loss of significant body function.

A. Reporting by Hospitals, Clinics, and Clinical Laboratories

Under the current proposal, FDA will have no means of knowing about deaths, injuries, or other problems that are not reported to manufacturers or middlemen. Administrators and staff in hospitals, clinics, and clinical laboratories could provide critical information about device hazards at an early stage if such institutions were included within the scope of the regulation.

According to Bureau of Medical Devices personnel, a voluntary defect reporting effort by nurses and other hospital staff, though initially valuable, came to an untimely end when hospital administrators, perhaps fearful of legal liabilities, ordered that the reporting effort be stopped.

We note also that a 1975 GAO report found serious deficiencies in FDA's efforts to gather information about problems with in vitro diagnostic products.8/ There is little if any evidence that FDA has taken systematic steps since then to determine the nature, frequency, and severity of the problems experienced by clinical lab personnel in handling these products.

We suggest that § 519 of the statute provides sufficient scope for FDA to require reporting from hospitals, clinics, and clinical laboratories by defining those institutions as "distributors" of devices and diagnostic products. They distribute these products, or (in the case of clinical labs) information derived from these products, from the manufacturers or middlemen to the ultimate users--health professionals or individual consumers.

B. Submission of Changed Labelling and Promotional Materials

FDA Enforcement Reports contains instances virtually every week of medical devices or drugs that have been recalled or seized by FDA because of manufacturers' claims or indications for use that are unsupported by scientific evidence. In the device area, FDA only learns of these unsubstantiated claims on a random, ad hoc basis. In fact, as Dr. Ann Holt, Director of Compliance Operations in the Bureau of Medical Devices, told us last month, the Bureau is able to devote only very limited staff resources to monitoring the advertising of medical devices for accuracy and truthfulness.

The Bureau of Drugs requires submission of labelling and, in the case of prescription drugs, of advertising as part of its monitoring efforts.[9/] Section 519 of the statute clearly authorizes the FDA to do the same for medical devices. This is particularly important in view of the final rule on restricted devices, which we trust will be promulgated in the near future. This rule will finally implement FDA's authority to protect the public's interest in truthful and accurate advertising of devices. Given the limits on FDA's staff resources, it is imperative that manufacturers directly provide FDA all promotional materials for restricted devices, instead of forcing the agency to expend its scarce resources searching these materials out.

C. Submission of New Studies

The Bureau of Drugs requires submission of new human or animal studies, whether published or unpublished, concerning approved new drugs.[10/] Such new information is obviously just as valuable for regulatory purposes as reporting of events in clinical practice. Section 519 of the statute clearly authorizes a similar reporting requirement for medical devices. Yet inexplicably FDA in this proposal has omitted such a requirement. We strongly suggest that FDA in its final rule include a requirement for submission of new studies of medical devices similar to the rule for drugs. Completed studies should be submitted to FDA within seven days of the time a manufacturer receives them.

D. Immediate Telephone Reporting of Deaths AND Serious Injuries

The FDA proposal requires manufacturers and distributors to report possibly device-related deaths to FDA within 72 hours of being informed of the death.11/ No explanation is given, and none can be conceived, of the proposal's failure to require immediate reporting of other serious injuries. There is no excuse for failing to report impending blindness, for example. We suggest that the regulation be modified to require 72-hour reporting for all deaths, for all life-threatening injuries, and for all injuries resulting in or threatening loss of significant body function.

E. Freedom of Information

Finally, we suggest that 21 C.F.R. Part 20, Freedom of Information, be amended to make explicit the public's right of access to all information submitted under these rules, after deletion of individual names to protect privacy and of legitimate trade secrets.

REFERENCES

1 Medical Devices; Mandatory Device Experience Reporting, 45 Fed. Reg. 76183-91 (Nov. 18, 1980)(proposed 21 C.F.R. § 803).

2 Medical Device Amendments, 1973: Hearings on S. 2368 et al. Before the Subcommittee on Health, [Senate] Committee on Labor and Public Welfare, 93d Cong., 1st Sess. 183 (1973) (statement of Dr. Edwards).

3 Id. at 187.

4 Statement of Robert B Leflar, Public Citizen Health Research Group, at FDA Ob.-Gyn. Devices Advisory Panel Public Hearing on Tampons and Toxic Shock Syndrome, Oct. 10, 1980.

5 45 Fed. Reg. 76185 (Nov. 18, 1980).

6 21 C.F.R. § 310.300(b)(2)(i) (1980).

7 MDDI Reports, Dec. 22, 1980, at 11.

8 Comptroller General, Public Hazards From Unsatisfactory Medical Diagnostic Products 29, 39-44, 49-52 (1975).

9 21 C.F.R. § 310.300(a)(5) (1980).

10 21 C.F.R. § 310.300(a)(1)-(3) (1980).

11 Proposed 21 C.F.R. §§ 803.24(a)(1) & 803.29(a)(1), 45 Fed. Reg. 76189 (Nov. 18, 1980).