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Ralph Nader, Founder

July 8, 1993

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

Re: Civil Money Penalties: Biologics, Drugs, and Medical Devices - Docket # 91N-0447

Public Citizen's Health Research Group offers the following comments regarding proposed regulations concerning the imposition of civil money penalties by FDA. It has now been 2 1/2 years since Congress, under the Safe Medical Devices Act of 1990, authorized FDA to impose civil money penalties against violators of the medical device laws. Although the civil money penalty provisions were effective upon enactment, according to FDA's Center for Devices and Radiological Health **there has not been a single instance in which FDA has utilized this potentially effective method for deterring violations of the laws by device manufacturers.**

We are supportive of the proposed "complaint and answer" procedure described, because it will provide a quicker and more efficient method for addressing the issues than a formal notice and hearing procedure. However, we urge the agency to be mindful of several important issues beyond the procedural ones, such as:

1. THE MAY 26, 1993 FEDERAL REGISTER NOTICE CONTAINS A SIGNIFICANT ERROR IN SUMMARIZING THE STATUTORY LANGUAGE.

The preamble to the proposed rules for civil money penalty hearings published in the May 26, 1993 Federal Register states that, "civil money penalties are not authorized against persons who violate section 519(a) of the act (21 U.S.C. 360i(a)), with respect to recordkeeping and reporting, or section 520(f) of the act (21 U.S.C. 360j(f)), with respect to current good manufacturing practice (CGMP) requirements, unless the violation constitutes a significant AND knowing departure from such requirements or a risk to the public health [emphasis added]." This misstates the language of the statute. Section 17 of the SMDA states that civil penalties shall not apply to any person who violates the requirements of section 519(a) or 520(f) "unless such violation

constitutes (I) a significant OR knowing departure from such requirements, or (II) a risk to public health [emphasis added]." Clearly, FDA would have a much greater burden in proving that a company's misconduct constituted both a significant departure and a knowing departure from the law, as opposed to proving that the violation was either a significant or a knowing departure. For example, we believe that any knowing failure to report a single death associated with a medical device should be met with civil money penalties. The sooner FDA is made aware of defective medical devices, the sooner the public can be protected from them.

Regardless of whether the foregoing reporting failure was knowing, it was undeniably significant. If it was intentional, it was unlawful, and should be punished. We hope that the inaccuracy is not indicative of a continuing reluctance on FDA's part to enforce civil money penalties, and we urge the FDA to correct this misstatement in the Federal Register in the final regulations, lest manufacturers misunderstand FDA's resolve. The days of the "slap on the wrist" for noncompliant companies should be over.

2. FDA DISCRETION IN ASSESSING CIVIL PENALTIES

Section 17(a) of The Safe Medical Devices Act of 1990 (SMDA) states that "...any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding." The SMDA gives FDA a great deal of discretion in the rules it promulgates to implement the civil penalties statute. Corporate misconduct can only be deterred by methods which counter such corporate behaviors, in the form of stiff money penalties. We urge the agency to adopt a strict posture in determining what sort of violations will constitute grounds for civil penalties, especially where Class III and other potentially dangerous devices are involved, and to communicate this clearly to manufacturers, distributors, user facilities and all persons subject to the medical device laws. The statutory language should be reduced to clear guidelines which can be relied upon by companies subject to enforcement as well as FDA officials attempting to enforce them. Obviously, civil penalties should be utilized in addition to, not in lieu of, all other sanctions presently available (FDA has been notably disinclined to utilize criminal penalties to punish violators, with only 8 companies criminally prosecuted in the 17 years since the enactment of the Medical Device Amendments of 1976).

3. AREAS WHERE CIVIL MONEY PENALTIES SHOULD BE UTILIZED

A. Medical Device Reporting Violations

The Medical Device Amendments of 1976 required that the FDA establish a reporting system for adverse events associated with the use of medical devices in order to assure the safety of these devices once they were allowed on the market. This medical device

reporting (MDR) system could be an extremely effective tool for rapidly getting dangerous devices relabelled or off the market and away from patients, if only all of those companies subject to it would comply. But a disturbing number of companies do not comply. We have been monitoring company compliance with MDR regulations since their effective date in 1986. In a letter we sent to Representative John Dingell in August 1989, we complained that because of poor enforcement by FDA, 35 manufacturers had been caught by the agency failing to report 7 deaths and 109 serious injuries during a two and a half year period from December 1985 to June 1988. A review of the MDR program from July 1988 to August 1991 showed that an additional 65 manufacturers were caught by FDA for failing to report hundreds of adverse events associated with their medical devices including 10 unreported deaths, 140 serious injuries and 168 malfunctions. FDA merely sent regulatory letters to these manufacturers.

The problem is more widespread than this. 3,000 random inspections by FDA between July 1988 and August 1991 found more than 1,000 cases in which medical device problems went unreported or were reported late. The vast majority of these firms received no citations from FDA. Within the past year, several hundred manufacturers have received Warning Letters for MDR violations (Warning Letters are sent only for serious violations, according to chapters 8-10 of FDA's Regulatory Practice Manual, May 23, 1991). To our knowledge, no company has yet been successfully criminally prosecuted for MDR noncompliance. This is an area where civil penalties (or, in the most serious cases, criminal prosecution) would represent a most appropriate sanction, because FDA may not wish to resort to other measures (seizure, injunction and recall) for reporting violations in the absence of good manufacturing practices violations.

B. Good Manufacturing Practices Violations

In the area of Good Manufacturing Practices (GMPs), the recent Congressional report by Representative John Dingell indicates that the GAO and the Inspector General of HHS found that the GMP compliance program "has been FDA's primary means to address the safety and effectiveness of preamendment Class II and III devices that have not had their PMA's called for and reviewed by the Agency." see "Less Than the Sum of Its Parts," a Report by the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, Print 103-N. Obviously, manufacturer compliance with GMP's is critical in providing assurance to patients that medical devices are safe. Unfortunately, approximately 400 Warning Letters were sent to manufacturers in the past year alone, because of serious GMP violations discovered during FDA inspections of medical device facilities. There were no civil money penalties assessed.

C. Violations of Tracking Laws for Implantable or Life-Sustaining Devices

Public Citizen thinks that the device tracking provision of SMDA represents a significant advance for medical device regulation. The need for this provision has become readily apparent over the last several years, as major recalls and after-the-fact patient notifications have been ordered to eliminate or mitigate the problems associated with defective medical devices. Unfortunately, in many cases, patients have not been contacted in time to prevent injury or death. As of August 29, 1993, manufacturers will be required to track the users of certain high risk medical devices. These tracking systems should significantly speed and assure the notification of patients using defective devices because the manufacturers will know who has their devices.

When referring to civil money penalties for violations of device tracking regulations, section 17 of the SMDA states that they shall not apply, "to any person who commits minor violations of section 519(e) [device tracking regulations] .... if such person demonstrates substantial compliance with such section." It is apparent that FDA has great discretion in determining the meaning of "substantial compliance." The agency should provide specific examples of what would constitute substantial compliance and what would not. Because this is another area where civil penalties, rather than seizure, recall, or injunction, may provide the most appropriate sanctions for companies with inadequate tracking systems in place, we hope that FDA will strictly construe the concept of "substantial compliance." We think that in order to be in substantial compliance with tracking laws, a manufacturer should be able to locate at least 95% of the patients implanted with or using its trackable devices.

4. FDA SHOULD UTILIZE CIVIL MONEY PENALTIES INSTEAD OF WARNING LETTERS IN SANCTIONING MANY VIOLATORS

Companies are often found to be in violation of MDR or GMP regulations, but their misconduct is not considered serious enough to warrant a Warning Letter. The Warning Letter is presently the last step before a more serious action such as seizure, injunction, or recall is imposed against a noncompliant company, but alone it provides little deterrent value. If the FDA were to utilize a formal notice of hearing procedure for assessing civil money penalties, it would be extremely burdensome for the agency to assess monetary penalties on a large scale. However, with a more efficient complaint and answer procedure to streamline the process, civil money penalties could be used often in place of Warning Letters. Serious misconduct should not be met with a mere warning. We urge FDA to assess civil money penalties in place of Warning Letters when violations discovered present a very serious risk to the public health.

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FDA will never have sufficient numbers of inspectors to

adequately monitor the device industry. The best tools that we have for removing dangerous medical devices from the market are the MDR, GMP, and tracking systems. The best method of ensuring compliance with the medical device laws and regulations is the use of all available legal means, including civil penalties, to sanction violators. In conclusion, we urge the following:

1. FDA should correct the significant misstatement of the statutory language published in its preamble to the proposed rule for civil money penalties, when publishing the final rules in the Federal Register.

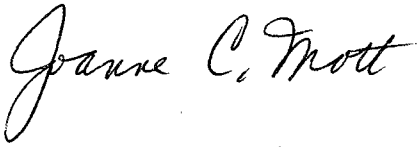
2. FDA should assess civil penalties against all persons or companies that (a) knowingly depart from compliance with MDR regulations, especially in reporting deaths and serious injuries; a knowing failure to report a single reportable death being grounds for civil penalties, or (b) significantly depart from MDR regulations by failing to report large numbers of reportable events, and/or by a pattern of late reporting, or (c) otherwise present a risk to the public health by departure from MDR regulations.

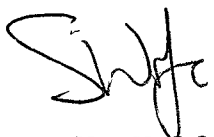
3. FDA should assess civil penalties against any manufacturer that deviates from GMP regulations to the extent which presents a risk to the public health, especially in the manufacture of Class III devices.

4. FDA should provide specific examples of what will constitute substantial compliance with tracking regulations, and what will not, when the final rule is published in the Federal Register. We think that (a) any manufacturer unable to locate 95% of the patients implanted with or using the manufacturer's trackable device should be subject to civil penalties, and (b) If a manufacturer is subject to penalties pursuant to (a), the penalty should be made a function of the estimated number of patients not tracked.

5. FDA should utilize civil money penalties instead of Warning Letters when companies are guilty of violations which present very serious risks to the public health.

Sincerely,





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