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Joan Claybrook, President

October 28, 1994

David Kessler, M.D., J.D.
Commissioner, Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

Today, in the U.S. District Court for the District of Columbia, Public Citizen Inc. has filed a lawsuit against you, the FDA, the Department of Health and Human Services, and Secretary Donna Shalala because of the FDA's unreasonable and illegal delay in promulgating final regulations mandated by the Safe Medical Devices Act of 1990 ("SMDA"). Public Citizen brings this action on behalf of itself and its over 125,000 members throughout the United States who are or may be exposed to unsafe and/or defective medical devices.

It has now been four years since Congress, in an effort to improve the regulation of the safety and effectiveness of medical devices, passed the SMDA. Yet, despite statutory deadlines, the FDA has failed to promulgate numerous mandatory regulations. The delayed regulations include the following:

- regulations requiring **user facilities**, including hospitals and nursing homes among others, to **report deaths and serious injuries** caused by medical devices to the Secretary. Although the FDA had a 12-month deadline (until November 28, 1991) to publish regulations, it has failed to issue a final rule. The prompt reporting of problems with medical devices by the facilities, where they occur, is crucial to getting defective and dangerous devices off the market and away from patients.

- regulations requiring a manufacturer to include an adequate **summary of safety and effectiveness information**, or a statement that such information will be made available upon request of any person, with its application to market a substantially equivalent device. The statutory deadline for issuing this regulation was also November 28, 1991. The FDA has not issued a final rule. Manufacturers often do not provide safety and effectiveness information to the FDA or to any person who requests it, as has been documented in industry surveys conducted by our organization and by the FDA. It is important that manufacturers be held accountable for providing this information to either the FDA or the consumer.

- regulations requiring each medical device manufacturer that is obligated to make reports to the FDA of deaths, serious injuries and malfunctions associated with its medical devices to submit to the FDA an **annual certification** either of the number of reports filed or that no reports were filed. The FDA has not published a final rule, and many manufacturers

are not providing the certification. This certification is an important tool to encourage manufacturers to file all reports they receive because it attaches criminal penalties to submitting a false figure.

- regulations requiring a manufacturer that claims its new product is substantially equivalent to pre-1976 class III medical device pending premarket approval to certify that the manufacturer has conducted a reasonable search of all information known or otherwise available respecting the device and other similar legally marketed devices. Submitters are also required to include in the report a summary of and citation to **all adverse safety and effectiveness data** associated with the devices being compared, and they may be required to submit such data with the report. The FDA has not issued a final rule. This certification is important in placing the burden on the manufacturers to investigate safety and effectiveness issues associated with their devices and to report adverse data.

- regulations requiring manufacturers to conduct **postmarket surveillance** of certain devices, including permanent implants. The FDA has not issued a final rule. Such postmarket surveillance is important in order for manufacturers to identify defective and/or unsafe medical devices, so they can be taken off the market and away from patients.

- regulations establishing **civil money penalties** against any person who violates a requirement of the Federal Food, Drug and Cosmetic Act that relates to medical devices. Civil money penalties are an important tool to ensure compliance with statutory requirements regarding medical devices.

The above provisions were mandated by the SMDA and are necessary to its implementation. Today, four years since the statute was enacted, these provisions remain in regulatory limbo. By not acting promptly, as required by the SMDA and the Administrative Procedure Act, the FDA is allowing many of the loopholes in the law regulating medical devices to go uncorrected. The agency's inaction continues to result in needless deaths and injuries to patients throughout the United States.

Sincerely,

Joanne C. Mott

Joanne C. Mott, J.D., M.P.H.
Staff Attorney

Sidney M. Wolfe, M.D.
Director

PUBLIC CITIZEN HEALTH RESEARCH GROUP

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN, INC.,
2000 P Street, NW
Washington, DC 20036

Plaintiff,

vs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES and DONNA SHALALA, Secretary of Department of Health and Human Services, 200 Independence Ave., SW, Washington, DC 20201, FOOD AND DRUG ADMINISTRATION and DAVID KESSLER, M.D., Commissioner of the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

Defendants.

CASE NUMBER 1:94CV02338

JUDGE: June L. Green

DECK TYPE: Civil General

DATE STAMP: 10/28/94

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This action is brought under the Administrative Procedure Act, 5 U.S.C. §§ 555(b) and 706(1), and arises from Defendants' failure to fulfill their statutory obligations under the Safe Medical Devices Act of 1990 ("SMDA") to issue regulations within statutory deadlines or without unreasonable delay. Defendants' failure to issue the required regulations endangers the health and lives of consumers of medical devices throughout the United States.

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and § 1361.

Parties

3. Plaintiff Public Citizen, Inc. ("Public Citizen") is a

non-profit public interest organization organized under the laws of the District of Columbia, with its principal office in the District of Columbia. Founded in late 1971, Public Citizen's objectives include fighting for safe, affordable, and effective drugs and medical devices, for responsible controls over the delivery of health care, for informed consent and consumer access to health care information, and for safer working conditions. Public Citizen brings this action on behalf of itself and its over 125,000 members throughout the United States.

4. Defendant Department of Health and Human Services ("HHS") is the federal agency charged by Congress with implementing the SMDA.

5. Defendant Donna Shalala is the Secretary of HHS and is charged by Congress with promulgating regulations to implement the SMDA.

6. Defendant Food and Drug Administration ("FDA") is the federal agency within HHS which has issued the existing regulations and tentative rules or interim regulations in connection with implementation of the SMDA.

7. Defendant David Kessler, M.D., is the Commissioner of the FDA.

Statutory Background

8. Prior to 1976, the FDA did not have specific authority to regulate the entry of medical devices on the market, as it had for many years with respect to drugs. The FDA could regulate medical devices only by treating them as drugs, over which the agency had

regulatory authority, but generally did so only if a specified number of injuries or deaths had been documented.

9. In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., which imposed a regulatory structure through which Defendants could pre-clear certain medical devices before they entered the market and other regulatory requirements. Congress placed responsibility for implementing and enforcing the MDA on the Secretary of HHS, which has delegated certain authority to the Commissioner of the FDA.

10. Under the MDA, devices fall into three classes. Class I devices are those for which only "general controls" applicable to all devices are sufficient to provide a "reasonable assurance" of safety and effectiveness. A class I device is not subject to any specific design, manufacturing, or labeling requirements or pre-market approval, but is subject to across-the-board guidelines concerning recordkeeping, good manufacturing practices, and the like, which apply to all medical devices in all classes.

11. Class II devices are those for which general controls alone are insufficient to protect public health. Originally, the statute required promulgation of performance standards for class II devices. Because by 1988, the FDA had failed to promulgate any such standards, the MDA was amended in 1990 so that class II devices are subject, in the FDA's discretion, to "special controls," which may include, in addition to performance standards, post-market surveillance, patient registries, and other measures

deemed appropriate by the FDA.

12. Class III devices are those that either operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose a potentially unreasonable risk to patients. In theory, class III devices must undergo pre-market approval ("PMA"). The PMA process requires the manufacturer to design and implement, with FDA pre-approval, a clinical investigation, and submit the results of that investigation, along with all other relevant studies to the FDA. In addition, the manufacturer's PMA application must contain proposed labeling for the device, a sample of the device, and other specified information. A device may be granted pre-market approval if the FDA finds that there is "reasonable assurance" that the device is safe and effective.

13. The PMA process does not apply to the majority of class III devices because of two major exceptions. First, under the MDA, all devices marketed prior to the effective date of the 1976 Act--so-called "grandfathered" devices--are not subject to pre-market approval, even if they are in the generic type of device later classified in class III. Second, a device marketed after the MDA's 1976 effective date may also bypass the PMA process if its manufacturer can show that the device is "substantially equivalent" either to a "grandfathered," pre-MDA device, or to a class I or class II device, until such time as the FDA issues a final regulation calling for PMA applications for that type of device.

14. Section 510(k) of the FDCA, 21 U.S.C. § 360(k), requires

persons who propose to begin commercial distribution of a device intended for human use to report to the FDA, 90 days prior to introducing the device into commerce, either (1) the device's classification or a statement that the device has no classification and the basis for the determination of classification, and (2) action taken by such person to comply with specified requirements applicable to the device.

15. The SMDA was enacted on November 28, 1990. The SMDA is intended by Congress to improve the regulation of the safety and effectiveness of medical devices. In enacting the SMDA, Congress considered difficulties in the implementation of the MDA and sought to modify the MDA to provide greater protection of the public health. The SMDA is, by and large, not self-executing but rather requires promulgation of regulations to take effect. The SMDA includes numerous provisions requiring Defendants to promulgate regulations on specific subject matters.

Plaintiff's Injuries

16. Over the past three years, employees of Public Citizen's Health Research Group ("HRG") have corresponded and met with representatives of Defendants regarding the FDA's statutory obligation to issue regulations under specific provisions of the FDCA. At various times, Defendants' representatives have assured HRG that issuance of certain regulations was imminent.

17. Notwithstanding their statutory obligations and their assurances of imminent promulgation of regulations, Defendants have failed to issue numerous required regulations, included but not

limited to the regulations specified in the claims for relief alleged herein.

18. Plaintiff brings this action on behalf of its 125,000 members throughout the United States, many of whom use or will use medical devices regulated under the SMDA. Defendants' failure to fulfill their statutory obligation to issue the regulations listed above is causing actual and threatened harm to the health and welfare of many of these individuals, especially those individuals who currently use class III medical devices and devices that entered the market throughout a finding of substantial equivalence.

19. Plaintiff also brings this action in its organizational capacity because defendants' failure to comply with the SMDA impairs Plaintiff's ability to inform and educate the public about the health risks and health benefits associated with certain medical devices and compels Plaintiff to devote a disproportionate amount of its resources to monitoring the performance of class III devices.

20. For the reasons set forth in paragraphs 18 and 19 above, Plaintiff's interests are adversely affected by Defendants' failure to perform their statutory duties under the SMDA.

First Claim For Relief

21. Plaintiff reasserts and incorporates herein by reference the allegations contained in Paragraphs 1 through 20, above, as though fully set forth herein.

22. Section 2 of the SMDA requires the Secretary of Health and Human Services to promulgate regulations to implement section

519(b) of the FDCA. Section 519(b) requires user facilities--which include hospitals, ambulatory surgical facilities, nursing homes, and outpatient treatment facilities which are not doctors' offices--to report deaths or serious injuries caused by a medical device to the Secretary.

23. Under the SMDA, the Secretary was required to promulgate regulations to implement § 519(b) "not later than 12 months after the date of enactment of the [SMDA]," that is, by November 28, 1991. In the event that Defendants did not promulgate regulations to implement section 2 within the statutory deadline, the statute specified that the proposed section 2 requirements stated in the statute were to go into effect 12 months from the date of enactment of the SMDA, that is, November 28, 1991.

24. On November 26, 1991, Defendants published a tentative final rule in the Federal Register. At that time, Defendants indicated that it would publish a final rule at some unspecified future date.

25. On September 1, 1993, Defendants published in the Federal Register a statement that it intended to issue final regulations governing user facility reporting requirements.

26. Defendants have not yet issued a final rule regarding user reports and are not enforcing the statute's proposed requirements.

27. On information and belief, Defendants' conduct in issuing a tentative rule, affirming that it intended to issue a final rule, taking no further action to issue regulations to implement section

2, and failing to enforce the statute's proposed requirements has caused user facilities to believe that the proposed regulations contained in the statute are not in effect and that they have no obligations under section 2 until Defendants issue regulations labelled "final" by Defendants. As a result of Defendants' inaction and failure to comply with the statutory deadline, user facilities are not making the reports required under section 2.

28. Defendants' failure to issue the required regulations implementing section 2 constitutes a violation of the SMDA and of the Administrative Procedure Act, 5 U.S.C. §§ 706(1) and 706(2)(A).

Second Claim For Relief

29. Plaintiff reasserts and incorporates herein by reference the allegations contained in Paragraphs 1 through 20, above, as though fully set forth herein.

30. Section 3 of the SMDA added to the FDCA section 519(d), requiring each medical device manufacturer, importer, and distributor obligated to make reports under section 519(a) to submit an annual statement certifying that it filed a certain number of such reports, or that is did not file any report under section 519(a). The statute does not set a specific deadline for publication of regulations to implement this section.

31. On November 26, 1991, Defendants published a tentative final rule regarding section 3. On September 1, 1993, Defendants published a final rule pertaining to distributors and importers and set effective dates for that rule. As to manufacturers, Defendants have not published a final rule.

32. On information and belief, because of the absence of implementing regulations and in light of the tentative rule, which indicated that Defendants planned to issue regulations, manufacturers have not been complying with section 3's certification requirement.

33. Defendants' conduct in failing to issue a final rule implementing section 3 as to manufacturers nearly four years after enactment of the SMDA constitutes unreasonable delay in violation of the Administrative Procedure Act, 5 U.S.C. §§ 555(b) and 706(1), and is arbitrary and capricious in violation of the Administrative Procedure Act, § 706(2)(A).

Third Claim For Relief

34. Plaintiff reasserts and incorporates herein by reference the allegations contained in Paragraphs 1 through 20, above, as though fully set forth herein.

35. Section 4 of the SMDA requires manufacturers that claim that a product is substantially equivalent to a class III medical device marketed prior to enactment of the Medical Device Amendments of 1976, for which the FDA has not yet called for pre-market approval, to certify that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting the class III device and other similar legally marketed devices. Submitters are also required to include in the report under section 510(k) a summary of and a citation to all adverse safety and effectiveness data associated with the devices being compared, and they may be required to submit

such data with the report. Section 4 does not set forth sufficient regulations to be self-executing, such as specification of how often the certification and summary must be submitted and under what circumstances the Secretary will determine that adverse safety and effectiveness data must be included in the submissions. Section 4 does not state a specific deadline for publication of regulations to implement this section.

36. Defendants published an interim rule in the Federal Register on April 28, 1992, and set an effective date of May 28, 1992. At the request of the Health Industry Manufacturers Association, a trade group comprised of medical device manufacturers, the effective date of the interim rule was stayed on June 1, 1992.

37. Defendants have not issued a final rule.

38. On information and belief, in the absence of implementing regulations and in light of the tentative rule, which indicated that Defendants planned to issue final regulations, manufacturers have not been complying with the requirements of section 4.

39. Defendants' conduct in failing to issue a final rule implementing section 4 nearly four years after enactment of the SMDA constitutes unreasonable delay, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 555(b) and 706(1), and is arbitrary and capricious in violation of the Administrative Procedure Act, § 706(2)(A).

Fourth Claim For Relief

40. Plaintiff reasserts and incorporates herein by reference

the allegations contained in Paragraphs 1 through 20, above, as though fully set forth herein.

41. Section 10 of the SMDA added to the FDCA section 522(a), which requires manufacturers to conduct post-market surveillance of any device that (1) is a permanent implant, the failure of which may cause serious adverse health consequences or death, or (2) is intended for use in supporting or sustaining human life, or (3) potentially presents a serious risk to human health. Enforcement of section 10 requires implementing regulations because the statute does not specify, for example, how often post-marketing surveillance is required, of what the surveillance protocol should consist, and who is qualified to perform it. The statute does not set a deadline for promulgation of regulations under section 10.

42. Defendants have failed to issue regulations to implement section 10 of the SMDA.

43. On information and belief, because of the absence of implementing regulations, manufacturers have not been complying with section 10's post-marketing surveillance requirement.

44. Defendants' conduct in failing to issue a final rule implementing section 10 nearly four years after enactment of the SMDA constitutes unreasonable delay in violation of the Administrative Procedure Act, 5 U.S.C. §§ 555(b) and 706(1), and is arbitrary and capricious in violation of the Administrative Procedure Act, § 706(2)(A).

Fifth Claim For Relief

45. Plaintiff reasserts and incorporates herein by reference

the allegations contained in Paragraphs 1 through 20, above, as though fully set forth herein.

46. Section 12 of the SMDA requires a 510(k) summary to include an adequate summary of any information on safety and effectiveness or a statement that such information will be made available upon request of any person.

47. Section 12 required that the Secretary issue "[w]ithin 12 months of the date of enactment of this Act," that is, by November 28, 1991, regulations establishing the requirements of the summaries under section 12.

48. Defendants published an interim rule regarding section 12 on April 28, 1992, and set an effective date of May 28, 1992. At the request of the Health Industry Manufacturers Association, the effective date of the interim rule was stayed on June 1, 1992.

49. Defendants did not promulgate the required regulations by November 28, 1991, and have not yet issued a final rule.

50. Defendants' failure to issue the required regulations implementing section 12 constitutes a violation of the SMDA and of the Administrative Procedure Act, 5 U.S.C. §§ 706(1) and 706(2)(A).

Sixth Claim For Relief

51. Plaintiff reasserts and incorporates herein by reference the allegations contained in Paragraphs 1 through 20, above, as though fully set forth herein.

52. Section 17 of the SMDA amends section 303 of the FDCA and provides that any person who violates a requirement of the FDCA that relates to medical devices shall be liable for civil

penalties. Except as to user facilities (for example, hospitals, ambulatory surgical facilities, nursing homes, or outpatient treatment facilities which are not doctors' offices) that fail to make certain required reports, this section took effect upon enactment of the SMDA.

53. Defendants published a proposed complaint-and-answer procedure for assessing civil penalties with respect to entities other than user facilities on May 26, 1993. No final rule has been published.

54. On information and belief, because of the absence of implementing regulations and in light of the proposed procedure, which indicated that Defendants planned to issue regulations, entities which Defendants attempt to penalize have successfully argued that civil penalties cannot be assessed.

55. Defendants' conduct in failing to issue a final rule implementing section 17 nearly four years after enactment of the SMDA constitutes unreasonable delay in violation of the Administrative Procedure Act, 5 U.S.C. §§ 555(b) and 706(1), and is arbitrary and capricious in violation of the Administrative Procedure Act, § 706(2)(A).

WHEREFORE, plaintiff prays for an order:

(1) Declaring that Defendants have failed to perform the duties imposed by the statutory provisions described herein;

(2) Enjoining and directing Defendants immediately to perform the actions mandated by the statutory provisions described herein;

(4) Granting plaintiff its attorney's fees and costs reasonably accrued; and

(5) Granting plaintiff such other relief as may be just and proper.

Dated: October 28, 1994 By: Allison M. Zieve

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