DEFIBRILLATORS

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Ralph Nader, Founder

August 11, 1993

Mr. Ronald M. Johnson
Director, Office of Compliance
1390 Piccard Drive
Rockville, MD 20850

RE: OPPOSITION TO THE EXEMPTION OF EXTERNAL DEFIBRILLATORS FROM FDA TRACKING REQUIREMENTS

Dear Mr. Johnson:

We at Public Citizen's Health Research Group have learned that on July 12, 1993, Physio-Control (a wholly-owned subsidiary of Eli Lilly, Inc.) petitioned FDA to exempt external defibrillators from tracking requirements (requiring the manufacturers of certain high-risk devices to develop a system for tracking these devices to enable them to be readily recalled if the need arises). In the event that the petition is denied, Physio-Control requests an extension of the tracking deadline (August 29, 1993) for the company, until 6 months after the date of disapproval. We are strongly opposed to the exemption of external defibrillators from tracking laws and are opposed to any extension of the August 29 deadline to accommodate Physio-Control. The company (as well as every other company) has had ample notice that external defibrillators will be trackable devices. FDA's "final rule" for tracking was published in the Federal Register on May 29, 1992, and pursuant to 21 CFR section 870.5300, "DC-defibrillator and paddles" require tracking. The company's eleventh-hour attempt to avoid the deadline should be rejected by FDA.

EXEMPTION OF EXTERNAL DEFIBRILLATORS FROM TRACKING LAWS WOULD BE CONTRARY TO THE INTENT OF THE STATUTE

Physio-Control argues in its petition to FDA that external defibrillators are used by emergency personnel and not by patients, thus they do not fall within the tracking provisions of the Safe Medical Devices Act of 1990 (SMDA). The SMDA required FDA to establish a system to track a selected group of critical devices, and also authorized the agency to designate other devices which, in FDA's discretion, must be tracked by their manufacturers. Neither

the legislative history nor the statute indicates an intent to limit FDA tracking regulations to ensuring patient notification only. The House Report of the SMDA states: "Subsection (b) contains a user tracking provision which requires the manufacturers of certain high-risk devices to develop a system for tracking these devices to enable them to be readily recalled if the need arises." Thus, Congress's primary objective is to facilitate recalls if high risk devices are found to be defective.

Section 3 of the SMDA, which adds section 519(e) to the Food, Drug, and Cosmetic Act (the act), states that, "[e]very person who registers under section 510 and is engaged in the manufacture of-

"(1) a device the failure of which would be reasonably likely to have serious adverse health consequences and which is (A) a permanently implantable device, or (B) a life sustaining or life supporting device used outside a device user facility, or

"(2) any other device which the Secretary may designate, shall adopt a method of device tracking."

The May 29, 1992 final tracking regulations, which will become effective as of August 29, 1993, are fully consistent with the intent of Congress, and within FDA discretion.

EMERGENCY HEALTH SERVICES ARE NOT DEVICE USER FACILITIES

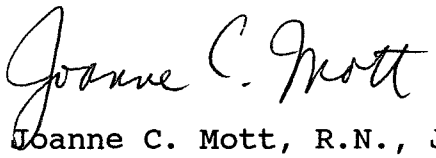
Another approach used by the company to attempt to avoid tracking regulations is to contend that emergency medical services (users of many external defibrillators) should be characterized as device user facilities, thus exempting them from tracking pursuant to section 519(e)(1)(B) of the act. FDA has characterized hospitals, nursing homes, ambulatory surgical facilities and diagnostic or outpatient facilities as device user facilities. We do not think that emergency medical services meet the definition of device user facilities, because they are not "facilities" at all. Emergency medical services (EMS) are often delivered by mobile units staffed by paramedics. Life-sustaining or life-supporting devices used by paramedics in ambulances should be subject to tracking regulations, because of the mobility of the milieu in which the device is used. This will make it easier for the manufacturer to recall the device if it is found defective.

EXISTING GMP REQUIREMENTS WOULD NOT ALLOW FOR ADEQUATE TRACKING OF PHYSIO-CONTROL EXTERNAL DEFIBRILLATORS

In its petition to FDA, Physio-Control argues that existing GMP regulations provide sufficient information to allow manufacturers to conduct an effective recall, adding that its current recall system is effective without any additional tracking requirements. We do not believe that existing regulations are

sufficient to facilitate prompt recalls of critical devices used in mobile units. We urge FDA to deny Physio-Control's petition for exemption of external defibrillators from tracking regulations, as well as the company's request for a 6-month time extension for complying with regulations published 15 months ago.

Sincerely,



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