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Human Resources Division

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February 10, 1994

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
House of Representatives

The Honorable Carlos J. Moorhead
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable Edward M. Kennedy
Chairman, Committee on Labor and Human Resources
United States Senate

The Honorable Nancy Landon Kassebaum
Ranking Minority Member
Committee on Labor and Human Resources
United States Senate

The Safe Medical Devices Act of 1990 (P.L. 101-629, Nov. 28, 1990) requires that we report no later than August 1994 on (1) device user facilities' compliance with the act's reporting requirements, (2) corrective actions manufacturers are taking in response to problem reports received, and (3) the cost effectiveness of the act's requirements and implementation.

The act also requires that the Secretary of Health and Human Services (HHS) report no later than November 1993 on such matters as the safety benefits of the act's requirements, the burdens placed on the Food and Drug Administration (FDA) and device user facilities by the act, and the cost effectiveness of the act's requirements.

This letter describes our work to date and confirms agreements reached with your offices to delay completing our study because FDA has not yet issued the final regulations required by the act and its new reporting system has not yet produced much data from device user facilities.

As of January 1994, FDA has not published the final regulation covering how user facilities, distributors, and manufacturers are to report device problems. The final

rule establishing those requirements and providing a standard form for reporting is scheduled to be published by March 30, 1994. Further, FDA is in the process of implementing a new federal device-reporting system--MedWatch--which will replace its existing device-reporting systems. Use of the MedWatch system began on a voluntary basis in July 1993. FDA officials told us that few user facilities appear to be aware of MedWatch; as of November 1993, fewer than 100 user facility reports had been submitted through the MedWatch system.

We have reviewed the legislative history of the act, studies conducted by the Emergency Care Research Institute (an independent evaluator of health care technology), and prior GAO reports dealing with medical devices and reporting problems. We also gathered information about FDA's efforts to educate over 60,000 device user facilities and about 12,000 device distributors and manufacturers who must comply with the reporting requirements of the act.

We reviewed three studies that FDA had contracted out to the Colorado, Texas, and Massachusetts departments of health to assess user facility compliance with reporting requirements and we visited FDA's data processing contractor to learn about the device-reporting process. In addition, we met with FDA officials to discuss FDA's efforts to implement the act and to develop and publish the regulations required by the act.

FDA officials told us that they have used several techniques to educate user facilities about reporting requirements under the act. These techniques include speeches by FDA officials at a number of conferences attended by health care professionals, distribution of information about the reporting requirements at conferences, and direct mailings of such information to user facilities and device manufacturers. Despite these efforts, it appears from studies conducted for FDA by the three state health departments that many user facilities in those states are still unaware of or unclear about their reporting responsibilities.

The study by the Colorado Department of Health included visits to 175 randomly selected medical device user facilities in the state. According to the Colorado report, only 36 percent of the facilities had fully implemented the act's provisions and only 26 percent of the various facility personnel fully understood the reporting requirements. All types of facilities (hospitals, nursing homes, ambulatory surgical facilities, and outpatient

treatment and diagnostic facilities) were unclear about reporting requirements.

A second study, prepared by the Texas Department of Health, covering 175 randomly selected facilities of different types, found that the awareness levels of the user facilities surveyed were low in view of the November 28, 1991, effective date of the reporting requirements. Only 45 percent of the facilities were aware of the act, and 35 percent had written procedures addressing the medical device reporting requirements.

On the other hand, a report by the Massachusetts Department of Public Health, covering 118 randomly selected facilities of different types, indicated that 72 percent of the facilities were aware of the act's reporting requirements before being contacted. Most of these facilities (82 percent) had established written policies and procedures that addressed at least one of the three required components: reporting procedures, training, and recordkeeping.

We have discussed the information included in this letter with your respective offices and have reached agreement to defer any further work until sufficient time has passed to allow us to better assess the matters defined by the act. At that time we will restart this study and notify your offices as to when we can provide you with the mandated report.

If you have any questions regarding these matters or would like to discuss them further, please contact me on (202) 512-7119.

Mark V. Nadel

Mark V. Nadel
Associate Director, National and
Public Health Issues

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