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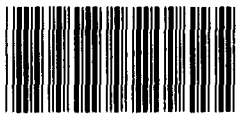

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Medical Device Problem Reporting: A Case Study of a Home Apnea Monitor

Statement of
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Before the
Subcommittee on Health and the Environment
Committee on Energy and Commerce
House of Representatives

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to be here today to discuss some of the work that the General Accounting Office (GAO) has done in the area of medical devices. During the last 4 years, we have issued eight reports in this area and have presented testimony before this Subcommittee on two previous occasions. These reports and testimonies have focused on the Food and Drug Administration's (FDA's) premarketing review processes for devices and device recalls and FDA's implementation of the medical device reporting regulation.

Medical devices include almost everything, other than drugs, that health-care professionals use to diagnose, treat, or prevent illness, improve human functioning, and support and sustain life.[1] More than 1,700 different types of medical devices are available in

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[1]Section 201(h) of the Federal Food, Drug, and Cosmetic Act of 1938, as amended by the Medical Device Amendments of 1976, defines "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is (1) recognized in the official National Formulary or the U.S. Pharmacopeia or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or (3) intended to affect the structure or any function of the human body or bodies of other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body and does not depend upon being metabolized in order to achieve any of its principal intended purposes. The effect of the amendments was to enlarge the 1938 definition of "device" to include (1) devices intended for use in the diagnosis of conditions other than disease, such as pregnancy, (2) in vitro diagnostic products, and (3) specific products previously regulated as new drugs, including soft contact lenses, bone cement, and sutures.

the United States today. They represent an industry of more than $17 billion a year. FDA is authorized to regulate medical devices during all phases of their development, testing, production, distribution, and use.

In February 1989, we reported to this Subcommittee that our review of the implementation of the medical device reporting regulation had found evidence that some medical device manufacturers may have been overreporting problems with devices, while others either were not reporting at all or were underreporting.[2] In its comments on the report, FDA said that our conclusion that the industry was underreporting was "questionable" and that FDA's medical device reporting regulation compliance inspection strategy was sufficient to identify compliance problems. Since the release of our report, we have received additional information from several sources suggesting that problems are underreported and that underreporting is not always identified through FDA's inspection program.[3]

On September 18, 1989, you asked us to investigate a citizen's report to GAO of numerous unreported deaths of patients

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[2]See U.S. General Accounting Office, Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10 (Washington, D.C.: February 1989), p. 3.

[3]The sources include citizen reports, device industry publications, consultation with members of our expert review panel, and review of individual recalls in connection with our report entitled Medical Device Recalls: Examination of Selected Cases, GAO/PEMD-90-6 (Washington, D.C.: October 1989).

associated with the Aequitron Medical, Inc., Model 8200 home apnea monitor and to include our investigation in our ongoing review of FDA's postmarketing surveillance of medical devices for the Subcommittee.

FDA has identified the apnea monitor as a "critical device." Critical devices are intended for surgical implant into the body or to support or sustain life. Their failure to perform when used properly in accordance with instructions provided in the labeling may sometimes be reasonably expected to result in a significant injury to the user.

Apnea is a prolonged lack of respiration that can result in low blood oxygen levels, which can lead in turn to brain damage and death. The condition can be induced by a variety of underlying medical disorders. However, premature and low birthweight infants are particularly prone to apnea.

Apnea monitors are electronic devices intended to detect episodes of apnea. In a typical device, when either breathing or heart rate falls below set levels or when the device's electrical leads are improperly attached to a patient, both audible alarms and flashing lights are triggered. Specialized models of apnea monitors are designed for hospital and home use. To avoid lengthy hospital stays, home apnea monitors have been increasingly used in recent years.

With the concurrence of the Subcommittee staff, we undertook a case study based on three specific questions:

-- How many complaints involving the death of patients have been associated with Aequitron's Model 8200 home apnea monitor?

-- Did the device manufacturer comply with FDA's existing problem-reporting regulations and procedures?

-- What actions did FDA take when it received information from the device manufacturer or other sources that Model 8200 had been associated with numerous deaths?

In this testimony, I will concentrate on the findings, conclusions, and recommendations of this case study.[4]

Our case study methodology precludes generalizing from these findings and conclusions to other devices and manufacturers. Instead, the study's function is to illustrate some of the critical concerns that we identified in our earlier generalized work on the implementation of the medical device reporting regulation. Included there were concerns about the overall efficacy of the FDA medical device reporting regulation compliance

[4]See U.S. General Accounting Office, Medical Devices: Underreporting of Serious Problems With a Home Apnea Monitor, GAO/PEMD-90-17 (Washington, D.C.: May 1990).

program and, in particular, the finding that a number of FDA inspections had discovered instances in which reportable serious injuries and deaths had been recorded in a manufacturer's files but not reported to the agency. The data on which this study is based were collected between September 1989 and December 1989.

I will begin with an overview of our findings and conclusions. Then, I will discuss our findings with regard to each of the evaluation questions in greater detail.

OVERVIEW

First, we found that between January 1983 and January 1989, Aequitron had received at least 70 complaints that the deaths of patients were associated with the use of the Model 8200 home apnea monitor.[5]

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[5]We found that an Aequitron document entitled "H/I/Death File" (or "Hazard, Injury, Death (HID) File") contained information abstracted from the special section of the record of complaints reserved for hazards to safety, injuries, and deaths that a device manufacturer is required to maintain under the good manufacturing practices (GMP) regulation (21 C.F.R. 820.198). The HID file listed 82 complaints, 68 of which referred to deaths. Two additional complaints of death were contained in a similar list drawn from the "general" portion of Aequitron's GMP record of complaints. According to the manufacturer, the HID file contains complaints alleging that serious injuries or deaths were associated with the device, but some of the complaints do not allege that a malfunction of the monitor occurred. We did not independently investigate each complaint on the list to determine the circumstances of the events; causal connections between the device and the safety hazard, injury, or death; or the actual occurrence of the events listed.

Second, we found that the manufacturer had maintained the required record of complaints but had not fully complied with the reporting requirements of the medical device reporting regulation.[6] A partial review of the manufacturer's complaint record by FDA found that 10 unreported complaints should have been reported, including 4 that involved the death of patients. We could verify that only 6 of the complaints of deaths dated after the implementation of the medical device reporting regulation were reported to FDA. Two of these complaints of death were reported only after FDA compliance actions, nearly 1 year after the events.

And, third, we found that when FDA received information about the association of the monitor with deaths, it investigated whether a sample of complaints should have been reported to FDA. Following the investigation, FDA cited the device manufacturer for noncompliance with the medical device reporting regulation and, in concert with the manufacturer, reviewed the manufacturer's problem-reporting policy. FDA then reviewed a revised problem-reporting policy submitted by the manufacturer and concluded that it

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[6]The medical device reporting regulation, effective December 13, 1984, requires that device manufacturers report to FDA whenever they become aware of information that reasonably suggests that one of their devices may have caused or contributed to a serious injury or death or has malfunctioned in such a way that, if the malfunction were to recur, the device would be likely to cause or contribute to serious injury or death. See Medical Devices: FDA's Implementation for a detailed discussion of the medical device reporting regulation.

"appeared adequate." These actions resulted in the submission of more than 150 additional reports to FDA.

In sum, our findings with regard to this study of an apnea monitor are consistent with our earlier finding of differences in the interpretation of medical device reporting requirements.[7] In this case, a manufacturer's interpretation of the requirements has resulted in the underreporting of serious problems associated with its device. It also illustrates a weakness in the compliance inspection process. Although the manufacturer had been the subject of several inspections, it was nearly 4 years after the medical device reporting regulation went into effect before FDA's inspection program identified and attempted to resolve the underreporting.

In the course of our study, we also learned that the parents and other laypersons who are the primary users of home apnea monitors are not always adequately informed about the limitations and risks of these devices. The current technology is, for example, unable to detect some kinds of apnea, and some monitors may be overly sensitive to interference from electronic appliances found in the home or the motion of other objects near them--for example, parents' bodies or fluttering window curtains. The instructions and training that accompany such devices may not make such limitations sufficiently clear to permit parents to make well-

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[7]Medical Devices: FDA's Implementation, p. 4.

informed decisions about the risks of using the devices or about using them in ways that minimize the risks.

Let me now turn to a more detailed discussion of our findings with regard to our three specific evaluation questions.

Question 1: Complaints of Death

Our first evaluation question was: How many complaints of the deaths of patients were associated with the Aequitron Medical, Inc., Model 8200 home apnea monitor?

We received information through the GAO hotline that there was evidence of serious nonreporting or underreporting of problems associated with Model 8200.[8] We were also told that many of the unreported complaints involved the deaths of the patients.

FDA's "good manufacturing practices" regulation requires that manufacturers maintain two types of records regarding the complaints they receive from users about their products.[9] The first is a general record of users' complaints. The second is a record exclusively devoted to complaints alleging that hazards to

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[8]This information was simultaneously provided to the staff of the Subcommittee.

[9]Section 520(f) of the 1938 Federal Food, Drug, and Cosmetic Act, added by the Medical Device Amendments of 1976, authorizes FDA to promulgate regulations that specify practices in the manufacture, packaging, storage, and installation of devices. The good manufacturing practices established by the regulation include controls over manufacturing, specifications, processing procedures, device components, packaging, labeling, manufacturing equipment, and records.

safety, injuries, or deaths are associated with a medical device.

Evidence subsequently provided to us included a table labeled "H/I/Death File" and identified users' complaints related to the Aequitron Medical, Inc., Model 8200 home apnea monitor. The table contained 82 complaints with four categories of information for each complaint.[10]

We investigated the origin and contents of the HID file and we determined that it was in fact a list of complaints derived from the device manufacturer's "hazard, injury, or death" record. This is the record required by the GMP regulation. The list contained complaints that the device manufacturer had received about its Model 8200 apnea monitor dated between January 1983 and January 1989.[11]

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[10]See footnote 5 above. The four data categories for each complaint were serial number, date of complaint, reason for return, and analysis. For 71 out of 82 complaints listed on the HID file, the "analysis" category listed the device as "in-spec" or "fully functional." It is important to note with regard to the analysis category that the general limitations of the technology employed in apnea monitors or the specific limitations of the design of a particular model may cause a monitor to fail to detect apnea events in some circumstances. Such an occurrence is known as a "false negative." If this happens, later testing of the monitor would not necessarily reveal that a component had malfunctioned, and the device could be found to be "within specifications" or "fully functional."

[11]Model 8200 was introduced into the market in June 1982. According to the manufacturer, approximately 30,000 of the monitors were distributed between 1982 and 1987, but it is not possible to estimate the number in actual use or their frequency of use.

Our analysis of the HID file showed that it listed 68 complaints in which the word "death" was included in the category of reasons for the device's return to the manufacturer. Further research found that a similar list drawn from the manufacturer's general complaint record contained 2 additional complaints in which the word "death" was included. There were therefore a total of 70 complaints in which the allegation of a patient's death was included in the complaint description.[12] The remaining 14 complaints in the HID file were complaints that included allegations of either hazards to safety or injuries. (See table 1. The remainder of the table is discussed below.)

Table 1: Complaints and Medical Device Reporting Regulation Reports on Aequitron Medical, Inc., Model 8200 Apnea Monitor

	Complaints in Aequitron's files			Medical device reporting regulation reports to FDA		
	In "H/I/Death File"	In "general" file	Total	Before FDA's May 1988 inspection	After FDA's May 1988 inspection	Total
Deaths	68	2	**70**	5	2	**7**
Nondeaths	14	66	**80**	78	193	**271**
Total	**82**	**68**	**150**	**83**	**195***	**278**

*150 of these reports were submitted in response to FDA compliance actions

Question 2: Compliance

Our second evaluation question was: Did the device manufacturer comply with FDA's existing problem-reporting regulations and procedures?

[12]The manufacturer confirmed that these were complaints alleging that a death had been associated with the use of the device.

FDA's primary source of information about problems associated with the use of medical devices consists of the manufacturer's reports generated by the requirements of the medical device reporting regulation (21 C.F.R. 803). This regulation requires that device manufacturers telephone an initial report to FDA on serious injuries and deaths within 5 calendar days, and it requires that this be followed by a more complete written report within 15 working days. Reportable malfunctions that do not involve serious injury or death must be reported within 15 working days of the manufacturer's receiving the device-problem information. One important source of information that leads to medical device problem reports is complaints to the manufacturer, which can be made by health-care professionals or other users of devices.[13]

We compared the 70 complaints that contained the word "death" with FDA's record of medical device problem reports and found that 14 complaints were dated before the medical device reporting regulation was promulgated. The significance of this is that before the regulation was promulgated, the device manufacturers' obligations were fulfilled by maintaining general complaint records and making them available to FDA during GMP inspections. However, we found 56 complaints associated with deaths whose listed dates fell after the medical device reporting regulation was implemented.

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[13]According to the GMP regulation, a complaint is a written or oral expression of dissatisfaction regarding the identity, quality, durability, reliability, safety, effectiveness, or performance of a device.

Only 4 reports in FDA's medical device reporting data base as of September 1989 could be confirmed as corresponding to complaints from the list of 56 and, therefore, as having been reported to FDA in accordance with the provisions of the regulation. One additional medical device problem report on a death associated with Model 8200 was reported to FDA during this time but could not be identified with a specific complaint on the HID file, because the manufacturer had not submitted a serial number with the medical device problem report. Thus, at least 51 of the 56 complaints of death had not been reported before FDA began to take compliance actions.

The information in the HID file alone was not sufficient for us to make a definitive judgment about the reportability of the complaints or to establish causal connections between the device and the safety hazard, injury, or death. The examination of the manufacturer's complete record for each complaint, which would be necessary for such assessment, was beyond the scope of our review. In a partial review of the complaint record, FDA found that 10 unreported complaints should have been reported, including 4 that alleged the death of patients.[14]

It is important to note that not all incidents in which a device is associated with the death of a patient must necessarily

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[14]A more detailed discussion of this review is contained in the following section of this report on FDA's actions.

be reported to FDA under the medical device reporting regulation. The regulation requires reporting incidents to FDA only if the information in the possession of the manufacturer "reasonably suggests" that a device may have caused or contributed to a death or a serious injury. If a health-care professional states to the manufacturer that this has happened, then the manufacturer is required to file a medical device problem report.[15] But in the case of a report from a layperson, if an immediate investigation by the manufacturer reveals that a patient was not connected to an apnea monitor at the time of death, or that the monitor's alarm sounded and the caregiver was alerted even though the patient could not be revived, then a report might not be required. FDA has characterized the circumstances in which home apnea monitors are used and the limitations of the technology they employ as sometimes making it difficult to determine whether a problem is reportable under the medical device reporting regulation.

Question 3: FDA's Actions

The third question our study addressed was: What actions did FDA take when it received information from the device manufacturer

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[15]According to the "per se" reporting rule, whenever a health care professional advises a manufacturer that one of its devices may have caused or contributed to a serious injury or death, the manufacturer is "per se" in receipt of information that "reasonably suggests" that a device may have caused or contributed to a serious injury or death and must therefore report the event. It does not, however, imply that similar reports from persons other than health-care professionals are not reportable.

or other sources that Model 8200 had been associated with numerous deaths?

One of the principal tools of FDA's postmarketing surveillance of medical devices is biennial inspections for compliance with the GMP regulation. In addition, FDA conducts "for cause" inspections when they are warranted by complaints or other evidence of problems with devices.[16] FDA assesses device manufacturers' compliance with the medical device reporting regulation by executing a special medical device reporting inspection program as part of its GMP inspections. The results of these inspections can lead to additional actions by the agency.[17]

We found that between August 1984 and June 1989, FDA had various contacts with Aequitron, including at least eight formal inspections. Three were GMP inspections, and two of these included the medical device reporting component. Five were "for cause," including three that were initiated in response to complaints FDA had received. One was a follow-up to a medical device problem report on Model 8200, and one was a follow-up to an

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[16]A principal rationale for "for cause" inspections is information developed by FDA analysts who monitor and compare reports submitted through FDA's voluntary problem-reporting program, device recalls, and the medical device reporting system.

[17]According to FDA, the inspection strategy adopted by the agency will result in a medical device reporting regulation compliance inspection for every firm manufacturing medium-risk (class II) and high-risk (class III) devices at least once every 4 years and incorporating manufacturers of low-risk (class I) devices less frequently.

FDA district office's recommendation to recall Model 8200.

During a May 1988 GMP inspection, FDA examined the manufacturer's complaint records and identified 10 unreported complaints that FDA inspectors believed met the medical device reporting regulation's definitions of reportable events. Four of these complaints contained allegations of the death of patients. As a result of this May 1988 inspection, a notice-of-adverse-findings letter indicating "noncompliance" with the medical device reporting regulation was issued to the manufacturer in October 1988.[18]

Representatives of the manufacturer stated that FDA's finding of "noncompliance" resulted from a difference in the interpretation of the medical device reporting requirements. According to the manufacturer, many of the unreported complaints had not been made by health-care professionals and could not be confirmed by the company within the required reporting time. Therefore, in accordance with its interpretation of the "per se" provision of the medical device reporting regulation and company policy, Aequitron did not submit these types of reports.

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[18]A notice-of-adverse-findings letter may be sent to a manufacturer when an inspection reveals that a manufacturer or individual is in violation of the laws and regulations or when there is information that an existing condition or practice may lead to a violation if left uncorrected (although the agency has concluded that the nature of the violation does not require immediate action against the manufacturer or individual).

In our earlier study of the implementation of the medical device reporting regulation, we reported that the evidence suggested an undetermined amount of overreporting by some device manufacturers and that others were either not reporting or underreporting.[19] The most frequently identified dimension of noncompliance noted by FDA inspectors was failure to establish adequate procedures for handling complaints to determine their reportability (20 percent of all such citations for the first series of medical device reporting regulation compliance inspections and 53 percent for the second series).[20] We also encountered variations in the interpretation of reporting requirements among the FDA officials and staff we interviewed.

As a result of the October 1988 notice-of-adverse-findings letter and negotiations between FDA officials and the apnea monitor manufacturer, the manufacturer agreed to review its complaint records and revise its medical device reporting policy. Subsequently, Aequitron submitted medical device problem reports on 6 of the 10 incidents listed in the notice-of-adverse-findings letter, including 2 of the complaints in the HID file involving deaths. These 2 reports of death were submitted 1 year and 9 months, respectively, after the events they described.[21] The

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[19]See Medical Devices: FDA's Implementation, p. 61.

[20]See Medical Devices: FDA's Implementation, p. 59.

[21]The manufacturer and FDA subsequently agreed that 4 of the 10 complaints cited in the notice-of-adverse-findings letter were not reportable incidents.

manufacturer also submitted 144 reports of malfunctions involving confirmed alarm failures.[22] Aequitron thus submitted at least 150 medical device problem reports in response to FDA compliance actions. (See table 1.)

After we had completed the data collection for our report, FDA conducted a comprehensive good manufacturing practices and medical device reporting regulation inspection of Aequitron. FDA indicated when it reviewed our draft report that it was reviewing the results of this inspection to determine what regulatory action was warranted.

Aequitron also submitted a revised medical device reporting policy to FDA, and FDA notified the manufacturer that its revised policy was adequate. However, we found certain aspects of the revised reporting policy to be inconsistent with the medical device reporting regulation. Specifically, we believe that it is improper to condition the reporting requirement on either the confirmation or the observation of a malfunction.[23] The Department of Health and Human Service (HHS) agreed with this opinion. The agency acknowledged that the Center for Devices and

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[22]Apnea monitor alarms meet FDA's definition of a "critical device component"--that is, any component of a critical device whose failure to perform can be reasonably expected to cause the failure of a critical device or to affect its safety or effectiveness.

[23]Medical device problem reports of malfunctions were submitted. Malfunction reports describe problems whose occurrence was not associated with the injury or death of a patient but that may result in injury or even death if they should recur.

Radiological Health (CDRH) made an error in allowing Aequitron to make its reporting of complaints contingent on the confirmation or observation of a malfunction. HHS stated that the firm was notified of the correct interpretation at the time of the inspection we referred to earlier.

The time required in this case for FDA to identify the underreporting problem raises questions about the effectiveness of the agency's inspection program and its capacity to identify potentially serious device problems through monitoring complaints. The inspection strategy is designed to include special emphasis on firms manufacturing the types of device that have demonstrated reportable problems and scheduling more frequent medical device reporting regulation inspections for those manufacturers.

A number of inspections took place after complaints of alarm failure had been received by the manufacturer. Nine of the complaints in the HID file involving alarm problems and the death of patients are dated before the manufacturer underwent its first GMP inspection. By the end of the manufacturer's third year of operations and before a second FDA inspection, it had received an additional seven complaints of alarm problems and deaths. According to the device manufacturer, all the complaints that had been received with allegations of hazards, injuries, or deaths were placed in the appropriate GMP record. The first GMP inspection, in 1984, found "no significant deviations." During

the second inspection in 1984, in response to a complaint of the monitor's failure to sound its alarm, FDA noted that the manufacturer had 17 monitors returned for problems with the alarm.

Subsequently, there were several inspections and other interactions between the manufacturer and FDA about a variety of problems associated with various models of apnea monitor. FDA reported that during an inspection in January 1987, it reviewed all complaints of hazards, injuries, and deaths received since 1985. It was not until a May 1988 inspection, 4 years after the first GMP inspection, that FDA dealt with the reportability of complaints about alarms. By that time, FDA had received a total of 83 medical device reporting regulation reports on the monitor.[24] (See table 1.) More than 88 percent of the reports involved allegations of an alarm failure, including the death of two patients.[25]

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[24]Many of these reports did not originate in complaints to the manufacturer. Reports must be made under the medical device reporting regulation, not only in response to complaints but also whenever a manufacturer acquires information from any source that reasonably suggests that one of its devices may have caused or contributed to serious injury or death or has malfunctioned in such a way that, if the malfunction were to recur, it would be likely to cause or contribute to serious injury or death. Some of the other sources of such information include the manufacturers' own research, testing, or servicing of their devices as well as the medical and scientific literature.

[25]Of 278 reports submitted by September 1989, consisting of 271 malfunction reports and 7 reports of deaths, the manufacturer's tests confirmed that Model 8200 had malfunctioned in 271 of the complaints. However, Aequitron's tests did not confirm that the device had malfunctioned in any of the 7 complaints in which the death of a patient occurred.

FDA did not provide evidence that its inspection procedures included any systematic evaluation of trends in the frequency, type, or severity of complaints involving the failure of alarms that were made to the manufacturer or reported under the medical device reporting regulation. There were also no comparisons of overall complaint rates of alarm failures of Aequitron's Model 8200 to those of other monitors. We believe that the inclusion of these procedures in the inspection program or in the monitoring of medical device reporting regulation reports at CDRH could have served to more quickly identify both problems of underreporting and potentially serious device problems.

CONCLUDING REMARKS

In sum, the evidence from the current case of an apnea monitor is consistent with our earlier finding that there are differences in the interpretation of medical device reporting requirements among device manufacturers and between manufacturers and FDA.[26] In this case, the manufacturer's interpretation resulted in undetermined underreporting of serious problems with a device.

We found that FDA's review of a sample of Aequitron's records determined that at least some complaints alleging that the device

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[26]See Medical Devices: FDA's Implementation, p. 62.

was associated with hazards to safety, injuries, or death had not been reported to the agency because of the manufacturer's incorrect interpretation of the medical device reporting requirements.

As a result of FDA's intervention in this case and the device manufacturer's review of its own records,more than 150 additional medical device problem reports were submitted, including 144 reports of device malfunctions. We believe that malfunction reports should be considered as seriously as reports of serious injury or the death of a patient, especially as a preventive measure.

Although FDA has provided all registered device manufacturers with some guidance on reporting requirements in the form of a "questions and answers" document, the example we have presented suggests a potentially serious problem in the manufacturer's interpretation of the requirements and formulation of a reporting policy based on that interpretation, rather than random or isolated failures to report. We believe that device-specific guidance on problem reporting may be warranted for some types of devices.

Our study illustrates the serious consequences that shortcomings in the implementation of the medical devices reporting regulation and subsequent inspection program can have. In this case, FDA did not have information on a number of adverse experiences with the device in question when the agency made

critical decisions with respect to recalls and other regulatory actions. FDA found that this manufacturer's interpretation of the reporting requirements differed from the agency's in ways that put it in noncompliance with the regulation. However, the compliance inspection program did not identify and resolve these differences for a substantial period of time after the regulation went into effect. During that time, FDA did not make valid comparisons of the monitor's problem rates or trends with those of other, similar monitors made by other manufacturers, thus compromising one of the most important uses for data collected under the medical device reporting regulation.

The design of our study precludes generalizing to other devices or manufacturers. However, these findings, taken with our earlier findings, raise a concern that the problem-reporting and inspection issues may pertain to a broader segment of the device manufacturing industry and to the safety and effectiveness of medical devices in general. Therefore, we believe they are worth further attention by FDA.

That concludes my statement, Mr. Chairman. I will be happy to respond to any questions that you or members of the Subcommittee may have.