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# MEDICAL TECHNOLOGY

# Implementing the Good Manufacturing Practices Regulation

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Mr. Chairman and Members of the Subcommittee:

It is a pleasure to be here this morning to discuss our evaluation of the Food and Drug Administration's (FDA's) Good Manufacturing Practices (GMP) compliance program for medical devices.[1] This compliance program assesses manufacturers' implementation of the quality assurance requirements contained in the 1978 good manufacturing practices regulation. FDA issued this regulation and implemented the compliance program to help prevent the production and distribution of unsafe and ineffective medical devices.

In our evaluation of the program, we determined that FDA has defined and established a number of criteria for quality assurance in the medical device manufacturing process that hold promise for strengthening the regulation's effectiveness. However, we also found that implementation of the GMP compliance program is characterized by (1) insufficient inspections of medical device manufacturers, (2) limited identification and targeting of serious problems when GMP inspections do occur, and (3) inadequate response by both FDA and medical device manufacturers to quality assurance problems that inspections have identified. These shortcomings are exacerbated by the minimal training in device technology that FDA provides to inspectors and incomplete GMP information in FDA's data systems.

My testimony today describes the GMP quality assurance criteria and identifies areas where GAO believes program implementation should be strengthened.

## BACKGROUND

Medical devices run the gamut from the very simple to the extremely complex, from common household items such as thermometers and bandages to programmable pacemakers and computerized infusion devices. Devices such as artificial hips, cardiac pacemakers, and hearing aids improve, for many people, both their personal independence and the quality of their lives. Diagnostic devices such as computerized axial tomography (CAT) scanners have increased the speed and accuracy of diagnosis and, in some cases, have replaced more dangerous and painful procedures.

FDA employs three principal programs to regulate the safety and effectiveness of medical devices: (1) premarketing review,

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[1]U.S. General Accounting Office, Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority, GAO/PEMD-92-10 (Washington, D.C.: February 1992).

(2) GMP, and (3) postmarketing surveillance.[2] Since 1986, the General Accounting Office (GAO) has examined the major components of both the premarketing review and postmarketing surveillance programs. Our work has revealed serious limitations in both the premarketing and postmarketing programs, and we have questioned their ability to protect the public from unsafe and ineffective medical devices.

We have presented detailed descriptions of our findings in these areas in prior reports and testimony.[3] With regard to the premarketing review system, we have expressed concern, starting in 1988, about the large number of devices that are routinely approved for manufacture after only a relatively cursory review. In the postmarketing surveillance system area, we discovered two major problems. First, we found a severe shortage of information about the nature and scope of problems associated with devices once they were available in the marketplace and had begun to be used. Second, even when information about problems encountered in using devices was in fact available, FDA was often ineffective in dealing with that information and taking remedial action. Many of the recommendations we made to address these problems were incorporated as provisions in the Safe Medical Devices Act of 1990, which was cosponsored by the Chairman and signed into law in 1990.

GAO undertook the present evaluation at the Subcommittee's request. We were asked to provide a review and analysis of the structures and procedures FDA established and implemented to promote good manufacturing practices for medical devices. To perform the study, we reviewed the medical device statutes and critiques of the GMP regulation and conducted structured interviews with FDA officials and experts in the private sector. We obtained both hard copy and automated data from FDA to analyze FDA's GMP surveillance activities and industry practices. Our analyses covered fiscal years 1987-90. We also surveyed 329 field inspectors to obtain information about their qualifications in device technology and quality assurance methods.

Let me turn now to our findings, and a more detailed discussion of the criteria for quality assurance defined and promulgated by FDA.

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[2]The Federal Food, Drug, and Cosmetic Act of 1938, the Medical Device Amendments of 1976, and the Safe Medical Devices Act of 1990 (the latter two being amendments to the 1938 act) are the three principal statutes that authorize FDA to regulate medical devices.

[3]A selected list of U.S. General Accounting Office reports and testimony related to medical devices is presented in appendix I on p. 16.

## GMP QUALITY ASSURANCE CRITERIA

The GMP regulation specifies quality assurance practices in the manufacture, packaging, storage, and installation of all finished medical devices, with the goal of preventing the distribution of defective devices that are unsafe or ineffective for their intended use. It requires medical device manufacturers to establish a quality assurance program that includes the traditional quality-control functions of product testing and inspection. It also includes requirements for buildings, equipment, device evaluation, and record keeping among its major subparts. These requirements apply to all medical devices and to all activities and inputs necessary to prevent device defects. According to FDA guidance, the application of these requirements should be flexible and in proportion to the potential for errors in manufacturing and the resulting risk of injury or death.

GMP requirements are defined in terms of two basic performance criteria, the first less stringent than the second.[4] Less stringent "adherence" criteria require only that manufacturers have a written quality assurance program and that they adhere to it. "Adequacy" criteria are at least potentially more demanding because they often require manufacturers to meet industry standards and practices in terms of both technical details and overall reliability.[5]

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[4]Industry performance criteria may exist as formal standards published by official industry associations, and some of these may also be sanctioned by the American National Standards Institute. However, performance criteria may also be unofficial, based only upon the inspector's experience in examining similar devices.

[5]Both adherence and adequacy criteria can be illustrated with regard to manufacturing change control and process validation procedures. Change control is closely related to process validation in that both involve the review of equipment and processes to ensure a consistent output of devices that meet predetermined specifications. However, process validation is ongoing, while change control procedures are applied before changes are made in device design or production processes. The regulation calls only for adherence to formal change control procedures. However, the current GMP compliance manual states that the change control procedures must be adequate. The manufacture of the Shiley heart valve, for example, involved both change control and process validation procedures that turned out to be inadequate. That is, over a 5-year period starting in 1979, the manufacturer made a series of product and process changes to prevent breakage. Despite these changes, the valves continued to break and were associated with 178 deaths.

Adequacy criteria authorize broader as well as more intensive inspections but they are also much more difficult to translate into operational terms. Consequently, adequacy criteria may not be different in practice from adherence criteria, unless inspectors can translate them into operational requirements for specific device manufacturing processes. Effective application of adequacy criteria during a GMP inspection requires extensive, up-to-date technical knowledge.

Since the initial promulgation of the GMP regulation in 1978, FDA has increased the number of adequacy criteria. We agree both with FDA's establishment of GMP requirements and with the agency's continuing development of more stringent criteria because both are consistent with practices in the larger field of quality assurance and with device manufacturing experience. FDA's proposed revisions to the 1978 regulation will codify current adequacy requirements as well as add new ones. These include requirements for preproduction quality assurance, for suppliers of services and components, and for the servicing of used devices by manufacturers. These three additional requirements would also harmonize GMP requirements with international quality assurance standards in order to facilitate exports by U.S. manufacturers.

In sum, we view FDA's development of more stringent criteria and the move toward harmonization of GMP requirements with international quality assurance standards as strengths of the GMP compliance program. However, our evaluation findings show that FDA's enforcement of the criteria has been less strong. Let me turn now to our findings in this area of the program.

## IMPLEMENTATION OF THE GMP COMPLIANCE PROGRAM

FDA implements a compliance program for the GMP regulation through on-site inspections of all medical device manufacturers. These GMP inspections are the nation's principal source of information about manufacturers' responses to GMP quality assurance requirements. The inspections also assist in identifying defective devices as soon as possible by uncovering related quality assurance problems. When inspections find serious GMP violations, FDA initiates compliance actions against manufacturers that require the correction of manufacturing problems. To evaluate FDA's implementation of the GMP compliance program, therefore, we examined the frequency of GMP inspections, the capacity of these inspections to identify and target serious problems with medical devices, and both FDA's and manufacturers' responses to the discovery of GMP violations.

### Frequency of GMP Inspections

The Medical Device Amendments of 1976 call for on-site inspections of all medical device manufacturers and require

inspection at least once every 2 years for those making class II and class III devices.[6] The latter is commonly called the "statutory obligation." For manufacturers of class II or class III devices, any track I, track II, or premarketing approval inspection fulfills or "qualifies" as meeting FDA's obligation.[7]

GMP program data for fiscal years 1987 through 1990 show that a total of 7,764 GMP inspections were conducted, for an average of 1,941 each year. Out of this total, 5,112 (66 percent) qualified as meeting the statutory obligation for class II or III devices; the rest were inspections of class I devices or follow-up inspections.[8] As shown in figure 1, during fiscal years 1987-90, there was a steady decline both in the total number of device GMP inspections and in the number of qualified inspections.

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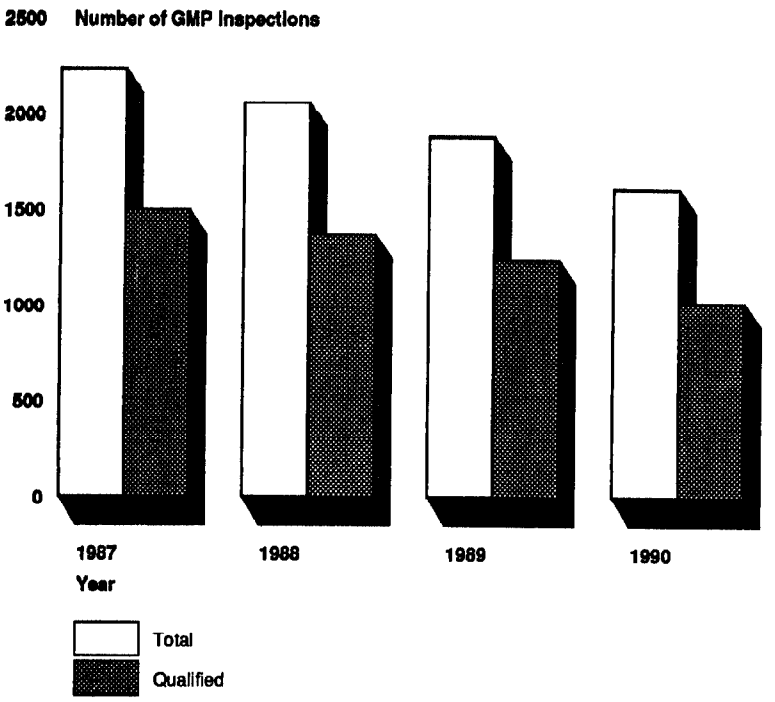
[6]The 1976 amendments created a three-tier system in which devices would be classified in ascending order according to their potential risk, with class I devices presenting the least risk and class III devices the most.

[7]An inspection is track I if a preinspection review indicates that a comprehensive (track II) inspection has been conducted within the last 2 years and if that prior inspection did not reveal serious violations that were not corrected and verified by a follow-up inspection. During a track II inspection, the inspector is supposed to review and evaluate all of the components of the manufacturer's quality assurance system that fall within the jurisdiction of the device GMP regulation. A premarketing approval inspection is an inspection performed for class III devices for which FDA has promulgated premarketing approval requirements. These include about 9 percent of the different device types in this class.

[8]Follow-up inspections are conducted to check whether GMP deficiencies noted during previous track I or II inspections have been corrected. If that is all they do, they are counted as follow-up GMP inspections in the annual total of GMP inspections. However, sometimes follow-up inspections are combined with track I or II inspections, and these would be counted in the annual totals as qualifying inspections.

**Figure 1: GMP Inspections for Fiscal Years 1987-90**




Domestic device manufacturers of all class II and III devices and some class I devices are required annually to register the sites where they manufacture devices and to list the devices they manufacture. From inspection records and these registration and listing data, FDA estimates that there are between 4,000 and 5,500 domestic manufacturers of class II and class III devices.[9] We estimate that 2,350 class II or III manufacturers have been inspected within the past 2 years. Using the lower boundary, this means that about 59 percent of these manufacturers would have been inspected on time; using the upper boundary, only about 43 percent. Therefore, even under the most conservative interpretation, our analysis indicates that the quality assurance systems of less than 60 percent of domestic manufacturers of class II and III devices were reviewed.

The frequency of inspections of medium- and high-risk devices is even lower for foreign-owned companies. FDA estimates that there are at least 1,450 foreign manufacturers that market class II and class III medical devices in the United States. FDA's records of foreign GMP inspections during recent years show that only about 175 manufacturers (12 percent of those exporting to the United States) have been inspected in a year. At this

[9]These two FDA numbers define the current range of uncertainty. They were obtained from the Office of Regulatory Affairs and the Center for Devices and Radiological Health, respectively.

rate, each foreign manufacturer would be inspected only about once every 8 years--four times less frequently than is required for domestic device manufacturers.[10]

According to FDA, the recent decline in the number of inspections, the agency's failure to meet the statutory obligation, and the relatively low frequency of foreign inspections can all be explained by the limited size of the field inspection force. In this view, inspections with the highest priority must be performed first, and they may involve blood banks or generic drugs instead of devices, especially during a crisis. One consequence of this prioritized inspection policy is that seriously defective devices may be marketed and recalled by the manufacturer before undergoing an inspection that could have prevented the problem or warned FDA that a recall was needed.[11] As a second step in our analysis of GMP inspection practices, therefore, we examined the capacity of GMP inspections to find and target medical device problems before they cause serious injury or death.

Problem Identification and Targeting Capacity of GMP Inspections

To determine the targeting capacity of GMP inspections, we looked at the association between inspections and medical device recalls. We assumed that an inspection would need to have occurred no more than 2 years prior to a recall for it to have served as an effective targeting mechanism. First, we focused on 322 manufacturers who initiated the first recall of a device during fiscal years 1987 through 1990. We found that only two thirds of these manufacturers had received an inspection before their first recall. In other words, for about a third of the manufacturers who recalled a device, GMP inspections could not have either initiated the recall or prevented the manufacture of a defective device because the inspection did not occur in time.

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[10]FDA has some authority over foreign manufacturers of new class III devices that have premarket approval requirements, because these devices cannot be marketed in the United States without an FDA inspection. According to FDA, all other class II and class III devices made abroad can be marketed here as long as the manufacturer lists the device with FDA, submits a 510(k) for devices introduced in 1976 or after, and the device does not appear to be adulterated or misbranded.

[11]A medical device "recall" is the removal from the market of a particular product or the correction of labeling or promotional materials that FDA considers to be in violation of the laws it administers. See U.S. General Accounting Office, Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR (Washington, D.C.: August 1989), for a description and analysis of the recall process.

Next, we examined cases in which the manufacturer had been inspected 2 years prior to a recall. For this analysis, we examined only recalls that were caused by manufacturing problems, since that is the focus of GMP inspections. There were 220 such cases during fiscal years 1987 through 1990. Seventy-three percent of these inspections found no serious GMP violations. Since recalls involve defective devices that could have serious health consequences, this means that even when GMP inspections were done on time, the inspection did not identify or target the GMP problems that later emerged.

FDA's Response to GMP Violations

During fiscal years 1987-90, more than half of all GMP inspections conducted found some type of GMP "problem." However, according to FDA district compliance officers, most of these inspections did not identify GMP violations. In fact, only about 16 percent of all inspections found violations for which compliance action was warranted.

When we tracked what happened to the inspections in which the most serious violations were detected, we found that compliance action was recommended and reported on only about half of them.[12] During fiscal years 1987-90, only 58 percent of these cases were forwarded to the Center for Devices and Radiological Health (CDRH). Yet, according to FDA policy, inspection reports that contain the most serious GMP violations should be forwarded to CDRH by district offices, including recommendations for compliance enforcement. Furthermore, it is also FDA policy for districts to report results from the same inspections, with compliance enforcement recommendations, to a central FDA file that includes inspections of food and drugs as well as devices. However, here again not all serious violations were reported, making it difficult to track GMP compliance enforcement for medical devices.

These doubly unreported cases involving serious violations are a cause for concern because they mean that central FDA authorities cannot effectively oversee the nature and scope of the most serious GMP problems and related compliance enforcement actions. The incomplete information about serious violations is compounded by the policy that allows district offices to issue notices for the least serious violations without reporting them

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[12]Only inspections classified as Official Action Indicated (OAI) involve sufficiently serious violations that district offices have been required to report inspection results and their recommendations for regulatory action to compliance reviewers at the Center for Devices and Radiological Health and to a special data base at FDA headquarters. This analysis was performed, therefore, on OAI inspections only.

to headquarters. Thus, national patterns in manufacturers' failure to comply with the GMP regulation and related FDA enforcement action may exist but not be recognized as such by the agency. When district offices did forward cases to CDRH, we found that CDRH approved most district recommendations for compliance enforcement action. Similarly, when CDRH forwarded recommendations for legal action to the FDA general counsel, most were approved. However, of a total of 4,259 FDA-483s issued during the time period our evaluation covered, only 208 compliance actions resulted.[13]

To augment the analysis of FDA's response to GMP violations, we surveyed device inspectors for their opinions about the appropriateness of compliance enforcement. We found that 83 percent of the device inspectors believe that persistent noncompliance with the GMP regulation could be reduced if enforcement actions were more certain. Sixty-two percent believe that noncompliance could be reduced if sanctions were more severe.

Manufacturers' Responses to GMP Violations

Medical device manufacturers' responses to FDA's notices of GMP violations were also disappointing. Our analysis shows that medical device firms have not lowered their rate of GMP violations over time. We tracked manufacturers' behavior in terms of the frequency of inspections that found GMP violations and the timeliness of corrections once GMP violations had been identified. For fiscal years 1987-90, we examined pertinent information reported from 2,460 domestic inspections that resulted in issuance of FDA-483s, looking at manufacturers of noncritical and critical devices separately.[14]

Among manufacturers of noncritical devices that received a notice of potential GMP violations on the first inspection, 34 percent of the inspections found violations that warranted compliance enforcement action. About the same percentage of subsequent inspections found potential violations. Manufacturers

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[13]The difference between the 4,259 FDA-483s issued and the 208 compliance actions ultimately approved by FDA is a result of (1) limited requirements for reporting violations to CDRH, (2) the fraction of inspections in which the most serious violations are found, and (3) incomplete reporting of and recommendations to headquarters for compliance action on the most serious violations.

[14]An FDA-483 is a "notice of inspectional observations" that an FDA inspector may leave with the manufacturer following a GMP inspection. The FDA-483 documents all potential GMP violations observed during the inspection.

of critical devices were issued notices of potential violations on 32 percent of initial inspections and 45 percent of subsequent inspections.[15]

We also examined the 44 percent of cases in this sample that involved manufacturers of both critical and noncritical devices who received two or more FDA-483s in succession. About half of these manufacturers did not correct the GMP violations from one inspection to the next.

This pattern persisted among manufacturers who had issued a manufacturing-related recall during the 2-year period prior to an inspection in which GMP violations were found. Among manufacturers of noncritical devices, about half had an inspection following the recall that warranted compliance enforcement action. Thirty-nine percent of critical device manufacturers had inspections in which GMP violations were found following a recall. These data indicate that the number of GMP problems has not decreased as manufacturers have gained experience with the GMP program and that GMP violations have tended to persist over time.

## RESOURCE REQUIREMENTS FOR THE GMP COMPLIANCE PROGRAM

In conjunction with the evaluation of FDA's implementation of the GMP compliance program, we examined two types of resources that are critical to effective program management: FDA inspectors' knowledge of medical device technology and the quality of FDA's GMP data system. We found that inspectors' investigative capability is limited by FDA's training and assignment policies and that information on the inventory of both medical device manufacturers and the devices themselves, as well as inspection results needed to monitor GMP compliance, is either unreliable or incomplete.

### Inspector Qualifications

By making GMP requirements more stringent, CDRH has also increased the need for training inspectors in the technology of medical devices. That is, inspectors are not likely to detect incipient device problems unless they are fully cognizant of the technology in question. FDA's training of device inspectors is mostly on the job, with classroom courses offered only intermittently. By and large, this approach to training develops only very limited competency in device technology, and as a result, FDA has trained only a handful of device experts. The agency also does not generally use inspection teams, which would

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[15]The data did not indicate whether the violations found during initial inspections were the same as or different from violations found on subsequent inspections.

permit these few technical experts to share their expertise.

According to FDA, this training policy permits administrative flexibility in meeting inspection requirements among all FDA-regulated products and facilities. However, two of FDA's own device experts as well as an industry expert told us that medical devices should be inspected differently from drugs or food because device technology is more diverse and complex and because it changes more rapidly. Consequently, they believe that better training is needed in order to target inspections to the production processes, devices, and manufacturers that are most likely to have significant GMP violations.

FDA Data Systems

CDRH has developed a number of data systems to help implement device regulations and to evaluate device programs. For program evaluation in particular, the Office of Compliance and Surveillance has documented and analyzed device recalls and monitored device users' experience as the empirical basis for improving GMP regulations and inspections. However, as we reported in a prior study, we found that FDA data systems have serious limitations.[16]

First, even though device manufacturers are required by the Food, Drug, and Cosmetic Act of 1938 to register their manufacturing facilities with FDA, the agency does not know the exact inventory of domestic manufacturers of medium- and high-risk medical devices, and its identification of foreign manufacturers is still less certain. Furthermore, neither inventory has been maintained as a historical record. Consequently, some manufacturers may not have been inspected either because they have never been identified by FDA or because the agency cannot track how its inspection responsibilities have evolved.

Second, the value of device recall data and users' reports of device problems in monitoring the effectiveness of GMP inspections is limited because FDA also does not estimate the inventory of medical devices. Without knowing the number and mix of devices on the market, FDA cannot assess the relative significance of device defects and their associated health and safety risks. Furthermore, without tracking the expansion of the device inventory, and comparing this expansion to the changing number and pattern of recalls, there is no basis for making an overall assessment of whether the GMP program is becoming more or less effective in preventing device defects. This is a

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[16]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), ch. 5.

particularly important time to begin such tracking if it can be started before FDA implements its proposed new GMP requirements.

In addition to these problems, district offices do not report inspection results and related information that are necessary to monitor GMP program operations. One example was discussed above--not meeting the requirement to report inspection results that justify official compliance enforcement action. Another is not reporting GMP violations and deficiencies as required. We also identified data that districts are not required to report but that would nonetheless help in evaluating the effectiveness of inspections.

These failures to report important data, as well as data system problems with obsolete and incompatible software and hardware, may be addressed by the new Field Information System that FDA is developing and deploying. According to the agency, this system has great potential to reduce the cost of sending and receiving information between district offices and FDA headquarters.

## RECENT DEVELOPMENTS

FDA has recently taken positive steps to use GMP inspections as a targeting mechanism during the premarketing review process. Coordination of inspections with market introduction is important because defects are most likely to be observed when devices are first used.

In December 1990, FDA instituted initial and follow-up GMP inspections as a requirement for premarketing approval. The premarketing approval inspection is the most comprehensive inspection that FDA performs. Initial inspection results can prevent a device from being marketed if the inspection shows that the manufacturer cannot produce devices according to the specifications submitted for premarketing approval. The follow-up inspection verifies that production plans reviewed during the initial inspection were implemented as specified.

FDA also has initiated a pilot program that monitors the manufacturing practices of a small group of high-risk devices

that reach the market through the 510(k) process.[17] Under this program, a GMP inspection is ordered only when the manufacturers' inspection record, reported in central FDA files, shows the need. Preliminary results of the pilot program showed that a GMP inspection was ordered for 34 percent of the devices submitted for 510(k) review. FDA is exploring whether to expand the pilot program to include all high-risk devices and to require a satisfactory GMP inspection record before these devices are cleared for market.

We believe that the expansion of the pilot program to include all high-risk devices is at best a limited substitute for premarketing approval certification. While the latter involves a special, more comprehensive inspection immediately before marketing a high-risk device, and a second inspection soon after, the pilot program approach relies on only one standard GMP inspection that may have occurred as long as 2 years before the 510(k) application.

In preparation for this hearing, we interviewed FDA officials concerning all aspects of the GMP compliance program addressed in our report, inquiring about activity during fiscal year 1991. We found improvements in four areas:

-- FDA will strengthen the targeting capacity of GMP inspections by expanding the GMP certification requirement to all critical devices. An inspection will be ordered when a 510(k) applicant's GMP inspection history is not satisfactory. Premarketing approval certification for all critical devices is not being considered, however.

-- FDA recognizes the need to evaluate the proposed GMP regulations and is planning to verify the inventory of medical device manufacturers.

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[17]The pilot program involves sterile cardiovascular devices that have been or will be sterilized by a traditional method and that are implants or that come into direct contact with blood or spinal fluid.

Premarketing notification is one of the two procedures that FDA has for reviewing a medical device prior to marketing. Section 510(k) of the Medical Device Amendments of 1976 contains three requirements. First, manufacturers must notify FDA at least 90 days before marketing a device. Second, manufacturers must provide their preliminary judgment of the class that a device belongs in. Finally, manufacturers must describe the actions they have taken to comply with the applicable performance standard or premarketing approval provisions of the amendments.

-- FDA has combined two forms of notification into a single warning letter and delegated authority to district offices to issue it, without prior approval from CDRH. Compliance actions of this type have increased.

-- FDA has developed a curriculum of both basic and advanced medical device courses. In 1991, 105 inspectors attended these courses.

These initiatives demonstrate that FDA recognizes the shortcomings we found in several areas of the GMP compliance program. However, we believe more effort is needed.

## CONCLUSIONS AND RECOMMENDATIONS

GMP inspections serve as the agency's principal source of information about industry compliance with the GMP regulation. GAO's conclusions about this process are that, although FDA's planning is meritorious in some areas--for example, the establishment of quality assurance criteria--implementation of its compliance program has been characterized by both weakness of thrust and weakness of effect. Inspections have been too infrequent to meet statutory minimum requirements; when inspections have occurred, they often did not find the problems that emerged later; when problems were identified and targeted, they often went unreported despite requirements to report them. We also note that FDA inspectors have not received enough training and that the GMP data system presents major gaps, precisely in the area of information needed for GMP evaluation.

FDA has undertaken some efforts to address our findings (see above); however, there has been no improvement in inspection frequency, in the reporting of inspection results and compliance actions to headquarters, and in data resources.

We therefore believe that FDA should take the following actions to strengthen the implementation of the GMP compliance program and enhance the staffing and information resources required for its execution:

-- inspect manufacturers of medium- and high-risk devices every 2 years;

-- include all high-risk medical devices in the premarketing GMP inspection pilot program;

-- evaluate the technical training needs of the GMP inspection force;

-- upgrade the inventory of device manufacturers and develop an inventory of medical devices;

-- complete the development of the Field Information System; and

-- assess the impact of proposed new GMP regulations.

Until these improvements are made, FDA's capacity to assess the effects of the proposed GMP regulations and to perform inspections under this regulation will be limited.

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

## SELECTED LIST OF U.S. GENERAL ACCOUNTING OFFICE REPORTS RELATED TO MEDICAL DEVICES

1. Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting, GAO/PEMD-87-1. Washington, D.C.: December 1986.

2. "Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting," statement of Eleanor Chelimsky, GAO/PEMD-87-4. Washington, D.C.: May 1987.

3. Medical Devices: FDA's Forecasts of Problem Reports and FTEs Under H.R. 4640, GAO/PEMD-88-30. Washington, D.C.: July 1988.

4. Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14. Washington, D.C.: August 1988.

5. Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation, GAO/PEMD-89-10. Washington, D.C.: February 1989.

6. Medical Device Recalls: An Overview and Analysis 1983-88, GAO/PEMD-89-15BR. Washington, D.C.: August 1989.

7. FDA Resources: Comprehensive Assessment of Staffing, Facilities, and Equipment Needed, GAO/HRD-89-142. Washington, D.C.: September 1989.

8. Medical Device Recalls: Examination of Selected Cases, GAO/PEMD-90-6. Washington, D.C.: October 1989.

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