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MEDICAL DEVICES

Challenges for FDA in Conducting Manufacturer Inspections

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Highlights of [GAO-08-428T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

As part of the Food and Drug Administration's (FDA) oversight of the safety and effectiveness of medical devices marketed in the United States, it inspects domestic and foreign establishments where these devices are manufactured. To help FDA address shortcomings in its inspection program, the Medical Device User Fee and Modernization Act of 2002 required FDA to accredit third parties to inspect certain establishments. In response, FDA has implemented two such voluntary programs. GAO previously reported on the status of one of these programs, citing concerns regarding its implementation and factors that may influence manufacturers' participation. (Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations, [GAO-07-157](#), January 2007.)

This statement (1) assesses FDA's management of inspections of establishments—particularly those in foreign countries—manufacturing devices for the U.S. market, and (2) provides the status of FDA's programs for third-party inspections of medical device manufacturing establishments. GAO interviewed FDA officials; reviewed pertinent statutes, regulations, guidance, and reports; and analyzed information from FDA databases. GAO also updated its previous work on FDA's programs for inspections by accredited third parties.

To view the full product, including the scope and methodology, click on [GAO-08-428T](#). For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

MEDICAL DEVICES

Challenges for FDA in Conducting Manufacturer Inspections

What GAO Found

FDA has not met the statutory requirement to inspect certain domestic establishments manufacturing medical devices every 2 years, and the agency faces challenges inspecting foreign establishments. FDA primarily inspected establishments located in the United States. The agency has not met the biennial inspection requirement for domestic establishments manufacturing medical devices that FDA has classified as high risk, such as pacemakers, or medium risk, such as hearing aids. FDA officials estimated that the agency has inspected these establishments every 3 years (for high risk devices) or 5 years (for medium risk devices). There is no comparable requirement to inspect foreign establishments, and agency officials estimate that these establishments have been inspected every 6 years (for high risk devices) or 27 years (for medium risk devices). FDA faces challenges in managing its inspections of foreign medical device establishments. Two databases that provide FDA with information about foreign medical device establishments and the products they manufacture for the U.S. market contain inaccuracies that create disparate estimates of establishments subject to FDA inspection. Although comparing information from these two databases could help FDA determine the number of foreign establishments marketing medical devices in the United States, these databases cannot exchange information and any comparisons must be done manually. Finally, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA in human resources and logistics.

Few inspections of medical device manufacturing establishments have been conducted through FDA's two accredited third-party inspection programs—the Accredited Persons Inspection Program and the Pilot Multi-purpose Audit Program (PMAP). From March 11, 2004—the date when FDA first cleared an accredited organization to conduct independent inspections—through January 11, 2008, five inspections have been conducted by accredited organizations through FDA's Accredited Persons Inspection Program. An incentive to participation in the program is the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. Disincentives include bearing the cost for the inspection, particularly when the consequences of an inspection that otherwise might not occur in the near future could involve regulatory action. The Food and Drug Administration Amendments Act of 2007 made several changes to program eligibility requirements that could result in increased participation by manufacturers. PMAP was established on September 7, 2006, and as of January 11, 2008, two inspections had been conducted by an accredited organization through this program, which is more limited than the Accredited Persons Inspection Program. The small number of inspections completed to date by accredited third-party organizations raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill its responsibilities.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you examine how the Food and Drug Administration (FDA) has been meeting its regulatory responsibilities. One area of FDA responsibility is the regulation of medical devices¹—such as hearing aids and pacemakers—marketed in the United States, whether manufactured in domestic or foreign establishments.² FDA classifies medical devices into one of three classes based on degree of potential risk and level of control needed to reasonably ensure safety and effectiveness.³ Inspection of establishments is FDA’s primary means of assuring that the safety and effectiveness of medical devices are not jeopardized by poor manufacturing practices. Requirements governing domestic and foreign inspections differ. Specifically, FDA is required to inspect domestic establishments that manufacture class II (medium risk) or III (high risk) medical devices every 2 years.⁴ There is no comparable requirement to inspect foreign establishments.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) addressed concerns about FDA’s ability to meet its responsibilities for inspecting medical device manufacturing establishments.⁵ MDUFMA included provisions designed to (1) increase the number of inspected medical device manufacturing establishments and (2) help manufacturers

¹Medical devices include instruments, apparatuses, machines, and implants that are intended for use to diagnose, cure, treat, or prevent disease, or to affect the structure or any function of the body. 21 U.S.C. § 321(h).

²FDA regulations define an establishment as a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed. 21 C.F.R. § 807.3(c) (2007). Medical device manufacturers may have more than one establishment. We use the term “manufacture” to refer to activities including manufacturing, preparing, and processing devices.

³21 U.S.C. § 360c. Medical devices are classified into one of three classes. Class I includes “low risk” devices, such as tongue depressors, elastic bandages, and bedpans. Class II includes “medium risk” devices, such as syringes, hearing aids, and electrocardiograph machines. Class III includes “high risk” devices, such as heart valves, pacemakers, and defibrillators.

⁴21 U.S.C. § 360(h). There is no statutory requirement for inspection of class I medical device manufacturing establishments, and FDA does not routinely inspect them. However, FDA periodically inspects establishments manufacturing surgeon’s gloves and patient examination gloves, which are both class I medical devices, due to ongoing problems with leakage. FDA also periodically inspects manufacturers of randomly selected class I devices.

⁵See Pub. L. No. 107-250, § 201, 116 Stat. 1588, 1602-09 (2002) (codified as amended at 21 U.S.C. § 374(g)).

meet the inspection requirements of both the United States and foreign countries in a single inspection. Specifically, MDUFMA required FDA to accredit third-party organizations to conduct inspections of certain domestic and foreign establishments.⁶ In response, FDA implemented its Accredited Persons Inspection Program, which permits certain establishments to voluntarily request inspections from third-party organizations to meet inspectional requirements. In January 2007, we reported on the status of this program citing, among other things, concerns regarding its implementation and potential incentives and disincentives that may influence manufacturers' participation.⁷ Additionally, in partnership with Health Canada,⁸ FDA has established another program for inspection by accredited third parties—the Pilot Multi-purpose Audit Program (PMAP)—that allows accredited organizations to conduct a single inspection to meet the regulatory requirements of both countries. A report by the House of Representatives Committee on Energy and Commerce that accompanied MDUFMA stated that inspections by accredited third parties would permit FDA to focus the agency's inspection resources on manufacturers that have greater problems and devices that present higher risks.⁹

In addition to the questions about medical devices that led to the creation of FDA's third-party inspection program, questions have also been raised about how FDA is meeting its regulatory responsibilities in other program areas, such as drugs. In November 2007, we testified on our preliminary findings regarding FDA's program for inspecting foreign drug manufacturers.¹⁰ Our findings suggested that FDA conducted infrequent inspections; had weaknesses in its data systems, including conflicting information on the number of foreign establishments; and faced challenges unique to foreign inspections, including those involving human resource issues. (See app. I for a summary of that testimony. We plan to

⁶In this report, unless otherwise noted, when we discuss inspections, we are referring to those conducted by FDA investigators.

⁷GAO, *Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations*, [GAO-07-157](#) (Washington, D.C.: Jan. 5, 2007).

⁸Health Canada is the governmental entity that regulates medical devices marketed in Canada.

⁹H.R. Rep. No. 107-728, pt. 1, at 35-36 (2002).

¹⁰GAO, *Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers*, [GAO-08-224T](#) (Washington, D.C.: Nov. 1, 2007).

issue a final report at a later date.) Also in November 2007, a subcommittee of the FDA Science Board¹¹ issued a report that identified growing demands on FDA, including the globalization of the industries that FDA regulates. The report found that disparities between FDA's responsibilities and its available resources—including human resources—have resulted in serious weaknesses that jeopardize the agency's ability to meet current and emerging regulatory responsibilities.¹² The subcommittee's report noted that these weaknesses include inadequate inspections of manufacturers. It also emphasized that FDA's information technology infrastructure is obsolete and unstable; provides an insufficient basis to access, integrate, and analyze data; and is subject to frequent system failures.

Third-party organizations have been identified as one mechanism that could help FDA address shortcomings in inspection programs, beyond the programs for medical devices. The federal Interagency Working Group on Import Safety recently suggested that the use of third-party organizations could provide FDA with information to help the agency target its inspection resources to those products of greatest risk.¹³ In addition, we recommended that FDA consider developing a third-party inspection program to help it meet its responsibilities for inspecting foreign firms importing seafood to the United States.¹⁴

Given the recent questions regarding FDA's inspection programs and suggestions that third-party organizations could supplement FDA's resources, you asked for information on FDA's management of its medical device inspection program. My remarks will focus on (1) our assessment of FDA's program for inspecting establishments that manufacture medical

¹¹The Science Board, which is an advisory board to the commissioner of FDA, provides advice on, among other things, specific complex and technical issues as well as emerging issues within the scientific community.

¹²FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (November 2007), http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html (accessed Jan. 18, 2008).

¹³In July 2007, the Interagency Working Group on Import Safety was established to conduct a comprehensive review of current import safety practices and determine where improvements could be made. Interagency Working Group on Import Safety, *Action Plan for Import Safety: A roadmap for continual improvement* (November 2007), <http://www.importsafety.gov/report/actionplan.pdf> (accessed Dec. 6, 2007).

¹⁴See GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements are Needed*, [GAO-04-246](#) (Washington, D.C.: Jan. 30, 2004).

devices for the U.S. market, particularly those located in foreign countries and (2) the status of FDA's programs for third-party inspections of medical device manufacturing establishments. Today, in a separate statement, we are also discussing the federal oversight of food safety as a high-risk area and ways in which FDA can better leverage its resources.¹⁵ These and other recent testimonies on drug safety and food safety offer some observations on FDA's inspection program capacity.

To address these issues, we interviewed officials from FDA's Center for Devices and Radiological Health (CDRH) and Office of Regulatory Affairs (ORA), which each have responsibilities for managing the medical device inspection program.¹⁶ We reviewed pertinent statutes and regulations, as well as agency documents that provide guidance on FDA's inspection requirements and programs for inspections by accredited third parties. To assess FDA's program for inspecting establishments that manufacture medical devices, we obtained information from FDA's Device Registration and Listing System (DRLS), as of September 19, 2007; Field Accomplishments and Compliance Tracking System (FACTS) for fiscal year 2002 through fiscal year 2007; and Operational and Administrative System for Import Support (OASIS) for fiscal year 2007. We assessed the reliability of these data by (1) reviewing existing information about the data and the databases that produced them, (2) interviewing agency officials knowledgeable about the data, and (3) performing electronic testing of data elements from DRLS and FACTS. We found the data in the FACTS database sufficiently reliable for our purposes. We also found that DRLS was sufficiently reliable, to the extent that it accurately reflects information provided by domestic and foreign establishments that register to market medical devices in the United States. However, we determined that these data do not necessarily reflect the number of establishments that manufacture medical devices for the U.S. market. In addition, we found that OASIS is likely to overestimate the number of foreign establishments whose medical devices have been imported into the United States, due to uncorrected errors in the data. Therefore, we present

¹⁵GAO, *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical*, [GAO-08-435T](#) (Washington, D.C.: Jan. 29, 2008).

¹⁶Within FDA, the Center for Biologics Evaluation and Research regulates medical devices involved in human immunodeficiency virus (HIV) testing and the collection, processing, testing, manufacture, and administration of licensed blood, blood components, and cellular products. We did not include medical devices regulated by this center in the scope of our work.

information from both DRLS and OASIS to illustrate the variability in information that FDA's databases provide to agency officials on this topic. These data represent the best information available and are what FDA relies on to manage its domestic and foreign medical device inspection activities.

To examine the status of FDA's programs for third-party inspections, we received FDA data on the number of inspections conducted by accredited third parties from March 11, 2004—the date when FDA first cleared an accredited organization to conduct inspections—through January 11, 2008. This updates the data we obtained for our January 2007 report for which data collection ended on October 31, 2006. We also obtained information from FDA about other critical aspects of their programs for inspections by accredited third parties, such as the number of accredited organizations. To gain perspective on recent changes to FDA's programs for inspections by accredited third parties, we contacted representatives of the same 13 affected entities we interviewed for our January 2007 report on this topic.¹⁷ We received responses from 2 of 4 accredited organizations, 2 of 3 organizations that represent medical device manufacturers, and 1 of 6 manufacturers. We received technical comments on a draft of this statement from FDA, which we incorporated, as appropriate. We conducted this performance audit from December 2007 to January 2008, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, we found that FDA has not met the requirement to inspect domestic establishments manufacturing class II or III medical devices every 2 years and faces challenges in inspecting foreign establishments. FDA primarily inspected domestic establishments. FDA officials estimated that the agency has inspected domestic class II manufacturers every 5 years and domestic class III manufacturers every 3 years. There is no comparable requirement to conduct foreign inspections and FDA has conducted relatively few. Officials estimated the agency has inspected foreign class II manufacturers every 27 years and foreign class III

¹⁷These affected entities included accredited organizations, organizations that represent medical device manufacturers, and medical device manufacturers.

manufacturers every 6 years. In addition, FDA faces challenges in managing its foreign medical device inspection program. Two databases that provide FDA with information about foreign medical device establishments and the products they manufacture for the U.S. market contain inaccuracies that create divergent estimates of establishments subject to FDA inspection. Despite the divergent estimates, FDA does not routinely verify these data. Although comparing information from these two databases could help FDA determine the number of foreign establishments marketing medical devices in the United States, these databases cannot exchange information and any comparisons must be done manually. While the agency has taken steps to improve these databases, it is too soon to know if these changes will improve FDA's data. Finally, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA, such as difficulties in recruiting investigators to voluntarily travel to certain countries and in extending trips if problems are identified during inspections. Our results are consistent with our November 2007 testimony on FDA's foreign drug inspection program, as well as the findings of the FDA Science Board.

Few inspections of medical device manufacturing establishments have been conducted through FDA's two programs for inspections by accredited third parties—the Accredited Persons Inspection Program and PMAP. From March 11, 2004—the date when FDA first cleared an accredited organization to conduct inspections—through January 11, 2008, five inspections have been conducted by accredited organizations through FDA's Accredited Persons Inspection Program. Manufacturers' decisions to request an inspection by an accredited organization might be influenced by both potential incentives and disincentives. An incentive to participation in the program is the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. Disincentives include bearing the cost for the inspection, particularly when the consequences of an inspection that otherwise may not occur in the near future could involve regulatory action. The Food and Drug Administration Amendments Act of 2007 (FDAAA) changed the requirements for inspections by accredited third parties in several ways, which could result in increased participation by manufacturers, although it is too soon to tell. For example, an eligibility requirement that foreign establishments be periodically inspected by FDA was eliminated. Device manufacturers may also request an inspection by an accredited third party through PMAP, which was established on September 7, 2006. As of January 11, 2008, two inspections had been conducted by an accredited organization through PMAP, which is more limited than the Accredited Persons Inspection Program. The small number of inspections completed

to date by accredited third-party organizations raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to help FDA fulfill other responsibilities.

Background

FDA is responsible for overseeing the safety and effectiveness of medical devices that are marketed in the United States, whether manufactured in domestic or foreign establishments. All establishments that manufacture medical devices for marketing in the United States must register with FDA.¹⁸ As part of its efforts to ensure the safety, effectiveness, and quality of medical devices, FDA is responsible for inspecting certain domestic and foreign establishments to ensure that they meet manufacturing standards established in FDA's quality system regulation.¹⁹ FDA does not have authority to require foreign establishments to allow the agency to inspect their facilities. However, FDA has the authority to prevent the importation of products manufactured at establishments that refuse to allow an FDA inspection.²⁰ Unlike food, for which FDA primarily relies on inspections at the border, physical inspection of manufacturing establishments is a critical mechanism in FDA's process to ensure that medical devices and drugs are safe and effective and that manufacturers adhere to good manufacturing practices.

Within FDA, CDRH assures the safety and effectiveness of medical devices. Among other things, CDRH works with ORA, which conducts inspections of both domestic and foreign establishments to ensure that devices are produced in conformance with federal statutes and regulations, including the quality system regulation. FDA may conduct inspections before and after medical devices are approved or otherwise cleared to be marketed in the United States.

- Premarket inspections are conducted before FDA will approve U.S. marketing of a new medical device that is not substantially equivalent to

¹⁸21 U.S.C. § 360(b), (i).

¹⁹21 C.F.R. pt. 820 (2007). The quality system regulation requires, among other things, that domestic or foreign manufacturers have a quality system in place to implement current good manufacturing practices in the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for human use in the United States. A quality system includes the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

²⁰See 21 U.S.C. § 381(a); 21 C.F.R. § 820.1(d) (2007).

one that is already on the market.²¹ Premarket inspections primarily assess manufacturing facilities, methods, and controls and may verify pertinent records.

- Postmarket inspections are conducted after a medical device has been approved or otherwise cleared to be marketed in the United States and include several types of inspections: (1) Quality system inspections are conducted to assess compliance with applicable FDA regulations, including the quality system regulation to ensure good manufacturing practices and the regulation requiring reporting of adverse events.²² These inspections may be comprehensive or abbreviated, which differ in the scope of inspectional activity. Comprehensive postmarket inspections assess multiple aspects of the manufacturer's quality system, including management controls, design controls, corrective and preventative actions, and production and process controls. Abbreviated postmarket inspections assess only some of these aspects, but always assess corrective and preventative actions. (2) For-cause and compliance follow-up inspections are initiated in response to specific information that raises questions or problems associated with a particular establishment. (3) Postmarket audit inspections are conducted within 8 to 12 months of a premarket application's approval to examine any changes in the design, manufacturing process, or quality assurance systems.

FDA determines which establishments to inspect using a risk-based strategy. High priority inspections include premarket approval inspections for class III devices, for-cause inspections, inspections of establishments that have had a high frequency of device recalls, and other devices and manufacturers FDA considers high risk. The establishment's inspection history may also be considered. A provision in FDAAA may assist FDA in making decisions about which establishments to inspect because it authorizes the agency to accept voluntary submissions of audit reports addressing manufacturers' conformance with internationally established standards for the purpose of setting risk-based inspectional priorities.²³

²¹Currently, most medical devices are cleared for marketing in the United States because they are "substantially equivalent" to a marketed device. FDA generally does not conduct premarket inspections of establishments manufacturing these types of medical devices.

²²21 C.F.R. pt. 803 (2007).

²³Pub. L. No. 110-85, § 228, 121 Stat. 858 (2007).

FDA's programs for domestic and foreign inspections by accredited third parties provide an alternative to the traditional FDA-conducted comprehensive postmarket quality system inspection for eligible manufacturers of class II and III medical devices. MDUFMA required FDA to accredit third persons—which are organizations—to conduct inspections of certain establishments. In describing this requirement, the House of Representatives Committee on Energy and Commerce noted that some manufacturers have faced an increase in the number of inspections required by foreign countries, and that the number of inspections could be reduced if the manufacturers could contract with a third-party organization to conduct a single inspection that would satisfy the requirements of both FDA and foreign countries.²⁴ Manufacturers that meet eligibility requirements may request a postmarket inspection by an FDA-accredited organization.²⁵ The eligibility criteria for requesting an inspection of an establishment by an accredited organization include that the manufacturer markets (or intends to market) a medical device in a foreign country and the establishment to be inspected must not have received warnings for significant deviations from compliance requirements on its last inspection.²⁶

MDUFMA also established minimum requirements for organizations to be accredited to conduct third-party inspections, including protecting against financial conflicts of interest and ensuring the competence of the organization to conduct inspections. FDA developed a training program for inspectors from accredited organizations that involves both formal classroom training and completion of three joint training inspections with FDA. Each individual inspector from an accredited organization must

²⁴H.R. Rep. No. 107-728, pt. 1, at 32-36 (2002). Some foreign countries have accredited, certified, or otherwise recognized organizations to conduct inspections. We use the term “single inspection” to mean a complete inspection that covers all requirements of two or more countries, without repeating those activities covered under more than one set of requirements. A complete inspection can be conducted during a single block of time or in multiple phases. Two or more separate inspection reports could be generated on the basis of that single inspection.

²⁵Accredited organizations may conduct comprehensive postmarket quality system inspections, but not other types of inspections of establishments that FDA has the authority to conduct, such as premarket or for-cause inspections. FDA may conduct its own inspections of establishments even after inspection by an accredited organization.

²⁶21 U.S.C. § 374(g). FDAAA eliminated certain previously established eligibility requirements. For example, it eliminated a limitation on the number of consecutive inspections allowed by an accredited organization and a limitation that foreign establishments must be inspected periodically by FDA.

complete all training requirements successfully before being cleared to conduct independent inspections. FDA relies on manufacturers to volunteer to host these joint inspections, which count as FDA postmarket quality system inspections.

A manufacturer that is cleared to have an inspection by an accredited third party enters an agreement with the approved accredited organization and schedules an inspection. Once the accredited organization completes its inspection, it prepares a report and submits it to FDA, which makes the final assessment of compliance with applicable requirements. FDAAA added a requirement that accredited organizations notify FDA of any withdrawal, suspension, restriction, or expiration of certificate of conformance with quality systems standards (such as those established by the International Organization for Standardization) for establishments they inspected for FDA.²⁷

In addition to the Accredited Persons Inspection Program, FDA has a second program for accredited third-party inspections of medical device establishments. On September 7, 2006, FDA and Health Canada announced the establishment of PMAP. This pilot program was designed to allow qualified third-party organizations to perform a single inspection that would meet the regulatory requirements of both the United States and Canada. The third-party organizations eligible to conduct inspections through PMAP are those that FDA accredited for its Accredited Persons Inspection Program (and that completed all required training for that program) and that are also authorized to conduct inspections of medical device establishments for Health Canada. To be eligible to have a third-party inspection through PMAP, manufacturers must meet all criteria established for the Accredited Persons Inspection Program. As with the Accredited Persons Inspection Program, manufacturers must apply to participate and be willing to pay an accredited organization to conduct the inspection.

FDA relies on multiple databases to manage its program for inspecting medical device manufacturing establishments.

- DRLS contains information on domestic and foreign medical device establishments that have registered with FDA. Establishments that are involved in the manufacture of medical devices intended for commercial

²⁷21 U.S.C. § 374(g)(3)(F).

distribution in the United States are required to register annually with FDA. These establishments provide information to FDA, such as establishment name and address and the medical devices they manufacture. As of October 1, 2007, establishments are required to register electronically through FDA's Unified Registration and Listing System and certain medical device establishments pay an annual establishment registration fee, which in fiscal year 2008 is \$1,706.²⁸

- OASIS contains information on medical devices and other FDA-regulated products imported into the United States, including information on the establishment that manufactured the medical device. The information in OASIS is automatically generated from data managed by U.S. Customs and Border Protection, which are originally entered by customs brokers based on the information available from the importer.²⁹
- FACTS contains information on FDA's inspections, including those of domestic and foreign medical device establishments. FDA investigators enter information into FACTS following completion of an inspection.

According to FDA data, more than 23,600 establishments that manufacture medical devices were registered as of September 2007, of which 10,600 reported that they manufacture class II or III medical devices.³⁰ More than half—about 5,600—of these establishments were located in the United States. As of September 2007, there were more registered establishments in China and Germany reporting that they manufacture class II or III medical devices than in any other foreign countries.³¹ Canada, Taiwan, and the United Kingdom also had a large number of registered establishments. (See fig. 1.) Registered foreign establishments reported that they manufacture a variety of class II and III medical devices for the U.S.

²⁸21 U.S.C. § 379j(a)(3), (b).

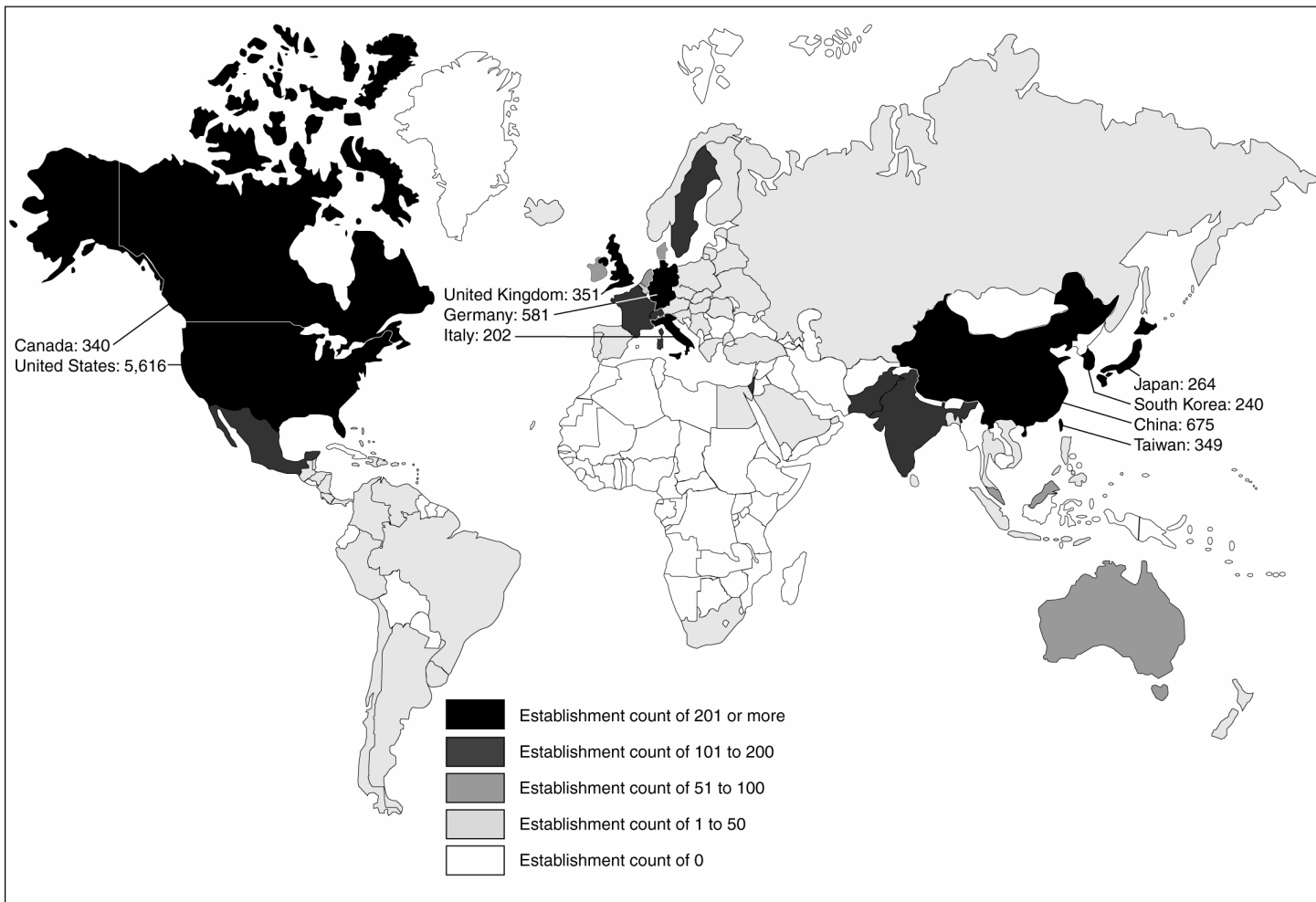
²⁹Customs brokers are private individuals, partnerships, associations, or corporations licensed, regulated, and empowered by U.S. Customs and Border Protection to assist in meeting federal requirements governing imports and exports.

³⁰Throughout this testimony, we use DRLS data because FDA officials told us that the agency would continue to use those data, as available on September 19, 2007, until it is confident that all device establishments required to register have done so through the new electronic system, FDA's Unified Registration and Listing System.

³¹Counts of registered establishments in China do not include establishments registered in Hong Kong or Taiwan as these establishments are tracked separately in DRLS.

market. For example, common class III medical devices included coronary stents,³² pacemakers, and contact lenses.

Figure 1: Registered Establishments That Reported Manufacturing Class II or Class III Medical Devices for the U.S. Market, by Country, September 2007



Source: GAO analysis of FDA data.

Note: Counts of registered establishments in China do not include establishments registered in Hong Kong or Taiwan as these establishments are tracked separately in DRLS. In addition, DRLS contained one additional registered establishment for which location information was not available.

³²A coronary stent is a small tube that is placed within a coronary artery to keep the vessel open.

FDA Is Not Inspecting Domestic Establishments Biennially as Required and Faces Challenges in Inspecting Foreign Establishments

FDA has not met the statutory requirement to inspect domestic establishments manufacturing class II or III medical devices every 2 years. The agency conducted relatively few inspections of foreign establishments. The databases that provide FDA with data about the number of foreign establishments manufacturing medical devices for the U.S. market contain inaccuracies. In addition, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA—both in human resources and logistics.

FDA Is Not Inspecting Domestic Establishments Biennially and Inspects Relatively Few Foreign Establishments

From fiscal year 2002 through fiscal year 2007, FDA primarily inspected establishments located in the United States, where more than half of the 10,600 registered establishments that reported manufacturing class II or III medical devices are located. In contrast, FDA inspected relatively few foreign medical device establishments. During this period, FDA conducted an average of 1,494 domestic and 247 foreign establishment inspections each year.³³ This suggests that each year FDA inspects about 27 percent of registered domestic establishments that reported manufacturing class II or class III medical devices and about 5 percent of such foreign establishments. The inspected establishments were in the United States and 44 foreign countries. Of the foreign inspections, more than two-thirds were in 10 countries. Most of the countries with the highest number of inspections were also among those with the largest number of registered establishments that reported manufacturing class II or III medical devices. The lowest rate of inspections in these 10 countries was in China, where 64 inspections were conducted in this 6-year period and almost 700 establishments were registered. (See table 1.)

³³We were unable to differentiate inspections according to medical device classification. FDA's inspection database contains the most recent information available to FDA about the class of device manufactured at the establishment, and consequently does not contain readily available information about the class of devices manufactured at the time of a specific inspection. As a result, the data we present include all inspections, regardless of the classification of the manufactured device or devices. According to FDA officials, FDA primarily conducts inspections of establishments manufacturing class II or III medical devices.

Table 1: Number of FDA Inspections of Medical Device Establishments, Fiscal Year 2002 through Fiscal Year 2007

Country	Number of inspections ^a							Total	Number of registered class II or III manufacturing establishments ^b
	FY2002	FY2003	FY2004	FY2005	FY2006	FY2007			
United States	1,261	1,736	1,631	1,471	1,501	1,362	8,962^c	5,616	
Germany	39	30	34	51	25	52	231	581	
United Kingdom	25	31	28	14	25	43	166	351	
Canada	17	17	24	11	13	26	108	340	
Japan	7	8	20	21	16	25	97	264	
Ireland	15	22	13	13	16	11	90	67	
France	16	14	17	14	12	10	83	190	
Switzerland	6	12	19	9	7	18	71	134	
China ^d	0	0	21	19	11	13	64	675 ^e	
Mexico	10	7	12	8	12	11	60	143	
Italy	8	7	10	6	13	11	55	202	
All other countries	66	83	102	67	69	69	456	2,036	
Total	1,470	1,967	1,931	1,704	1,720	1,651	10,443	10,600^f	

Source: GAO analysis of FDA data.

^aWe were unable to differentiate inspections according to medical device classification. FDA's inspection database contains the most recent information available to FDA about the class of device manufactured at the establishment, and consequently does not contain readily available information about the class of devices manufactured at the time of a specific inspection. As a result, the data we present include all inspections, regardless of the classification of the manufactured device or devices. According to FDA officials, FDA primarily conducts inspections of establishments manufacturing class II or III medical devices.

^bThese counts represent the number of registered establishments as of September 2007.

^cIn addition to inspections conducted by FDA personnel, from fiscal year 2002 through fiscal year 2007, FDA contracted with states to conduct 164 quality system inspections. These inspections are not included in the total.

^dThe inspection counts for China do not include inspections conducted in Hong Kong or Taiwan as these inspections are tracked separately in FACTS.

^eCounts of registered establishments in China do not include establishments registered in Hong Kong or Taiwan as these establishments are tracked separately in DRLS.

^fRegistration numbers do not add to total because DRLS contained one additional registered establishment for which location information was not available.

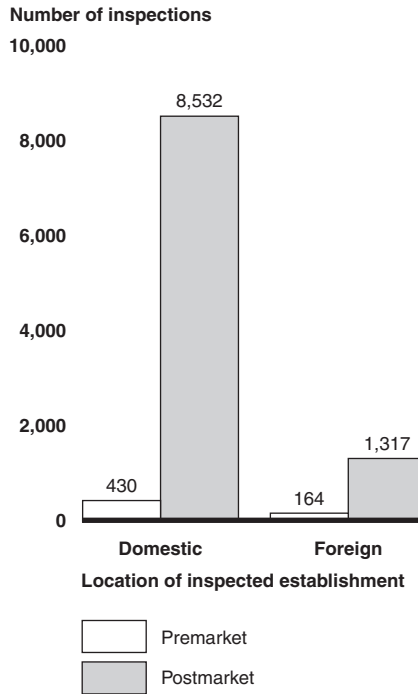
Despite its focus on domestic inspections, FDA has not met the statutory requirement to inspect domestic establishments manufacturing class II or III medical devices every 2 years. For domestic establishments, FDA officials estimated that, on average, the agency inspects class II

manufacturers every 5 years and class III manufacturers every 3 years. For foreign establishments—for which there is no comparable inspection requirement—FDA officials estimated that the agency inspects class II manufacturers every 27 years and class III manufacturers every 6 years.

FDA's inspections of medical device establishments, both domestic and foreign, are primarily postmarket inspections. While premarket inspections are generally FDA's highest priority, relatively few have to be performed in any given year.³⁴ Therefore, FDA focuses its resources on postmarket inspections. From fiscal year 2002 through fiscal year 2007, 95 percent of the 8,962 domestic establishment inspections and 89 percent of the 1,481 foreign establishment inspections were for postmarket purposes. (See fig. 2.)

³⁴Currently, most medical devices are cleared for marketing in the United States because they are "substantially equivalent" to a marketed device. FDA generally does not conduct premarket inspections of establishments manufacturing these types of medical devices.

Figure 2: Number of Inspections of Domestic and Foreign Establishments That Manufacture Medical Devices for the U.S. Market, by Type of Inspection, Fiscal Year 2002 through Fiscal Year 2007



Source: GAO analysis of FDA data.

Note: If an inspection had both premarket and postmarket components, we classified it as a premarket inspection. Of the 430 domestic premarket inspections, 256 contained both premarket and postmarket components. Of the 164 foreign premarket inspections, 95 contained both premarket and postmarket components. FDA may conduct other types of inspections—such as a postmarket quality system, compliance follow-up, for-cause, or postmarket audit inspection—at the same establishment at which they are conducting a premarket inspection. These inspections may focus on different products manufactured at the same establishment.

FDA's Databases Provide Inconsistent Information Regarding the Number of Foreign Medical Device Manufacturing Establishments Subject to Inspection

FDA's databases on registration and imported products provide divergent estimates regarding the number of foreign medical device manufacturing establishments. DRLS provides FDA with information about domestic and foreign medical device establishments and the products they manufacture for the U.S. market. According to DRLS, as of September 2007, 5,616 domestic and 4,983 foreign establishments that reported manufacturing a class II or III medical device for the U.S. market had registered with FDA.³⁵ However, these data contain inaccuracies because establishments may register with FDA but not actually manufacture a medical device or may manufacture a medical device that is not marketed in the United States. FDA officials told us that their more frequent inspections of domestic establishments allow them to more easily update information about whether a domestic establishment is subject to inspection.

In addition to DRLS, FDA obtains information on foreign establishments from OASIS, which tracks the import of medical devices. While not intended to provide a count of establishments, OASIS does contain information about the medical devices actually being imported into the United States and the establishments manufacturing them. However, inaccuracies in OASIS prevent FDA from using it to develop a list of establishments subject to inspection. OASIS contains duplicate records for a single establishment because of inaccurate data entry by customs brokers at the border. According to OASIS, in fiscal year 2007, there were as many as 22,008 foreign establishments that manufactured class II medical devices for the U.S. market and 3,575 foreign establishments that manufactured class III medical devices for the U.S. market.³⁶ Despite the divergent estimates of foreign establishments generated by DRLS and OASIS, FDA does not routinely verify the data within each database. Although comparing information from these two databases could help FDA determine the number of foreign establishments marketing medical devices in the United States, the databases cannot exchange information to be compared electronically and any comparisons are done manually.

Efforts are underway that could improve FDA's databases. FDA officials suggested that, because manufacturers are now required to pay an annual establishment registration fee, manufacturers may be more concerned

³⁵DRLS contained one additional registered establishment for which location information was not available.

³⁶According to FDA officials, a single establishment could be manufacturing more than one class of device.

about the accuracy of the registration data they submit. They also told us that, because of the registration fee, manufacturers may be less likely to register if they do not actually manufacture a medical device for the U.S. market. In addition, FDA officials stated that the agency is pursuing various initiatives to try to address the inaccuracies in OASIS, such as providing a unique identifier for each foreign establishment to reduce duplicate entries for individual establishments.

Challenges Unique to Foreign Inspections Influence the Manner in Which FDA Conducts Such Inspections

Inspections of foreign establishments pose unique challenges to FDA—both in human resources and logistics. FDA does not have a dedicated cadre of investigators that only conduct foreign medical device establishment inspections; those staff who inspect foreign establishments also inspect domestic establishments. Among those qualified to inspect foreign establishments,³⁷ FDA relies on staff to volunteer to conduct inspections. FDA officials told us that it is difficult to recruit investigators to voluntarily travel to certain countries. However, they added that if the agency could not find an individual to volunteer for a foreign inspection trip, it would mandate the travel. Logistically, foreign medical device establishment inspections are difficult to extend even if problems are identified because the trips are scheduled in advance.³⁸ Foreign medical device establishment inspections are also logistically challenging because investigators do not receive independent translational support from FDA or the State Department and may rely on English-speaking employees of the inspected establishment or the establishment's U.S. agent to translate during an inspection.

³⁷Staff members must meet certain criteria in terms of their experience and training to conduct inspections of foreign establishments. For example, they are required to take certain training courses and have at least 3 years of experience conducting domestic inspections before they can be considered qualified to conduct a foreign inspection.

³⁸Typically, FDA investigators travel abroad for about 3 weeks at a time, during which they inspect approximately three establishments.

Few Third-Party Inspections Are Conducted, but Recent Changes Could Eliminate Some Obstacles to Manufacturers' Participation

Few inspections of medical device manufacturing establishments have been conducted through FDA's two accredited third-party inspection programs—the Accredited Persons Inspection Program and PMAP. FDAAA specified several changes to the requirements for inspections by accredited third parties that could result in increased participation by manufacturers.

Few inspections have been conducted through FDA's Accredited Persons Inspection Program since March 11, 2004—the date when FDA first cleared an accredited organization to conduct independent inspections. Through January 11, 2008, five inspections had been conducted independently by accredited organizations (two inspections of domestic establishments and three inspections of foreign establishments), an increase of three since we reported on this program one year ago.³⁹

As of January 11, 2008, 16 third-party organizations were accredited,⁴⁰ and individuals from 8 of these organizations had completed FDA's training requirements and been cleared to conduct independent inspections.⁴¹ As of January 8, 2008, FDA and accredited organizations had conducted 44 joint training inspections.⁴² Fewer manufacturers volunteered to host training inspections than have been needed for all of the accredited organizations

³⁹In January 2007, we reported that two inspections had been independently conducted by accredited organizations through the Accredited Persons Inspection Program—one inspection of a domestic establishment and one inspection of a foreign establishment. [GAO-07-157](#), 11.

⁴⁰FDA officials told us that no additional organizations have applied for accreditation since we issued our January 2007 report.

⁴¹In January 2007, we reported that 7 of the 16 accredited organizations had been cleared to conduct independent inspections. [GAO-07-157](#), 11. One additional accredited organization was cleared to conduct independent inspections on October 18, 2007. Specific foreign jurisdictions that have certified, accredited, or otherwise recognized one or more of the FDA-accredited organizations that have been cleared to conduct independent inspections include all member states of the European Community, Australia, Canada, New Zealand, Norway, Taiwan, and the United Kingdom. Of the 8 third-party organizations that have been cleared to conduct independent inspections through the Accredited Persons Inspection Program, 4 may conduct inspections through PMAP.

⁴²In January 2007, we reported that FDA and accredited organizations had conducted 37 joint training inspections. [GAO-07-157](#), 11.

to complete their training.⁴³ Moreover, scheduling these joint training inspections has been difficult. FDA officials told us that, when appropriate, staff are instructed to ask manufacturers to host a joint training inspection at the time they notify the manufacturers of a pending inspection. FDA schedules inspections a relatively short time prior to an actual inspection,⁴⁴ and as we reported in January 2007, some accredited organizations have not been able to participate because they had prior commitments.

As we reported in January 2007, manufacturers' decisions to request an inspection by an accredited organization might be influenced by both potential incentives and disincentives. According to FDA officials and representatives of affected entities, potential incentives to participation include the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. For example, one inspection conducted by an accredited organization was a single inspection designed to meet the requirements of FDA, the European Union, and Canada. Another potential incentive mentioned by FDA officials and representatives of affected entities is the opportunity to control the scheduling of the inspection by an accredited organization by working with the accredited organization. FDA officials and representatives of affected entities also mentioned potential disincentives to having an inspection by an accredited organization. These potential disincentives include bearing the cost for the inspection,⁴⁵ doubts about whether accredited organizations can cover multiple requirements in a single

⁴³As we reported in January 2007, some representatives of affected entities speculated that manufacturers might not have volunteered to host training inspections because they believed that training inspections would require more time and effort for their staff (and would thus be more disruptive) than inspections conducted by fully trained personnel, or that manufacturers might have believed that training inspections would be more rigorous than nontraining inspections if the trainees and FDA personnel were to take particular care to demonstrate their thoroughness to each other.

⁴⁴FDA generally notifies manufacturers about a week in advance of postmarket quality system inspections of domestic establishments and about 6 to 8 weeks in advance of postmarket quality system inspections of foreign establishments.

⁴⁵In January 2007, we reported that representatives of accredited organizations indicated that the cost to manufacturers would vary depending on such factors as the size of the manufacturer and how much extra time would be required to assess compliance with FDA requirements. Representatives suggested that covering FDA's requirements could take 2 or more days in addition to the time spent assessing other countries' requirements, plus time for advance preparation and writing the inspection report. They speculated that they would probably charge manufacturers from \$1,700 to \$2,500 per day, plus the cost of travel and living expenses.

inspection, and uncertainty about the potential consequences of an inspection that otherwise may not occur in the near future—consequences that could involve regulatory action.

Changes specified by FDAAA have the potential to eliminate certain obstacles to manufacturers' participation in FDA's programs for inspections by accredited third parties that were associated with manufacturers' eligibility. For example, an eligibility requirement that foreign establishments be periodically inspected by FDA was eliminated. Representatives of the two organizations that represent medical device manufacturers with whom we spoke about FDAAA told us that the changes in eligibility requirements could eliminate certain obstacles and therefore potentially increase their participation. These representatives also noted that key incentives and disincentives to manufacturers' participation remain. FDA officials told us that they are currently revising their guidance to industry in light of FDAAA and expect to issue the revised guidance during fiscal year 2008. It is too soon to tell what impact these changes will have on manufacturers' participation.

FDA officials acknowledged that manufacturers' participation in the Accredited Persons Inspection Program has been limited. In December 2007, FDA established a working group to assess the successes and failures of this program and to identify ways to increase participation. Representatives of the two organizations that represent medical device manufacturers with whom we recently spoke stated that they believe manufacturers remain interested in the Accredited Persons Inspection Program. The representative of one large, global manufacturer of medical devices told us that it is in the process of arranging to have 20 of its domestic and foreign device manufacturing establishments inspected by accredited third parties.

As of January 11, 2008, two inspections, both of domestic establishments, had been conducted through PMAP, FDA's second program for inspections by accredited third parties. Although it is too soon to tell what the benefits of PMAP will be, the program is more limited than the Accredited Persons Inspection Program and may pose additional disincentives to participation by both manufacturers and accredited organizations. Specifically, inspections through PMAP would be designed to meet the requirements of the United States and Canada, whereas inspections conducted through the Accredited Persons Inspection Program could be designed to meet the requirements of other countries. In addition, two of the five representatives of affected entities noted that in contrast to inspections conducted through the Accredited Persons

Inspection Program, inspections conducted through PMAP could undergo additional review by Health Canada. Health Canada will review inspection reports submitted through this pilot program to ensure they meet its standards. This extra review poses a greater risk of unexpected outcomes for the manufacturer and the accredited organization, which could be a disincentive to participation in PMAP that is not present with the Accredited Persons Inspection Program.

Concluding Observations

Americans depend on FDA to ensure the safety and effectiveness of medical products, including medical devices, manufactured throughout the world. However, our findings regarding inspections of medical device manufacturers indicate weaknesses that mirror those presented in our November 2007 testimony regarding inspections of foreign drug manufacturers. In addition, they are consistent with the FDA Science Board's findings that FDA's ability to fulfill its regulatory responsibilities is jeopardized, in part, by information technology and human resources challenges. We recognize that FDA has expressed the intention to improve its data management, but it is too early to tell whether the intended changes will ultimately enhance the agency's ability to manage its inspection programs. We and others have suggested that the use of accredited third parties could improve FDA's ability to meet its inspection responsibilities. However, the implementation of its programs for inspecting medical device manufacturers has resulted in little progress. To date, its programs for inspections by accredited third parties have not assisted FDA in meeting its regulatory responsibilities nor have they provided a rapid or substantial increase in the number of inspections performed by these organizations, as originally intended. Although recent statutory changes to the requirements for inspections by accredited third parties may encourage greater participation in these programs, the lack of meaningful progress raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill other responsibilities.

Mr. Chairman, this completes my prepared statement, I would be happy to respond to any questions you or the other Members of the subcommittee may have at this time.

Contacts and Acknowledgments

For further information about this testimony, please contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may found on the last page of this testimony. Geraldine Redican-Bigott, Assistant Director; Kristen Joan Anderson; Katherine Clark; Robert Copeland; William Hadley; Cathy Hamann; Mollie Hertel; Julian Klazkin; Lisa Motley; Daniel Ries; and Suzanne Worth made key contributions to this testimony.

Appendix I: Summary of GAO Testimony on FDA's Program for Inspecting Foreign Drug Manufacturers

In congressional testimony in November 2007, we presented our preliminary findings on the Food and Drug Administration's (FDA) program for inspecting foreign drug manufacturers.¹ We found that (1) FDA's effectiveness in managing the foreign drug inspection program continued to be hindered by weaknesses in its databases; (2) FDA inspected relatively few foreign establishments; and (3) the foreign inspection process involved unique circumstances that were not encountered domestically.

Our preliminary findings indicated that more than 9 years after we issued our last report on FDA's foreign drug inspection program,² FDA's effectiveness in managing this program continued to be hindered by weaknesses in its databases. FDA did not know how many foreign establishments were subject to inspection. Instead of maintaining a list of such establishments, FDA relied on information from several databases that were not designed for this purpose. One of these databases contained information on foreign establishments that had registered to market drugs in the United States, while another contained information on drugs imported into the United States. One database indicated about 3,000 foreign establishments could have been subject to inspection in fiscal year 2007, while another indicated that about 6,800 foreign establishments could have been subject to inspection in that year. Despite the divergent estimates of foreign establishments subject to inspection generated by these two databases, FDA did not verify the data within each database. For example, the agency did not routinely confirm that a registered establishment actually manufactured a drug for the U.S. market. However, FDA used these data to generate a list of 3,249 foreign establishments from which it prioritized establishments for inspection.

Because FDA was not certain how many foreign drug establishments were actually subject to inspection, the percentage of such establishments that had been inspected could not be calculated with certainty. We found that FDA inspected relatively few foreign drug establishments, as shown in table 2. Using the list of 3,249 foreign drug establishments from which FDA prioritized establishments for inspection, we found that the agency may inspect about 7 percent of foreign drug establishments in a given year. At

¹GAO, *Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers*, [GAO-08-224T](#) (Washington, D.C.: Nov. 1, 2007).

²GAO, *Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program*, [GAO/HEHS-98-21](#) (Washington, D.C.: Mar. 17, 1998).

this rate, it would take FDA more than 13 years to inspect each foreign drug establishment on this list once, assuming that no additional establishments are subject to inspection.

Table 2: Number of FDA Inspections of Foreign Establishments Involved in the Manufacture of Drugs for the U.S. Market, Fiscal Year 2002 through Fiscal Year 2007

Country	Number of inspections						Total	Number of establishments ^b
	FY2002	FY2003	FY2004	FY2005	FY2006	FY2007 ^a		
India	11	19	38	33	34	65	200	410
Germany	24	15	35	25	19	22	140	199
Italy	17	30	26	21	18	19	131	150
Canada	29	12	17	23	23	19	123	288
United Kingdom	19	22	15	18	15	13	102	169
France	14	15	13	12	16	24	94	162
China	11	9	17	21	17	13	88	714
Japan	11	13	14	21	13	15	87	196
Switzerland	12	12	11	17	9	14	75	83
Ireland	11	5	11	14	3	11	55	61
All other countries	63	38	63	61	45	80	350	817
Total	222	190	260	266	212	295	1,445	3,249

Source: GAO analysis of FDA data.

^aInspection data for fiscal year 2007 may not be complete because FDA provided these data as of September 26, 2007, prior to the end of the fiscal year.

^bThis count represents the number of establishments FDA used to plan its fiscal year 2007 prioritized surveillance inspections.

FDA's data indicated that some foreign drug manufacturers had not received an inspection, but FDA could not provide the exact number of foreign drug establishments that had never been inspected. Most of the foreign drug inspections were conducted as part of processing a new drug application or an abbreviated new drug application,³ rather than as current good manufacturing practices (GMP) surveillance inspections, which are used to monitor the quality of marketed drugs. FDA used a risk-based

³FDA must approve a new drug application before a new drug product may be marketed in the United States; approval for a generic drug is sought through an abbreviated new drug application. FDA also reviews scientific and clinical data contained in the applications, as part of its process in considering them for approval to be marketed.

process, based in part on data from its registration and import databases, to develop a prioritized list of foreign drug establishments for GMP surveillance inspections in fiscal year 2007. According to FDA, about 30 such inspections were completed in fiscal year 2007, and at least 50 were targeted for inspection in fiscal year 2008. Further, inaccuracies in the data on which this risk-based process depended limited its effectiveness.

Finally, the very nature of the foreign drug inspection process involved unique circumstances that were not encountered domestically. For example, FDA did not have a dedicated staff to conduct foreign drug inspections and relied on those inspecting domestic establishments to volunteer for foreign inspections. While FDA may conduct unannounced GMP inspections of domestic establishments, it did not arrive unannounced at foreign establishments. It also lacked the flexibility to easily extend foreign inspections if problems were encountered due to the need to adhere to an itinerary that typically involved multiple inspections in the same country. Finally, language barriers can make foreign inspections more difficult to conduct than domestic ones. FDA did not generally provide translators to its inspection teams. Instead, they may have had to rely on an English-speaking representative of the foreign establishment being inspected, rather than an independent translator.

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