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Report to the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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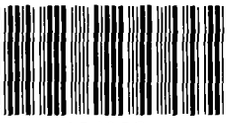
FOOD AND DRUG ADMINISTRATION

HHS Inspector General Should Be Involved in Criminal Investigations



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Human Resources Division

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November 4, 1987

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

Dear Mr. Chairman:

This report discusses the authority of the Food and Drug Administration (FDA) and the Department of Health and Human Services' (HHS) Office of the Inspector General to conduct criminal investigations relating to (1) counterfeit and diverted drugs and (2) the training and resources available to conduct such investigations. The report recommends that the HHS Inspector General become involved in criminal investigations at FDA. The FDA Commissioner and the Inspector General agreed and are taking action to implement the recommendation.

Copies of this report are being sent to the HHS Secretary and Inspector General, the FDA Commissioner, and other interested parties.

Sincerely yours,

Richard L. Fogel
Assistant Comptroller General

Executive Summary

Purpose

What is the authority of the Food and Drug Administration (FDA) to conduct criminal investigations, and are resources available for such investigations?

Are FDA personnel specifically hired and trained as criminal investigators?

What is the Department of Health and Human Services (HHS) Inspector General's involvement in FDA criminal investigations, and are resources available to conduct such investigations?

The Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to respond to these questions because proposed legislation would increase the number of activities subject to criminal sanctions under the Federal Food, Drug, and Cosmetic (FD&C) Act.

Background

Under the FD&C Act, FDA can remove from the market all counterfeit drugs (forgeries of legitimate drugs) and diverted drugs (removed from the normal distribution channels) that are adulterated or misbranded or both. Persons and firms violating the act's provisions can be prosecuted and fined from $100,000 to $500,000. These violators can also be imprisoned for up to 3 years.

The Prescription Drug Marketing Act of 1987 would, if enacted, amend the FD&C Act and (1) ban, regardless of whether products were adulterated or misbranded, the "reimportation of drugs produced in the U.S." (except in emergency situations) and (2) restrict the distribution of drug samples and certain resales of drug products. Violators could be fined not more than $1,000,000 and imprisoned for not more than 10 years.

Results in Brief

The FD&C Act authorizes FDA to plan and conduct inspections of FDA-regulated industries to protect consumers. The FDA employs consumer safety inspectors and officers with the scientific background and training needed to carry out FDA's various program responsibilities. FDA safety inspectors and officers collect information for use in criminal prosecutions and, when FDA deems necessary, seek specialized criminal investigative skills of other federal agencies, such as the Federal Bureau of Investigation. FDA does not hire nor specifically train its personnel to become criminal investigators.

Although the HHS Inspector General has authority to conduct criminal investigations of FDA programs and activities, the Inspector General conducts investigations relating only to allegations of criminal wrongdoing involving an FDA employee. The HHS Inspector General hires and trains personnel to become criminal investigators and conducts all criminal investigations for HHS agencies other than FDA.

FDA has been involved in a limited number of counterfeit and diverted drug investigations. If the proposed legislation is enacted, the number of criminal investigations could increase. The Inspector General believes he can assume this added responsibility without additional resources and that he should be involved in all FDA criminal investigations. Increasing the HHS Inspector General's involvement in FDA criminal investigations is an appropriate alternative to FDA's (1) hiring criminal investigators, (2) providing its safety officers with criminal investigative training, or (3) relying on other federal or state agencies.

Principal Findings

FDA and HHS Inspector General Have Authority to Conduct Investigations

FDA can inspect (1) any domestic factory, warehouse, or establishment in which drugs are manufactured, processed, packed, or held for introduction into interstate commerce or (2) any vehicle used to transport drugs in interstate commerce. FDA can seek, through the Department of Justice, the prosecution of persons and firms violating provisions of the act.

The Inspector General is also authorized to (1) direct and conduct inspections, audits, and investigations related to fraud, waste, and abuse in all HHS programs and operations and (2) identify and recommend to Justice that participants involved in such activities be prosecuted.

In 1981, Justice commented that the legislation establishing the HHS Office of the Inspector General (OIG) was generally not intended to replace FDA's regulatory function, such as investigating possible violations of the FD&C Act. However, Justice noted that it envisioned situations where the Inspector General, FDA, or both would investigate alleged violations of the FD&C Act. Justice suggested that FDA be given an opportunity to review matters investigated by the Inspector General before any referrals to Justice for criminal prosecution.

FDA Has Investigated the Counterfeiting and Diversion of Drugs

FDA officials commented that they have been involved in criminal investigations for many years, but do not distinguish these investigations from their normal surveillance work, which may result in discovery of a criminal act. Evidence developed during the routine inspection of a regulated firm could result in a possible criminal prosecution. Investigations involving counterfeit drugs may require more extensive investigational time and effort, including assistance and increased coordination with the Federal Bureau of Investigation and U.S. attorneys.

In the last 16 years, FDA has been involved in criminal investigations of six counterfeit drug cases. Three cases resulted in violators' being imprisoned or fined or both; persons were indicted in a fourth case, and a grand jury was requested in a fifth case. FDA continues to investigate the remaining counterfeit case.

In addition, FDA, since 1985, has been involved in a joint investigation with the Federal Bureau of Investigation of a major drug diversion case. According to FDA, as of July 1987, 28 persons have been convicted. FDA's investigation of three other significant drug diversion cases did not disclose evidence of adulteration or misbranding. Since February 1986, FDA has also followed up on 11 reports of allegedly diverted drugs that were misbranded or adulterated. Of the eight investigations completed, six have not disclosed diversion activities or criminal wrongdoing.

FDA officials told GAO that because of the small number of counterfeit and diverted cases FDA has been involved in over the past several years, resources have not been specifically designated for the investigation of such cases.

FDA Hires Consumer Safety Inspectors and Officers

FDA hires and trains consumer safety inspectors and officers to do inspections, sample collections, and special investigations to verify that FDA-regulated products or manufacturers (or both) are in compliance with requirements of the FD&C Act.

FDA has about 780 consumer safety officers in its district offices. The Office of Personnel Management standard for FDA consumer safety officers requires a knowledge of basic science. In addition, during the first 6 months of employment, they receive on-the-job training and classroom instruction related to doing FDA inspections.

FDA officials estimated that the agency would require an additional 30 full-time-equivalent positions, costing $1.5 million, to implement the proposed legislation. Such resources would also be used to implement regulations and maintain liaison with the drug industry, but would not be used to hire criminal investigators.

OIG Hires and Trains Criminal Investigators

OIG hires persons with investigative skills to fill its criminal investigator positions. The Office of Personnel Management standard specifies that criminal investigators have a primary knowledge of investigative techniques and be skillful in such activities as maintaining surveillances, performing undercover work, making arrests, and taking part in raids. Throughout their careers, criminal investigators receive various training and have access to specialized equipment related to conducting investigations. In addition, criminal investigators must complete an 8-week training program, sponsored by the Federal Law Enforcement Training Center in Glynco, Georgia.

The Inspector General believes OIG should be involved in FDA criminal investigations because OIG conducts criminal investigations for other HHS agencies and has 261 investigators that are specifically hired and trained to conduct such investigations. The Inspector General stated that OIG could carry out FDA criminal investigations with current resources.

Recommendation

GAO recommends that the Secretary of HHS direct the FDA Commissioner and the HHS Inspector General to develop and implement a plan for involving the Inspector General in FDA criminal investigations. Such a plan should identify the types of FDA investigations that will be referred to the Inspector General, when such referrals should be made, and the specific responsibilities of FDA and Inspector General personnel in carrying out criminal investigations.

Agency Comments

The HHS Inspector General stated, in a September 1987 letter, that (1) he and the FDA Commissioner generally agreed with the report's findings and (2) FDA and OIG staff will meet over the next several months to identify specific approaches to address the recommendation.

Contents

Abbreviations

FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic
HHS	Department of Health and Human Services
OIG	HHS Office of the Inspector General
USDA	U.S. Department of Agriculture

Introduction

FDA is responsible for protecting the public from unsafe or ineffective drugs. It derives its authority from the Federal Food, Drug, and Cosmetic (FD&C) Act, which prohibits distribution of adulterated or misbranded drugs in the United States or their importation. Adulterated drugs are those that are defective, unsafe, filthy, or not produced in conformity with current good manufacturing practices; misbranded drugs include those on which labeling is false, misleading, or lacking in sufficient facts to provide important or required information. FDA has authority to remove from the market all counterfeit drugs—forgeries of legitimate drugs—regardless of whether they are misbranded or adulterated. Diverted drugs—drug products removed from normal and usual channels of distribution—can now be removed by FDA only if they are adulterated or misbranded.

In general, the act permits FDA to inspect (1) any domestic factory, warehouse, or establishment in which drugs are manufactured, processed, packed, or held for introduction into interstate commerce or (2) any vehicle used to transport drugs in interstate commerce. The act requires that domestic drug manufacturers be inspected at least once every 2 years. FDA also has authority to inspect foreign manufacturers' products at various U.S. points of entry and can investigate instances where there is evidence that a violation of the act has occurred or may occur.

FDA has been provided with specific investigative authority relating to counterfeit drugs. Section 702(e) of the act permits any Department of Health and Human Services (HHS) officer or employee to (1) conduct examinations, investigations, or inspections of counterfeit drugs and (2) when authorized by the Secretary, carry firearms and serve and execute search and arrest warrants.

Diverted drugs include (1) those that have been manufactured in the United States for foreign markets and returned to the United States by parties other than the original manufacturer, (2) the sale of physician drug samples, and (3) the resale of drugs bought by institutions at reduced prices. By removing drugs from the usual channels of distribution, there is a potential for manipulating the drugs in ways that could result in their becoming adulterated or misbranded or both under the FD&C Act. FDA officials told us that diverted drugs have to be adulterated or misbranded before FDA can take action to remove them from the marketplace. For example, the sale of physician samples does not constitute a violation of the FD&C Act.

Legislation, proposed in the 100th Congress, would amend the FD&C Act, providing FDA with additional authority for regulating diverted drugs. This legislation—Prescription Drug Marketing Act of 1987 (H.R. 1207 and S. 368)—if enacted, would ban the "reimportation of drugs produced in the United States" (except in emergency situations), place restrictions on the distribution of drug samples to physicians, and ban certain resales of drugs by hospitals and other health care facilities. Violators would be imprisoned for not more than 10 years or fined not more than $1 million or both.

FDA officials estimated that the agency would require an additional 30 full-time-equivalent positions, costing $1.5 million, to implement this legislation. Such resources would be used to implement regulations, establish new or revised surveillance programs to ensure compliance with the legislation, and maintain liaison with the drug industry. FDA officials pointed out that these resources would not be used to hire or train criminal investigators.

The FD&C Act provides FDA with authority to seek court-ordered seizures and injunctions for removing or keeping adulterated and misbranded products from the market. In addition, an FDA attorney stated that the Federal Rules of Criminal Procedures allow FDA to obtain criminal search warrants, which authorize FDA to seize all evidence of criminal activity. Persons and firms can be prosecuted or fined or both for violating provisions of the act. Depending on the circumstances, violators can be fined from $100,000 to $500,000 under the Criminal Fines Enforcement Act of 1984. The first conviction can result in imprisonment for up to 1 year; however, if the violator had the intent to defraud or mislead, the conviction can result in imprisonment for up to 3 years. A second conviction can also result in imprisonment for up to 3 years. On the average, about 20 persons or firms are prosecuted annually for all violations of the FD&C Act. The process of initiating any of these legal actions requires clearances from FDA district, regional, and headquarters offices as well as interaction with the Department of Justice and other federal agencies.

FDA does not have authority to detain adulterated and misbranded domestic food and drug products to prevent their entering the marketplace. It can, however, detain other FDA-regulated products, such as medical devices and imported products. We have recommended, in other

reports, that Congress amend the FD&C Act to give FDA detention authority.[1]

Objectives, Scope, and Methodology

In a June 1986 letter and in subsequent meetings with his office, the Chairman of the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked us to provide information on the authority of FDA and the HHS Office of the Inspector General (OIG) to conduct criminal investigations relating to (1) counterfeit and diverted drugs and (2) the training resources available to conduct such investigations. We determined

- how FDA detects and monitors drug counterfeiting and diversion activities,
- the number of FDA personnel that are specifically trained to conduct criminal investigations of drug counterfeiting and diversion, and
- OIG's authority and involvement in FDA's criminal investigations and the OIG resources available to conduct criminal investigations.

We were also asked to provide information on FDA's legal authority to obtain search warrants, detain counterfeit and diverted drugs, and refer cases to OIG and the Department of Justice.

We did the majority of our work at FDA headquarters in Rockville, Maryland; here we obtained information on headquarters and field office policies, procedures, and resource allocation for conducting investigations of drug counterfeiting and diversion activities. We also obtained information from the following: the headquarters offices of OIG, the Office of Personnel Management, the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service and Office of the Inspector General, and the Federal Bureau of Investigation (FBI) in Washington, D.C.; U.S. Pharmacopeial Convention, Inc. (a private organization) in Rockville, Maryland; and the Federal Law Enforcement Training Center in Glynco, Georgia.

We interviewed FDA officials to discuss FDA policies for conducting criminal investigations and officials' efforts to regulate the counterfeiting and diversion of drugs. We reviewed records and developed information on FDA's involvement in drug counterfeit cases—six over the past 16

[1]GAO reports recommending detention authority include Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public From Adulterated Food Products (GAO/HRD-84-61, Sept. 26, 1984) and Legislative and Administrative Changes Needed to Improve Regulation of Drug Industry (GAO/HRD-83-24, Apr. 5, 1983).

years. In addition, we obtained information on 15 FDA investigations of reported allegations of drug diversion. We also reviewed FDA reports of diverted drugs involving the return of American drugs, between October 1986 and February 1987, to the United States.

We discussed with FDA officials and obtained documentation on the number of FDA personnel that can conduct criminal investigations and their involvement in counterfeit and diverted drug cases. We reviewed the qualification standards, training requirements, and summary descriptions of training courses provided for these personnel. Because of the availability of this information at FDA headquarters, we did not visit any FDA district offices.

Officials at U.S. Pharmacopeial Convention were also interviewed to (1) determine what role they play in FDA's efforts to identify drug counterfeiting and diversion activities and (2) obtain information on reports they receive concerning these activities. FDA contracts with U.S. Pharmacopeial to administer FDA's Drug Product Problem Reporting Program, which solicits and receives information from pharmacists on problem drugs.

We also met with officials of OIG and obtained and reviewed documentation to determine (1) its authority and role concerning FDA criminal investigations of drug counterfeiting and diversion, (2) the qualifications and training requirements of a criminal investigator, and (3) the criminal investigative resources it has available. We also reviewed the position description of a criminal investigator, which was obtained from the Office of Personnel Management.

Officials at USDA's Food Safety and Inspection Service and Office of the Inspector General were interviewed because of similar regulatory responsibilities to protect the consumers from adulterated and misbranded meat and poultry. We obtained information on the roles and responsibilities of both offices in conducting criminal investigations.

Our work was done between July 1986 and July 1987 in accordance with generally accepted government auditing standards.

HHS Inspector General Should Be Involved in FDA Criminal Investigations

Both FDA and OIG have authority to conduct criminal investigations involving FDA programs. Although FDA has recognized the need to obtain criminal investigative assistance for some of its investigations of drug counterfeiting and diversion activities, it has not involved OIG in these investigations. FDA personnel assigned to these investigations have not been hired or trained as criminal investigators, but OIG has criminal investigative resources that could be used in FDA criminal investigations. Nevertheless, when assistance was needed in criminal investigations concerning its programs, FDA worked with the FBI and other federal and state agencies.

FDA and OIG Have Authority to Conduct Investigations

Through the Department of Justice, FDA has authority to seek the prosecution of persons and firms violating provisions of the FD&C Act. Violators can be fined or imprisoned or both. In addition, as mentioned earlier, section 702(e) of the act permits any HHS officer or employee to (1) conduct examinations, investigations, or inspections of counterfeit drugs and (2) when authorized by the Secretary, carry firearms and serve and execute search and arrest warrants. Although this authority has been delegated to FDA, it has not used such authority in conducting past investigations of counterfeit drugs. However, FDA officials recently advised us that it may be necessary to use the authority in section 702, and they are developing procedures for implementing this section.

FDA officials commented that they have been conducting criminal investigations for many years, but do not distinguish them from their normal surveillance work, which may result in discovery of a criminal act. For example, officials noted that evidence developed during the routine inspection of a regulated firm could result in a possible criminal prosecution. They also noted that special investigations of counterfeit drugs would be handled the same as other FDA investigations, except that these investigations may require more extensive time and effort, as well as the assistance of and increased coordination with the FBI and U.S. attorneys.

Public Law 94-505, enacted October 15, 1976, authorizes OIG to (1) direct and conduct audits and investigations related to fraud and abuse in HHS programs and operations and (2) identify and refer for prosecution participants involved in fraud and abuse. In 1981, the HHS general counsel asked the Department of Justice to clarify the procedures for OIG's referring possible violations of the FD&C Act to Justice for consideration of criminal prosecution.

Justice commented that it believed the legislation establishing OIG's authority to conduct criminal investigations was, generally, not intended to replace the regulatory function of FDA, such as investigating possible violations of the FD&C Act. However, Justice noted that it also believed that OIG was authorized to investigate allegations of improprieties relating to programs and operations of HHS; Justice envisioned situations where OIG or FDA or both would investigate alleged violations of the FD&C Act. Justice suggested that FDA be given an opportunity to review matters investigated by OIG before any referrals to Justice for criminal prosecution.

Because FDA has criminal enforcement powers, OIG has made it a practice to do criminal investigations of FDA activities only when these investigations involve an allegation of criminal wrongdoing by an FDA employee. Between January 10, 1983, and November 18, 1986, FDA referred seven cases to OIG that primarily involved employee fraud or conflict of interest. One of the seven cases involved personal threats to an FDA employee made by a nonemployee.

OIG has not been involved in any FDA drug diversion or counterfeit cases. The Inspector General noted that it may be time for FDA and his office to reexamine their handling of such investigations because it is unlikely that the problem of drug diversion will diminish. FDA officials told us that they have not involved OIG in their criminal investigations because FDA officials have always obtained assistance from the FBI and others when needed. FDA officials told us that they have not met with OIG officials to discuss FDA criminal investigations. However, FDA officials said that they are willing to meet with OIG to determine what resources and special investigative skills OIG could make available. We noted such an arrangement at USDA: the Food Safety and Inspection Service has a working agreement with the Office of the Inspector General about their mutual investigative and enforcement responsibilities concerning various USDA laws and regulations. The Service is responsible for ensuring that meat and poultry products are safe, wholesome, and properly labeled. When investigations disclose violations, various sanctions—such as seizure, detention of products, or criminal prosecution of violators—can be used. The Office of the Inspector General is responsible for supervising and coordinating the criminal investigative activities within USDA.

The agreement states that the Service will request that the USDA Office of the Inspector General investigate alleged violations that are particularly significant, complex, or sensitive. Such referrals will generally

include matters that are likely to require serving and executing search and arrest warrants or using investigative grand juries. Under this agreement, about 20 cases per year are referred to the Office of the Inspector General. USDA officials told us that the cooperative arrangement has worked well over the years.

FDA Depends on Voluntary Reporting of Counterfeit and Diverted Drugs

FDA officials stated that because of the small number of counterfeit and diverted drug cases, resources are not directly assigned to identifying these drugs. Both the drug manufacturers and distributors regulated under the FD&C Act are generally not involved in counterfeiting and diverting drugs, according to these officials; therefore, FDA drug inspections, for the most part, will not identify persons involved in such activities. To be alert to possible counterfeit or diverted drugs, FDA depends on voluntary reporting and seeks information from health professionals, pharmacists, manufacturers, consumers, and others. FDA prioritizes the reports based on the seriousness of the problem and assigns them for follow-up by FDA district offices.

Through FDA's Drug Product Problem Reporting Program, FDA alerts pharmacists and health care facilities to its concern about counterfeit and diverted drugs. This program is jointly sponsored by FDA, the U.S. Pharmacopeial Convention, 50 state pharmaceutical associations, and other state and national organizations in various health care areas. The U.S. Pharmacopeial advises health care professionals and pharmacists on FDA's concerns about the risk to consumers in buying problem drugs, including those that have been counterfeited or diverted. The U.S. Pharmacopeial sends out about 70,000 preaddressed drug report pamphlets to pharmacists and health care facilities three times a year and operates a 24-hour toll free telephone hotline.

Reported problems are entered into an FDA computer system and also forwarded to the drug manufacturer or the company that labelled the drug or both for review and possible response. About 3,500 reports are received annually from U.S. Pharmacopeial, FDA officials stated. But officials could not remember many reports that dealt with drug counterfeiting and diversion. They noted, however, that in the past the FDA computer system did not specifically collect data on drug counterfeiting and diversion. A new computer system in the planning stage may collect such information, stated an FDA official. In addition, in September 1985, FDA appointed a coordinator for drug counterfeiting and diversion activities; he works with drug company security officers who investigate alleged drug counterfeiting and diversion activities.

FDA Has Investigated the Counterfeiting and Diversion of Drugs

Over the last 16 years, FDA has conducted 21 investigations of alleged counterfeiting and diversion of drugs. FDA made a determination in 18 of these investigations, which disclosed six cases of drug counterfeiting and three cases of drug diversion. No evidence of counterfeiting or diversion of drugs was found in the remaining nine cases. FDA had sought investigative assistance in some of the cases that resulted in numerous indictments and a criminal conviction.

On July 15, 1986, the FDA Commissioner testified before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, about FDA's investigations of counterfeit and diverted drugs. FDA had been involved in five counterfeit drug cases over the past 15 years, according to the Commissioner. He summarized three of FDA's significant diverted drug cases, which did not disclose any evidence of adulteration or misbranding. Concerning the five counterfeit cases, two resulted in violators' being imprisoned or fined or both; indictments have been handed down in a third case, and a grand jury was requested for a fourth case. FDA's investigation of the remaining case continues.

In September 1985, FDA issued an import alert to its district offices to help assure that American drugs coming back into the country or foreign drugs falsely offered as American goods returned are not counterfeit, adulterated, or misbranded. The alert specifies the requirements for importation of drugs, including a "paper trail" of the drug since it was manufactured in the United States and a visual inspection by FDA personnel before the drug can be released. Through February 1987, 395 import entries (drugs) entered the United States as American goods returned.[1] One entry was found to have counterfeit labeling and, according to an FDA official, it was seized. FDA's investigation is still ongoing.

In addition to the five counterfeit drug cases discussed by the Commissioner, we identified FDA efforts involving one other counterfeit case. In 1981, FDA learned from a drug manufacturer that approximately 1 million expired ampicillin capsules were stolen from its warehouse facility. Information obtained by FDA showed that an employee of the manufacturer and a pharmacist stole the capsules, bottled them under another manufacturer's name, and sold them using counterfeit labels. In April 1984, the employee pleaded guilty to three misdemeanor counts of shipping misbranded drugs in interstate commerce; he was sentenced to 500 hours of community service and 5 years' probation and also fined $2,000. In addition, the pharmacist pleaded guilty to two misdemeanors

[1] An entry is a documented offer for importation of goods into the United States.

for shipping misbranded drugs in interstate commerce; he was sentenced to 300 hours of community service and 3 years' probation and also fined $2,000. This investigation was overlooked, FDA officials stated, when the Commissioner's testimony was prepared.

We also identified 12 FDA diverted drug cases, in addition to the 3 cases discussed by the Commissioner. FDA, in 1985, began a joint investigation with the FBI that uncovered the diverting of counterfeit anabolic steroids and other drugs used to enhance athletic performance. An FDA official reported that underground distributors were recommending that athletes (1) take doses of these drugs that were many times higher than medically accepted and (2) use these drugs in various combinations, the dangers of which were unknown. In some cases, drugs for animals were promoted and sold through underground channels to enhance athletic performance. FDA's initial investigations revealed a network of underground distributors; in order to obtain evidence on the operations and the firms involved, FDA sought assistance from the Department of Justice and the FBI.

In May 1985, FDA and the FBI seized about $2 million worth of the prescription drugs in six states. A year later, the Department of Justice announced a nationwide investigation into the manufacture and distribution of steroids and other drugs. According to FDA, as of July 1987, 28 defendants had been convicted. The investigation continues, and more indictments are expected.

In addition, since February 1986, consumers, pharmacists, and State Boards of Pharmacies have reported 11 alleged diverted drug cases, according to FDA officials. The reports are forwarded by FDA headquarters to the appropriate FDA district office for follow-up with the drug manufacturer or persons making the report. FDA has completed its investigation of 8 of the 11 cases; work is still under way on the remaining 3 cases. In two of the completed cases, FDA officials stated, FDA determined that drugs had been diverted. In one case state officials seized and destroyed the drugs. No persons were prosecuted. In the other case, the person suspected of diverting drugs went out of business and disappeared.

In the remaining six completed cases, FDA did not find evidence that drugs were being diverted. FDA follow-up efforts included undercover purchases of drugs at a pharmacy suspected of distributing samples, inspection of a drug manufacturer, and interviews with persons making the reports. In two of these cases, FDA and State Boards of Pharmacies

worked together and had drugs destroyed or voluntarily recalled because they were either outdated or in violation of the FD&C Act; that is, a drug wholesaler distributed drugs that were under FDA's detention.

FDA Hires and Trains Consumer Safety Inspectors and Officers

To verify that FDA-regulated products are in compliance with requirements of the FD&C Act, FDA hires and trains consumer safety inspectors and officers to do inspections, sample collections, and special investigations. They enforce laws and regulations to protect consumers from foods, drugs, cosmetics, and medical devices that are impure, unwholesome, ineffective, improperly labeled, or dangerous. FDA does not hire or train its personnel, however, to become criminal investigators. FDA's Director of Field Investigations told us that FDA assigns its more experienced consumer safety officers to lead special investigations of counterfeit and diverted drug cases and sometimes assigns consumer safety inspectors to provide assistance. As of June 1987, FDA had approximately 108 inspectors and 783 officers located in its 21 district offices.

The Office of Personnel Management's minimum standard for FDA inspectors and officers requires a knowledge of basic science. FDA inspectors must have 12 semester hours in various sciences in order to do such tasks as collecting product samples, conducting inspections of manufacturers that do not require scientific evaluations, and following up on routine consumer complaints that do not present a serious hazard to public health or safety. FDA officers must have a total of 30 semester hours of college-level science in any of the following fields: biology, chemistry, engineering, epidemiology, food technology, home economics, nutrition, pharmacy, and physical sciences, as well as additional appropriate experience or education or both. These courses are necessary for officers to carry out their primary responsibilities, including planning and conducting inspections; following up on consumer complaints of (1) violations of the FD&C Act and (2) reported injuries and illnesses caused by FDA-regulated products; developing information to support initiating legal actions, such as criminal prosecutions; and advising industry, as well as state and local officials and consumers, on FDA's enforcement of regulations and policies.

On completion of an internal orientation program dealing with FDA's organization and mission, new FDA inspectors and officers enter an on-the-job 6-month training program. This program (1) integrates formal

classroom instruction with field experiences to provide the fundamentals of FDA inspections and (2) covers such topics as the FD&C Act, sanitation measures for protecting the public's health, evidence development, and drug inspections.

Numerous other courses are available to inspectors and officers on a continuous basis as resources permit, according to the FDA training director within the Office of Regulatory Affairs. Related to FDA's primary responsibilities, the available courses are ones such as food microbiology and sanitation, import operations, drug manufacturing quality control, and medical devices. According to FDA officials, several courses provide some training related to criminal investigations, such as

- Basic Food and Drug Law and Evidence Development: This is a 2-week course, initially developed in fiscal year 1984, that provides 1 week of training on the FDA food and drug laws and 1 week of evidence development. According to an FDA division director, approximately 90 percent of FDA inspectors and officers have taken the course; in the future, this course will be required for all inspectors and officers as they are hired.
- Criminal Investigations Training: This is a joint FDA/FBI course, held in 1987 because FDA was getting many drug-tampering cases. This 1-week course, given once to date, includes discussions on legal procedures that frequently arise out of criminal investigations, such as searches, grand jury proceedings, and the admissability of evidence. Also discussed were techniques on evidence development, such as handling informants, surveillance activity, and witness preparation. Selected consumer safety officers at or above the GS-11 level attended this course. In the future, FDA officials plan to (1) provide this training for consumer safety inspectors and (2) develop an in-house training course patterned after this course.
- Drug Diversion and Counterfeiting: This is a 2-day training course, held in January 1986. Corporate officials from various drug firms spoke to FDA program directors, compliance officers, and supervisory consumer safety officers about the methods used by drug counterfeiters and diverters. The objectives of the course are to exchange ideas and explore cooperative efforts between FDA and the drug industry to protect the quality of the nation's drug-supply system.

OIG Hires and Trains Criminal Investigators

OIG's Office of Investigations is responsible for investigating fraud and abuse activities within HHS. As a result, it seeks people with investigative skills to fill HHS criminal investigator positions and trains them to conduct criminal investigations. The Office's investigative staff is

located in Washington, D.C., and in 47 field and sub-offices throughout the United States; the staff consists of 261 criminal investigators and 149 professional and support personnel, such as paralegal specialists and program analysts.

The Office of Personnel Management qualifications standards, followed by OIG, specify that criminal investigators have (1) a primary knowledge of investigative techniques and (2) a knowledge of the laws of evidence, the rules of criminal procedure, court decisions concerning the admissibility of evidence, constitutional rights, search and seizure techniques, and the availability and use of modern detection devices and laboratory services.

In addition, the standard requires that criminal investigators be skillful in such activities as maintaining surveillances, doing undercover work, making arrests, and taking part in raids. Criminal investigators must also be able to follow leads indicating that a crime will be committed rather than begin an investigation after a crime has been committed. Prior investigative experience or the successful completion of study at an accredited university or college helps applicants qualify as HHS criminal investigators. OIG seeks applicants with college degrees in areas such as accounting and criminal justice, according to an OIG official.

OIG criminal investigators receive training, both internal and external, in various laws of HHS and other federal agencies, surveillance and interviewing techniques, report writing, and several HHS program matters such as social security and health care. All OIG criminal investigators must complete an 8-week basic Criminal Investigator Training Program, sponsored by the Federal Law Enforcement Training Center in Glynco, Georgia. This program gives instruction in the skills necessary to carry out criminal investigations. The primary objective, according to course material, is to train law enforcement officers through classroom lectures and practical exercises in which students participate in law enforcement scenarios. Specialized topics in the program include counterfeiting, crime scene investigation, surveillance, search and seizure, detention and arrest, federal court procedures, and firearms safety rules and regulations.

Although there is no formal timetable for follow-up training, an OIG official said, criminal investigators will usually begin receiving it within 12 to 18 months after completing the basic training. Investigators can take other programs at the Center as part of their training, according to OIG officials, such as a 2-week Inspector General Follow-On Basic Training

Program or programs on white-collar crime and advanced law-enforcement photography.

In addition to OIG's specialized training for criminal investigators, an official stated, it has special equipment for conducting criminal investigations, such as 35mm cameras and lenses, video tape cameras and lenses for surveillance purposes, miniature radio and tape-recording equipment for electronic surveillance, and devices for obtaining telephone numbers dialed from telephone lines.

According to the Inspector General, FDA criminal investigations can best be performed by OIG because it routinely conducts such investigations; OIG has sufficient resources to carry out FDA criminal investigations of counterfeit and diverted drugs. He said that investigators work with U.S. attorneys on a regular basis, which gives them an advantage over other investigators, who only occasionally deal with the attorneys. For example, OIG's efforts resulted in 1,055 successful prosecutions and 412 administrative sanctions in fiscal year 1986.[2]

OIG investigators are trained not only in public health laws, the Inspector General added, but also in criminal laws and procedures. In addition, OIG and the FBI have a memorandum of understanding about their specific roles and responsibilities in referring and conducting criminal investigations involving HHS programs and operations. According to the memorandum, OIG will refer to the FBI criminal matters that require resources or expertise not available within OIG. It also states that the FBI's primary role is to investigate allegations of bribery and corruption involving U.S. employees. In addition, the FBI will provide assistance to OIG based on the availability of resources.

Conclusions

Although violators of the FD&C Act are subject to criminal penalties, FDA's primary responsibility is not to conduct criminal investigations. FDA has properly focused its resources on conducting inspections of regulated manufacturers and products to help ensure that products are not adulterated or misbranded. Since FDA's primary responsibility is to protect the public health, FDA consumer safety inspectors and officers need a scientific background and training to equip them with the necessary skills for carrying out the various FDA program responsibilities.

[2]Under administrative sanctions, people are either barred from participation in HHS programs or fined or both.

FDA has recognized that there are times when it must seek specialized skills of other federal and state agencies to carry out criminal investigations. However, the HHS Inspector General has not been involved in FDA criminal investigations. Because the proposed legislation (see p. 9) would amend the FD&C Act by adding a number of prohibited activities that could subject persons and firms to criminal sanctions, it is likely that FDA's involvement in criminal investigations could increase. But FDA should not hire criminal investigators or train its consumer safety inspectors and officers to meet the Office of Personnel Management's criminal investigator qualification standards, regardless of whether the proposed legislation is enacted.

Rather, FDA should seek assistance from OIG because it has trained criminal investigators and believes it can carry out additional investigations within its current resources. In our view, OIG should be involved in investigating the criminal aspects of FDA cases. This would allow FDA's consumer safety inspectors and officers to continue to focus their attention on matters related to protecting the public's health.

Recommendation to the Secretary of HHS

We recommend that the HHS Secretary direct the FDA Commissioner and the HHS Inspector General to develop and implement a plan for involving the Inspector General in FDA criminal investigations of its regulatory programs. Such a plan should identify the types of FDA investigations that will be referred to the Inspector General, when such referrals should be made, and the specific responsibilities of FDA and the Inspector General in carrying out criminal investigations.

Agency Comments

In a letter dated September 11, 1987, the HHS Inspector General stated that he and the FDA Commissioner agree with many of the report's findings, and appropriate FDA and OIG staff will meet over the next several months to identify specific approaches to address our recommendation.

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

SEP 11 1987

Mr. Richard Fogel
Assistant Comptroller General
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

Thank you for the opportunity to comment on the General Accounting Office draft report, "Food and Drug Administration: HHS Inspector General Should Be Involved in Criminal Investigations." The FDA Commissioner and I agree with many of the report's findings. Appropriate staff from OIG and FDA will be meeting over the next several months to identify specific approaches that will best address this problem.

Sincerely yours,

Richard P. Kusserow
Inspector General

*U.S. G.P.O. 1987- 201-749:60154

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