United States General Accounting Office

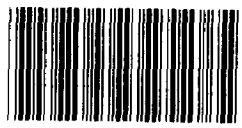
GAO

Fact Sheet for the Chairman,
Special Committee on Aging,
United States Senate

August 1986

FOOD AND DRUG ADMINISTRATION:

Resources for Division of Scientific Investigations Have Been Reduced



GAO/HRD-86-136FS

United States General Accounting Office

GAO

Fact Sheet for the Chairman,
Special Committee on Aging,
United States Senate

August 1986

FOOD AND DRUG ADMINISTRATION

Resources for Division of Scientific Investigations Have Been Reduced

GAO/HRD-86-136FS

GAO

United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-224063

August 28, 1986

The Honorable John Heinz
Chairman, Special Committee on Aging
United States Senate

Dear Mr. Chairman:

In response to your April 1986 inquiry and later discussions with your office, we obtained information on the activities of the Food and Drug Administration's (FDA's) Division of Scientific Investigations (DSI). DSI, part of the Office of Compliance within the Center for Drugs and Biologics, is responsible for the Bioresearch Monitoring program. In carrying out this responsibility, DSI conducts or directs inspections of (1) clinical investigators performing studies on humans to support new drug and biologics products, (2) drug firms that sponsor the clinical investigations, (3) Institutional Review Boards that oversee the conduct of studies on humans, and (4) toxicology laboratories that perform animal testing in support of drug and biologics products.

In discussions with your office, we agreed to provide information we have obtained on four questions you raised about DSI's resources and operations:

--Have there been major reductions in DSI's work force since 1981?

--Has FDA filled vacant positions in DSI?

--Have travel funds been reduced?

--Has the fact that DSI is located away from FDA headquarters in Rockville, Maryland, affected its program activities?

During this review, we interviewed DSI management officials and staff and Office of Compliance management officials. We also spoke with officials in the Center for Drugs and Biologics and the Division of Management Services, in FDA's Office of the Commissioner. In addition, we reviewed staffing and budget information for DSI and the Office of Compliance and FDA documents that outline DSI's regulatory roles and responsibilities.

In summary, we found that:

--From fiscal year 1981 to July 1986, DSI staff devoted to Bioresearch Monitoring activities has been reduced from 37 to 30, or about 19 percent, although DSI's monitoring responsibilities have increased.

--FDA did not fill a vacant medical officer position in DSI's Clinical Investigations Branch.

--From fiscal years 1983 to 1986, DSI's travel expenditures have been reduced about 28 percent, and in 1986, headquarters involvement in field inspections has decreased over 25 percent.

--According to FDA officials, the location of the Office of Compliance in general, and DSI specifically, has caused some decrease in overall efficiency. The decision to move the Office of Compliance to its present location was based on the need to accommodate additional staff at FDA headquarters to implement recently enacted legislation and to meet other office space restrictions. FDA has taken steps to increase DSI's accessibility to headquarters.

At your request, we are continuing our work to determine the impact of the reductions in DSI's staffing and travel and the change in physical location on DSI's ability to carry out its Bioresearch Monitoring responsibilities.

We discussed the information contained herein with FDA program officials and considered their views in developing this document. Unless you publicly announce its contents earlier, we plan no further distribution of this fact sheet until 30 days from its issue date. At that time we will send copies to the Commissioner of FDA and other interested parties. Should you need additional information on the contents of this document, please call me on 275-6207.

Sincerely yours,

David J. Blades
for

David P. Baine
Associate Director

RESOURCES FOR FDA'S DIVISION OF SCIENTIFIC INVESTIGATIONS HAVE BEEN REDUCED

In evaluating the safety and effectiveness of new drugs and biologics products, the Food and Drug Administration (FDA) relies on data obtained by clinical investigators generally selected by manufacturers to conduct studies on humans. The premature marketing of a number of inadequately tested drugs was one factor that led to the passage of the Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act in 1962 and FDA's 1963 Investigational Drug Regulations. These required FDA to exercise greater control over clinical studies involving human test subjects.

According to FDA, after some unscrupulous investigators had been exposed, the Division of Scientific Investigations (DSI) (then known as the Scientific Investigations Staff) was formed in 1967. Its primary function was to investigate clinical investigators who were suspected of performing improper research. In its early years DSI, with a staff of four, conducted only seven or eight inspections annually.

In the following years, increasing public concern was directed toward the use of human subjects in clinical studies, and questions were raised about FDA's ability to adequately carry out its enforcement responsibilities. In 1975, joint hearings were held by Senator Edward Kennedy, Chairman of the Subcommittee on Health of the Senate Committee on Labor and Public Welfare, and the Subcommittee on Administrative Practice and Procedure of the Senate Committee on the Judiciary. These hearings disclosed that, with a staff of six, DSI was responsible for monitoring the activities of some 12,000 investigators, 9,000 institutional review committees, and 550 laboratories and testing facilities involved in studies supporting new drugs. It was also pointed out at the hearings that DSI's workload was growing rapidly.

As a result, in fiscal year 1977, the Congress authorized additional money and staff for FDA to establish a comprehensive agency-wide Bioresearch Monitoring program. In March 1977, DSI was authorized 52 staff positions, given division status as part of the Office of New Drug Evaluation in the Bureau of Drugs, and operated in parallel with six other drug review divisions.

In 1983, FDA reorganized, combining the Bureau of Drugs and the Bureau of Biologics into the Center for Drugs and Biologics. DSI became a part of the Center's Office of Compliance. In December 1985, DSI was physically consolidated with the Office of Compliance at its present location in Gaithersburg, Maryland--about 5 miles from FDA's Rockville headquarters. At that time, DSI also acquired the staff from the Biologics Bioresearch Monitoring program and assumed responsibility for monitoring studies related to biologics products.

In carrying out its monitoring efforts, DSI conducts or directs about 600 inspections annually. These inspections focus on (1) clinical investigators who conduct human studies in support of new drug and biologics products; (2) sponsor/monitors, generally drug firms, who select and oversee clinical investigators; (3) Institutional Review Boards, which are organizations made up of both medical professionals and citizens from the community who monitor study design, paying particular attention to the protection of human subjects; and (4) toxicology laboratories, which perform animal studies in support of new drug and biologics products. These include routine inspections assigned by DSI to FDA's field offices to support DSI's programs and "for-cause" investigations, which generally involve greater participation by headquarters staff. For-cause investigations are generally done because (1) a clinical investigator's data are suspect, (2) the clinical study is singularly important in the approval of a product, or (3) a clinical investigator is conducting an unusually large number of studies.

Following is the information we have obtained concerning the four questions about DSI's resources and operations.

HAVE THERE BEEN MAJOR REDUCTIONS IN DSI'S WORK FORCE?

From fiscal year 1981 through July 1986, DSI has had a net decrease of seven staff (37 to 30) devoted to Bioresearch Monitoring activities. However, in December 1985, DSI assumed responsibility for the Biologics Bioresearch Monitoring program when the two programs were merged.

Table 1 shows DSI's staffing from fiscal year 1981 to July 1, 1986. Fiscal year figures represent the number of staff on board at the beginning of each fiscal year.

Table 1:
DSI Bioresearch Monitoring Staffing
Fiscal Year 1981-July 1, 1986

DSI component	Fiscal year 81	82	83	84	85	86	July 1, 1986
Office of the Director	4	4	4	4	4	4	4
Clinical Investigations Branch	16	12	11	10	9	11	10
Non-Clinical Studies Branch	6	6	6	6	6	6	6
Institutional Review Branch	4	6	5	5	5	7	7
Regulatory Management Branch	7	7	7	7	7	4	3
Total	37	35	33	32[a]	31	32[b]	30

[a]This table does not include staff positions dedicated to the Methodone Monitoring program, for which DSI assumed responsibility in 1984. This program is not considered part of DSI's traditional Bioresearch Monitoring activities.

[b]This includes eight staff transferred from the Biologics Bioresearch Monitoring program when it was combined with DSI's drug activity. At the beginning of fiscal year 1981, the Biologics Bioresearch Monitoring program consisted of 9 staff members, who in addition to the 37 involved in drug monitoring activities, brought FDA's headquarters staff commitment to the monitoring of both drug and biologics products to 46.

During fiscal year 1985, DSI lost nine staff members through transfers, resignations, or retirements and replaced two of them. The other seven positions have since been eliminated. According to Office of Compliance records, eight positions were transferred to DSI when it assumed responsibility for the Biologics Bioresearch Monitoring function in December 1985. Thus, as shown in the table, DSI's staffing has in effect remained relatively level since fiscal year 1983 even though it assumed the increased responsibility for monitoring biologics

products. Also it should be noted that FDA's overall level of effort for Bioresearch Monitoring of both drug and biologics products has been reduced from 46 staff members at the beginning of fiscal year 1981 to 30 as of July 1986. This represents a 35-percent decrease in staffing to carry out the full range of Bioresearch Monitoring activities for drugs and biologics products.

HAS FDA FILLED VACANT POSITIONS?

DSI currently has one vacant position. The Director, Office of Compliance, told us that an additional medical officer position is authorized for DSI's Clinical Investigations Branch. According to the branch chief, no one has yet been hired, and the position is not currently being advertised. Instead, DSI hopes to obtain eligible candidates through an ongoing search for medical officers authorized for the Center for Drugs and Biologics. An FDA personnel officer told us it plans to advertise the need for medical officers in eight major medical journals in the near future.

HAVE TRAVEL FUNDS BEEN REDUCED?

DSI's travel expenditures are expected to be about 28 percent less in fiscal year 1986 than in fiscal year 1983. In fiscal year 1983, DSI spent $55,100 on travel. As of August 1, 1986, DSI's fiscal year 1986 travel expenditures were $37,750, and the Office of Compliance estimates that DSI will expend an additional $2,000 during the remainder of the fiscal year. According to FDA, the Balanced Budget and Emergency Deficit Control Act of 1985 (Public Law 99-177) was a factor for the fiscal year 1986 reduction. Much of DSI's reduction in travel funds has been absorbed by the Office of the Director, the Institutional Review Branch, and the Clinical Investigations Branch. Table 2 shows travel expenditures for fiscal year 1983 through August 1, 1986.

Table 2:
DSI Travel Expenditures
Fiscal Year 1983 Through August 1, 1986

DSI component	Fiscal year 83	Fiscal year 84	Fiscal year 85	August 1, 1986
Office of the Director	$ 3,350	$ 4,100	$ 6,500	$ 600
Institutional Review Branch	6,200	8,700	5,000	1,700
Regulatory Management Branch	2,300	3,300	2,700	500
Non-Clinical Studies Branch	18,800	20,200	10,100	17,550
Clinical Investigations Branch	24,450	26,800	26,200	17,400
Total	$55,100	$63,100	$50,500	$37,750

The number of inspections involving the Clinical Investigations Branch has been reduced significantly in fiscal year 1986. Information supplied by the branch shows that the number of for-cause investigations assigned to the field has remained relatively constant from 1983 through 1986. The branch chief told us that because of the lack of travel funds, headquarters participation in these inspections in 1986 has been reduced significantly. From 1983 through 1985, headquarters participation ranged from 73 to 84 percent. In 1986, headquarters staff has been involved in 50 percent of the inspections.

WHAT IMPACT HAS THE PHYSICAL LOCATION OF DSI HAD ON PROGRAM ACTIVITIES?

The Director, Office of Compliance, estimates that the overall efficiency in the office, including DSI, has been reduced by less than 10 percent because of the office's physical separation from FDA's headquarters in Rockville, Maryland. However, he believes face-to-face contact between the staff in his office and FDA headquarters personnel has suffered because of the separation and this loss may be more important. Several DSI personnel told us they feel isolated from the mainstream of FDA information.

Discussions with officials from the Office of Compliance, the Center for Drugs and Biologics, and the Office of the Commissioner indicated general dissatisfaction with the Office of Compliance's physical separation from the headquarters building. However, these officials stated that because the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) authorized the hiring of 73 additional staff, which the Commissioner wanted placed in the headquarters building, coupled with office space restrictions imposed by the General Services Administration, FDA had to move certain units from Rockville. Officials in the Commissioner's office told us these decisions were made from a management efficiency point of view with no thought of downgrading any program. At this time there are no plans to return the Office of Compliance to Rockville.

Since the move, steps have been taken to ease the situation for DSI and other Office of Compliance components. An hourly shuttle between Gaithersburg and Rockville has been instituted, government vehicles have been made available for Office of Compliance personnel, and parking spaces in the headquarters complex have been provided for Office of Compliance personnel when use of personal vehicles may be required.

(108875)

Requests for copies of GAO reports should be sent to:

U.S. General Accounting Office
Post Office Box 6015
Gaithersburg, Maryland 20877

Telephone 202-275-6241

The first five copies of each report are free. Additional copies are $2.00 each.

There is a 25% discount on orders for 100 or more copies mailed to a single address.

Orders must be prepaid by cash or by check or money order made out to the Superintendent of Documents.

Requests for copies of GAO reports should be sent to:

U.S. General Accounting Office
Post Office Box 6015
Gaithersburg, Maryland 20877

Telephone 202-275-6241

The first five copies of each report are free. Additional copies are $2.00 each.

There is a 25% discount on orders for 100 or more copies mailed to a single address.

Orders must be prepaid by cash or by check or money order made out to the Superintendent of Documents.

United States
General Accounting Office
Washington, D.C. 20548

Official Business
Penalty for Private Use $300

Address Correction Requested

First-Class Mail
Postage & Fees Paid
GAO
Permit No. G100