REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Financial Disclosure System For Employees Of The Food And Drug Administration Needs Tightening

Standards of ethical conduct for Government officials are prescribed by an Executive Order of the President. In line with this order the Food and Drug Administration of HEW developed a financial disclosure system for its employees. GAO noted deficiencies in the Agency's system and recommends improved procedures for ensuring collection of statements from all employees required to file, more timely reviews of financial disclosure statements, and followup on divestiture requests and internal program reviews.

FPCD-76-21

JAN. 19, 1976

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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To the President of the Senate and the
Speaker of the House of Representatives

Executive Order 11222 prescribed standards of ethical conduct for Government officials and directed the Civil Service Commission to establish guidelines for agency financial disclosure systems. This report discusses improvements that are needed in the Food and Drug Administration's financial disclosure system.

Although we made our review pursuant to several requests from Members of Congress to review the effectiveness of Federal agencies' financial disclosure systems, we are sending this report to the Congress because of the widespread congressional interest in this subject.

We did not obtain formal comments from officials of the Food and Drug Administration. However, we discussed the report informally with the Associate Commissioner for Administration and subordinate officials responsible for the financial disclosure system, and they generally agreed with its contents. We also discussed the contents of the report with appropriate officials in the Department of Health, Education, and Welfare.

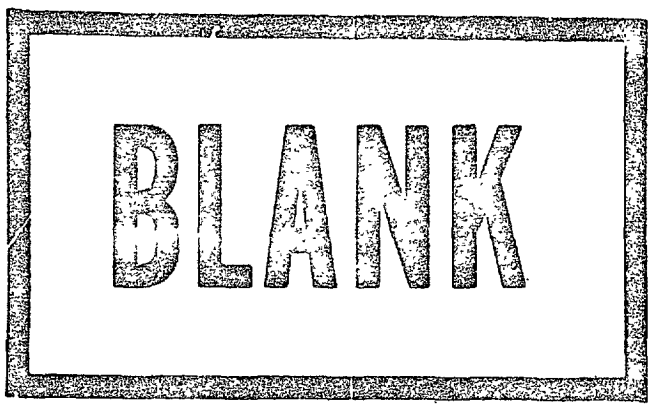
We are sending copies of this report to the Director, Office of Management and Budget; the Secretary, Department of Health, Education, and Welfare; and other interested parties.

Comptroller General
of the United States

Contents

ABBREVIATIONS

CSC	Civil Service Commission
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare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COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

FINANCIAL DISCLOSURE SYSTEM FOR EMPLOYEES OF THE FOOD AND DRUG ADMINISTRATION NEEDS TIGHTENING

D I G E S T

Over 20 cents of every dollar spent by consumers goes for products regulated by the Food and Drug Administration (FDA) to guard against potential impurities, unsafe contents, and similar hazards. In regulating the industries, the Food and Drug Administration must be sure that its employees maintain the highest standards of ethical conduct. This agency is a constituent of the Department of Health, Education, and Welfare (HEW).

In line with several congressional requests, GAO reviewed:

--The effectiveness of the agency's financial disclosure system.

--The financial interests reported by employees.

--Whether other agency officials should be filing financial disclosure statements.

Food and Drug Administration reviewing officers noted during their review of the 1974 statements that 134 employees owned 181 interests which were prohibited by its regulations:

--60 owned 73 prohibited interests which directly related to their responsibilities;

--70 owned 94 interests in which there was no relationship to the employees' duties and responsibilities but the interests were prohibited by FDA's regulations; and

--4 owned 14 interests in both of the above categories.

The agency asked most of the employees with prohibited interests related directly to their responsibilities to divest of such interests.

Employees with prohibited financial interests not related to their duties and responsibilities were not asked to divest because the agency and HEW were about to request approval from the Civil Service Commission to institute new policies, one of which would give these employees the opportunity to request an exception to hold prohibited interests provided they meet certain criteria. The new policies were approved by the Civil Service Commission on September 25, 1975.

GAO's review of these financial disclosure statements generally concurred with the findings of agency reviewing officials. However, GAO found that 25 employees owned an additional 27 prohibited interests which were overlooked by FDA reviewing officials.

In addition, GAO found that

--203 regulatory employees had not filed financial disclosure statements;

--FDA had not developed a policy on real estate holdings and as a result, 50 employees owned farmland interests which had not been adequately reviewed to determine whether a real or potential conflict existed; and

--the General Counsel, Department of Health, Education, and Welfare, had not promptly acted on several exception requests referred by FDA for review and consideration.

Although HEW's regulations and FDA's supplemental regulations as applied to its employees conformed generally to the Civil Service Commission's financial disclosure guidelines, improvements still are needed.

GAO recommended that the Secretary, HEW, make sure that HEW takes timely action on employee requests to retain prohibited interests and consider having the internal audit agency perform periodic reviews of the FDA financial disclosure system.

GAO also recommended that the Secretary, HEW direct the Commissioner of FDA to

--develop effective procedures for collecting employee statements;

--insure that all employee financial disclosure statements are reviewed within 60 days after they are filed;

--develop policies concerning employee property interests;

--develop procedures to insure certification of the review of the statements;

--develop followup procedures to insure prompt action on divestiture requests, and on failures to comply with the regulations; and

--provide guidelines to employees to help them determine whether they should retain or acquire a particular financial interest.

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CHAPTER 1

INTRODUCTION

The Food and Drug Administration (FDA), a constituent agency of the Department of Health, Education, and Welfare (HEW), conducts programs directed at a single overall objective--consumer protection. FDA-regulated products account for over 20 cents of every consumer dollar spent.

FDA's responsibilities include:

--Assuring the consumer that (a) foods are pure and wholesome, safe to eat, and produced under sanitary conditions, (b) drugs and medical devices are safe and effective for their intended uses (including drugs used in medicated feeds for animals), (c) cosmetics are safe and properly labeled, and (d) packaging and labeling of these products are truthful and informational;

--Protecting the public from unnecessary radiation exposure from electronic products such as color television sets, microwave ovens, and X-ray machines;

--Regulating the sale of biological products, such as vaccines, serums, and blood by assuring that these products are safe, pure, and potent;

--Assuring the safety of pasteurized milk and shellfish, and the sanitation of food services and the food, water, and sanitary facilities for travelers on trains, planes, and buses in interstate commerce; and

--Assuring that all imported teas meet the quality standards set by the U.S. Board of Tea Experts.

FDA is continuously involved with private industry in fulfilling its responsibilities; therefore, it is imperative that its employees maintain the highest standards of ethical conduct in performing their duties.

SCOPE OF REVIEW

Our review, conducted at the FDA headquarters, Rockville, Maryland, and HEW headquarters, Washington, D.C., was made pursuant to requests from Members of Congress. Primary concerns expressed in these requests were whether

--Federal agencies have effective financial disclosure systems for revealing conflict-of-interest situations,

--all financial disclosure statements required were filed promptly and properly, and

--the financial disclosure statements were adequately reviewed and analyzed.

We reviewed all financial interests listed by employees on their 1974 financial disclosure statements, and in previous years to the extent available. We also reviewed position descriptions of employees required to file statements. We did not determine whether the employees that filed 1974 statements were on FDA's employment rolls during our review; nor did we talk with specific individuals regarding their actual duties or their financial holdings. The confidentiality of employees who filed these statements was maintained at all times. We also reviewed existing and proposed regulations governing employees' standards of conduct, as well as the responsibilities of several positions not currently required to file financial disclosure statements to determine whether they should be filing a statement.

Our review did not focus on existing statutory criminal provisions concerning the activities of Federal employees affecting their personal financial interests (18 U.S.C. § 208 (1974)). We note, however, that the disclosure requirements of the statute are no more stringent than the requirements of the regulations we reviewed.

CHAPTER 2

FINANCIAL DISCLOSURE REQUIREMENTS AND AGENCY PROHIBITIONS

Executive Order 11222, dated May 8, 1965, prescribed standards of ethical conduct for Government officers and employees, and directed the Civil Service Commission (CSC) to establish implementing regulations. In November 1965 CSC issued instructions requiring each agency to prepare employee conduct standards and establish a review system for employee financial disclosure statements. Standards of conduct regulations established by each agency must be approved by CSC.

In March 1966, HEW issued regulation 45 C.F.R. 73.735 governing employees' responsibilities and conduct. In 1972, FDA issued supplemental regulations (45 C.F.R. 73a.735), providing interpretative definitions to certain of the Department's regulations and additional requirements for FDA employees. The Department's and FDA's supplemental regulations established the financial disclosure system for all FDA employees.

The Assistant General Counsel, Business and Administrative Law Division, Office of the General Counsel, was designated the Department's ethics counselor to administer regulations governing employee responsibility and conduct. He is responsible for rendering authoritative advice on employee conduct matters, providing guidance to deputy counselors on questions concerning conflicts of interest, and resolving conflicts which are not resolved by deputy counselors. If the ethics counselor cannot resolve a conflict, pertinent information is forwarded the Secretary of HEW, for his consideration.

The Associate and Deputy Associate Commissioner for Administration and the Director, Division of Personnel Management, are responsible for reviewing the financial disclosure statements of occupants of designated positions in FDA that must be filed within 30 days after entrance on duty and updated annually as of June 30. HEW's regulations require employees having a conflict to divest themselves of the interest, disqualify themselves from particular assignments, be reassigned to a different position, or be subject to disciplinary action.

PROHIBITIONS AGAINST FDA EMPLOYEES

FDA issues to each employee a booklet of regulations which apply to FDA officers and employees. This booklet contains HEW's standards of conduct, and FDA supplemental regulations concerning financial interests, work assignments involving regulated industries, and outside activities. FDA also defines key terms used in the Department's regulations to make the regulations clearly applicable to FDA employees.

HEW's regulations prohibit employees from

--having a direct or indirect financial interest that conflicts substantially or appears to conflict substantially with his Government duties and responsibilities;

--participating in his Government capacity in any manner in which he, his spouse, his minor child, or an outside business associate or organization with which he is connected or is negotiating employment, has a financial interest; and

--engaging directly or indirectly in financial transactions as a result of or primarily relying on information obtained through his Government employment.

HEW's regulations also prohibit employees in regulatory, procurement, and contracting activities from having certain types of financial interests.

Employees engaged in regulatory activities shall not have a financial interest in any company whose business activities are regulated by FDA unless the regulated activities of the company are an insignificant part of its total business operations. FDA interprets this regulation stating that employees may not have an interest in any organization whose FDA-regulated products constitute more than 10 percent of the organization's annual gross sales.

An employee who serves as a procurement or contracting officer or whose duties include authority to recommend or prepare specifications, negotiate noncompetitive contracts, or evaluate bids, shall not have financial interests in companies with which his office has a significant procurement or contracting relationship. An insignificant relationship exists only when all the following conditions are met:

--The company is one with which the employee would rarely or never do official business;

--Such business as he would do with the company is with respect to items of a standard type on the basis of competitive bids or regulated prices, or for utility services; and

--The amount of the financial interest is very small in relation to the company's size.

The regulations provide for exception to the prohibitions if enforcement appears contrary to the Government's best interests or causes extreme and undue individual hardship.

FDA, in its supplemental regulations, also provides prohibitions on financial interests of employees not required to file financial disclosure statements. Such employees may have a financial interest in a significantly regulated organization provided

--the holding is less than $5,000 (value or cost at time of initial reporting),

--the holding represents less than 1 percent of the organization's total outstanding stock shares, and

--no more than 50 percent of the employee's total investment value is concentrated in significantly regulated industries.

Since these employees do not file financial disclosure statements, they are, according to FDA, on the honor system not to go beyond the bounds of the above criteria. On September 25, 1975, CSC informed the Department that it did not agree with the above regulation. CSC stated that "It is our present view that a holding of $5,000 can be very substantial for many employees, * * *." The issue of dollar value exemption for financial holdings was considered during a November 1975 CSC conference for Ethics Counselors; however, no decisions were rendered at that time.

CHAPTER 3

REVIEW OF EMPLOYEES' FINANCIAL DISCLOSURE STATMENTS

In 1974, approximately 2,500 FDA employees, primarily in regulatory positions, and about 900 consultants were required to file financial disclosure statements listing creditors, interests in real property, and business entities in which they have an interest. The employees were not required to show the amount of financial interest, indebtedness, or the value of real property.

Because of the many firms (approximately 500,000) whose products are FDA regulated, and because the percent of regulated products can fluctuate, FDA had not developed a listing of prohibited firms for employees to consult to ascertain whether financial interest in a certain company is prohibited. FDA had developed a list of examples of FDA-regulated products for its internal use in reviewing financial disclosure statements; however, this listing was not distributed to its employees. Therefore, when employees file financial disclosure statements indicating interests in business entities, their listing of interests will most likely include companies in which an interest is prohibited.

The financial disclosure system's purpose is to detect conflicts when they appear on the employees' statements and take action to resolve the conflict. FDA reviewing officers noted during their review of the 1974 statements that 134 employees owned 181 interests which the regulations prohibited.

This included

1. 60 employees with 73 prohibited interests which directly related to their responsibilities,

2. 70 employees with 94 interests in which no relationship to the employee duties and responsibilities existed but were prohibited because the companies annual gross sales of FDA-regulated products exceeded 10 percent, and

3. 4 employees that had 14 prohibited interests in both of the above categories (8 prohibited interests directly relating to their responsibilities and 6 prohibited interests which did not directly relate to their responsibilities).

Following FDA's review of the 1974 statements, 61 employees who owned 74 prohibited interests directly relating to their duties were sent letters instructing them to divest of these interests. Three employees with seven prohibited interests directly related to the employees' duties and responsibilities were not asked to divest because the employee either had requested a waiver from HEW General Counsel to hold the interest or the HEW General Counsel had ruled the interests could be retained because they were in a trust arrangement beyond the employee's control.

In March 1975, the Associate Commissioner for Administration instructed the Division of Personnel Management to defer sending divestiture letters to the 74 employees with 100 prohibited interests not related to their duties and responsibilities. The Associate Commissioner believed this was equitable because FDA and HEW were about to request approval from CSC to institute certain new policies, one of which would give employees the opportunity to request an exception to hold prohibited interests if the employee can meet the criteria set forth below:

--The financial interest was acquired via marriage, inheritance, and/or was held before a reorganization, change in regulations, or similar circumstance beyond the control of the employee.

--The financial interest retention does not give rise to an actual conflict-of-interest situation.

--There is no direct relationship between the employees' official duties and the regulated activities of the organization in which the financial interest is held.

--The employee occupies a position below that of Bureau or Deputy Bureau Director (or Assistant or Deputy General Counsel, FDA Division).

--The employee agrees to refrain from engaging either directly or indirectly in transactions which are designed to increase the value and/or shares of the excepted financial interest.

Approved exceptions would be filed with the FDA Public Records and Documents Center for public inspection within 10 days after the date of the Commissioner's decision.

The regulations were approved by CSC on September 25, 1975, and divestiture letters were sent to employees starting November 11, 1975.

Our review of FDA employees' financial disclosure statments filed in 1974 generally concurred with the findings of the FDA reviewing officers. However, we did find that 25 employees owned an additional 27 prohibited interests which were overlooked by FDA reviewing officials. The Associate Commissioner for Administration; Acting Director, Division of Personnel Management; and subordinate officials agreed with our findings and stated that employees with direct prohibited interests would be asked to divest of these interests if they appeared on the employees' 1975 statement. Those with prohibited interests not related to their duties and responsibilities would be sent divestiture letters and would also be informed of their right to request an exception once the new regulations were approved. The first letters were sent starting November 11, 1975.

We also noted that 50 FDA employees owned interests in farmlands. FDA had not developed a policy on the ownership of such interests, and as a result, had not adequately reviewed them to determine what use was made of these lands or their products. FDA should examine these interests to insure that no real or potential conflict exists. Since no written policy exists by which these interests can be examined, FDA should develop such a policy.

During our analysis of the employee financial disclosure statements, we also found that there were seven employees that requested an exception to FDA's letter requiring divestitures of eight prohibited interests reported on their 1973 statements. The employees generally asked for an extension of time to divest of their prohibited interests or an allowance to retain the interests due to extreme personal hardship. These same prohibited interests were reported on the employees' 1974 statements. FDA had forwarded such requests to the HEW General Counsel for review and consideration. The Deputy Assistant General Counsel, Business and Administrative Law Division, HEW, stated that after they had had the exception requests about 3 to 6 months FDA instructed them not to process the requests because FDA was developing the new exception request policy mentioned on page 7 which could allow these employees to retain their prohibited interests. He also stated that HEW returned the requests to FDA on October 11, 1974. Department officials said that other priority work assignments and inadequate staff prevented them from acting on the exception requests before FDA's instructions to stop processing them. An FDA official stated that these employees were again notified starting November 11, 1975, that they must divest if they could not meet the new exception request criteria.

CHAPTER 4

IMPROVEMENTS NEEDED IN FDA'S FINANCIAL DISCLOSURE SYSTEM

The Department's regulations generally conformed with CSC's financial disclosure guidelines. The supplemental regulations issued by FDA have added to the financial disclosure system's effectiveness. However, certain improvements are needed in the system, including

- --improved statement collection procedures,
- --more timely review of the financial disclosure statements,
- --improved followup procedures on divestiture requests, and
- --periodic internal reviews.

COLLECTION OF STATEMENTS

The Department's regulations require new employees entering into positions requiring filing of financial disclosure statements to do so within 30 days of appointment. Supplemental statements reporting financial interests as of June 30 are to be filed annually thereafter by July 31.

Each year, FDA asks its various organizations to identify incumbents of positions required to file statements, develop a list of such employees, provide the blank statements to and collect the completed statements from the identified employees, and identify any new positions which should be required to file. FDA requires the completed statements along with the lists of employees to be forwarded to the Division of Personnel Management by July 31 of each year. In making the requests, FDA provides its organizations with the list of positions required to file and the Department's criteria for determining positions required to file.

We examined the duties and responsibilities of about 65 of the positions above and below GS-11 for which the incumbents currently do not file statements. This included chemists, microbiologists, program analysts, pharmacologists, entomologists, public health officers, and consumer safety officers. We believe the incumbents of all of the positions could have an effect on FDA regulated industry and should file statements. FDA, in its new regulations, will require the incumbents of about 1,500 other positions, including the above, to file statements.

We noted, during the review, that 205 employees required to file statements in 1974 had not filed. These employees were in regulatory positions and about 62 percent occupied GS-13 or equivalent and above positions. This occurred because (1) various FDA organizations did not adequately identify by name all employees required to file and (2) FDA had not verified the organizations' identification of employees required to file.

FDA officials agreed that the 203 employees should have filed statements. We were told that since the 1975 statements are now being filed, FDA would not require the employees to submit 1974 statements. We were told that a check will be made to insure 1975 statements are submitted by the above employees. FDA officials stated that they developed a computer listing of all GS-11 and above employees. A copy was sent to each organization for the collection of the 1975 statements. They stated that they will use this computer listing to verify the organizations' identification and the submission of statements from employees required to file.

MORE TIMELY REVIEW OF STATEMENTS

FDA does not have adequate procedures to insure timely reviews of the statements. As a result employees with prohibited interests retain such interests for a considerable period of time before being notified that they must divest of their interests.

The HEW regulation states that new employees will file a statement within 30 days of being hired for a position meeting the criteria for filing. Such employees found to have a prohibited interest must divest of such interest within 90 days of entrance into the position. In effect, this requires the statements for new employees to be reviewed within 90 days of the employees' entrance on duty. The regulations, however, do not state when statements for other than new employees--those that file annual supplemental statements--must be reviewed.

FDA's review of the 1974 statements was done between November 1974 and February 1975. Resulting from FDA's review, 61 employees were asked to divest of 74 prohibited interests. For the majority of the 61 employees, letters ordering divestiture of the interests were not sent until May 1975, since the determinations had to be reviewed by a supervisory official. This represented an average of about 9 months from the time the employees signed their statements. We believe that a more prompt review of the statements and divestiture requests is needed to provide adequate protection for employees in direct or potential conflict-of-interest situations.

We also noted that in most cases FDA reviewers had not signed or dated the statements which they were assigned to review. FDA does not have written procedures requiring the reviewers' certification of review. We noted for example that some inconsistency in the review of the statements existed. Some employees were noted by FDA reviewers to own interests prohibited by FDA's regulations, while other employees with the same prohibited interests were not. Additionally, as pointed out on page 8, FDA reviewers did not detect 25 employees with 27 prohibited interests because they overlooked them during the review. We believe that a procedure requiring certification of the review of the statements will improve the review process and help identify and correct any inconsistencies that may exist.

NEED TO IMPROVE FOLLOWUP PROCEDURES

Generally, FDA asked the employees to divest of their prohibited interest within 30 days of notification. However, FDA had not followed up on divestiture requests to insure employee action. FDA did not have written procedures for following up on required divestitures. For example, we found that seven employees, with eight prohibited interests reported on their 1973 statements, were requested in October 1973, to divest of their financial interests within 30 days of notification; however, FDA had not followed up to insure divestiture and these employees reported the same prohibited interests again on their 1974 statements. These are not the same seven employees referred to on page 8.

Regarding the 61 employees FDA asked to divest of the 74 prohibited interests reported on their 1974 statements, we found that as of August 1975:

--30 employees had taken action on 33 prohibited interests either by way of divestiture, transfer of ownership, etc.;

--14 employees with 19 prohibited interests had requested an exception or an extension of time to divest; and

--18 employees had not responded.

FDA did perform some followup on the above 18 employees that did not respond; however, most of the followup had not been performed until about 2 months after FDA sent the divestiture letters to the employee. The followup consisted of telephoning the employee to determine what action the employee planned to take. As of August 1975 the average time-lag for the nonresponses was 46 days beyond the 30-day divestiture requirement. FDA had not taken any disciplinary action against these employees for failure to comply with FDA's regulations.

We believe the lack of adequate followup action and disciplinary action hinders the program effectiveness and is indicative of a weakness in the system for preventing conflicts of interest.

NEED FOR INTERNAL PROGRAM REVIEW

An FDA official stated that during the 5 years which he had been involved with the FDA financial disclosure system there had not been an internal audit of the system. FDA does not have an internal audit office and responsibility for internal reviews of FDA programs and operations is within the HEW Audit Agency under the Deputy Assistant Secretary, Comptroller.

We spoke with the Director, Washington Area Audit Office of the HEW Audit Agency, who said that the Audit Agency had not done an internal review of the FDA financial disclosure system and that they had no plans for a review of the system. He stated that they did very little audit work in FDA because of GAO's large involvement in FDA.

Due to the important weakness noted during our review of FDA's financial disclosure system, we believe consideration should be given to having the HEW Audit Agency periodically review the system. We believe such an audit should include reviewing the adequacy of the procedures developed for insuring financial disclosure and enforcing the regulations governing conduct standards.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

FDA is responsible for protecting the Nation's consumers against impure and unsafe foods, drugs, cosmetics, and other potential hazards. Because of this responsibility, FDA must insure, through its financial disclosure system, that its employees maintain the highest ethical standards. We believe FDA's supplemental regulations have aided in making the system more effective; however, certain deficiencies exist which must be corrected. These include inadequate procedures for collecting financial disclosure statements, delays in reviewing the statements, inadequate followup procedures on divestiture requests, and the lack of internal reviews.

RECOMMENDATIONS

To improve the effectiveness of the FDA financial disclosure system, we recommend that the Secretary of HEW:

--Insure that the Department takes timely action on employee requests to retain prohibited interests;

--Consider having the internal Audit Agency periodically review the FDA financial disclosure system; and

--Direct the Commissioner of FDA to

(a) develop effective procedures for collecting employee statements;

(b) insure that all employee financial disclosure statements are reviewed within 60 days after they are filed;

(c) develop policies concerning employee property interests;

(d) develop procedures to insure certification of the review of the statements;

(e) develop followup procedures to insure prompt action on divestiture requests, and on failures to comply with the regulations; and

(f) provide guidelines to employees to help them determine whether they should retain or acquire a particular financial interest.

PRINCIPAL OFFICIALS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

	Tenure of office	
	From	To
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
David Mathews	Aug. 1975	Present
Caspar W. Weinberger	Feb. 1973	Aug. 1975
Frank C. Carlucci (acting)	Jan. 1973	Feb. 1973
Elliot L. Richardson	June 1970	Jan. 1973
Robert H. Finch	Jan. 1969	June 1970
ASSISTANT SECRETARY FOR HEALTH (note a):		
Theodore Cooper	May 1975	Present
Theodore Cooper (acting)	Jan. 1975	May 1975
Charles C. Edwards	Mar. 1973	Jan. 1975
Richard L. Seggel (acting)	Dec. 1972	Mar. 1973
Merlin K. Duval, Jr.	July 1971	Dec. 1972
Roger O. Egeberg	July 1969	July 1971
COMMISSIONER, FOOD AND DRUG ADMINISTRATION:		
Alexander M. Schmidt	July 1973	Present
Sherwin Gardner (acting)	Mar. 1973	July 1973
Charles C. Edwards	Feb. 1970	Mar. 1973

a/Until Dec. 1972 the title of this position was Assistant Secretary (Health and Scientific Affairs).