Improvements Needed In Regulating And Monitoring The Manufacture And Distribution Of Licit Narcotics

Drug Enforcement Administration

Department of Justice

The Drug Enforcement Administration is responsible for regulating and monitoring the manufacture and distribution of controlled substances which include narcotics, such as methadone and the various opium derivatives. This report discusses and contains recommendations to the Attorney General for further improvements needed in

--setting and administering quotas for production of narcotics,

--monitoring the compliance inspection activites and the practices and procedures for conducting such inspections, and

--training investigators who perform compliance inspections.

GGD-75-102

AUG. 28, 1975

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

B-175425

The Honorable
The Attorney General

Dear Mr. Attorney General:

We reviewed the Drug Enforcement Administration's program for regulating and monitoring the manufacture and distribution of narcotics--methadone and opium derivatives--to determine the adequacy of its system for preventing diversion. This report discusses the need to improve the program.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We invite your attention to the fact that this report contains recommendations to you which are set forth on pages 10, 23, and 28. As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House and Senate Committees on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

Because of the interest in the areas discussed in the report, copies are being sent to interested House and Senate committees, individual Members of Congress, and the Director, Office of Management and Budget.

We appreciate the cooperation and assistance provided our representatives by the Drug Enforcement Administration.

Sincerely yours,

D.J. Anderson

for Victor L. Lowe
Director

Contents

ACRONYMS

ARCOS	Automation of Reports and Consummated Order System
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
NTI	National Training Institute
SAODAP	Special Action Office for Drug Abuse Prevention

GENERAL ACCOUNTING OFFICE
REPORT TO THE ATTORNEY GENERAL

IMPROVEMENTS NEEDED IN REGULATING AND MONITORING THE MANUFACTURE AND DISTRIBUTION OF LICIT NARCOTICS
Drug Enforcement Administration
Department of Justice

D I G E S T

The Federal regulatory system over legitimate sources of supply for narcotics, specifically methadone and opium derivatives, should be administered as effectively as possible. The excess production of licit narcotics--for which there is an illicit demand--increases the potential for diversion throughout the legitimate distribution system.

Substantial quantities of legitimately produced narcotics have been diverted into the illicit market. This is clearly shown by the number of reported thefts and pilferages from the legitimate sources of supply. In fiscal year 1974, over 11 million dosage units were diverted. (See p. 3.)

In addition, some registrants--manufacturers, distributors, and dispensers--have diverted licit narcotics and other controlled substances through willful noncompliance with the Controlled Substances Act and Federal regulations. (See p. 4.)

This act requires compliance by registrants with recordkeeping, security, and reporting provisions.

The Drug Enforcement Administration is responsible for monitoring compliance. The Agency has had some success in insuring compliance. However, further improvements are needed.

QUOTAS

Improvements are needed for establishing and monitoring quotas for licit narcotics. In setting quotas through 1974, the agency

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did not have officially approved procedures nor did it fully document how quotas were set. Thus it could not, for example, explain how the 1973 methadone manufacturing quotas were determined at the manufacturing level.

Primarily, the Drug Enforcement Administration establishes and sets quotas for manufacturing and procurement on information provided by the manufacturers. As a result, quotas are established on the basis of market demand.

The Department of Health, Education, and Welfare is required to report annually to the Attorney General the results of studies undertaken to determine the quantities of controlled substances necessary to supply the normal and emergency medical, scientific, and reserve requirements of the United States. However, the Department has not provided such estimates.

To improve its ability to set quotas, the Drug Enforcement Administration:

--Requested the Department on February 5, 1974, to provide estimates on the legitimate needs for controlled substances to be used in establishing quotas for 1975. These were provided last January 14.

--Implemented an automated system for reporting controlled substance transactions by registrants to give the Agency an improved data base for setting quotas. (See pp. 6 to 8.)

In determining manufacturing quotas, the Drug Enforcement Administration allows each manufacturer an amount sufficient to maintain a reserve inventory equal to 50 percent of its average yearly net sales and other disposals.

The allowances should not be arbitrary, but should be based upon an analysis of the desired inventory levels for each controlled substance. (See p. 9.)

COMPLIANCE INVESTIGATIONS

Further improvements are needed in the Agency's monitoring of its regions' compliance inspection activities and in the practices followed in conducting compliance inspections at registrants. Because it did not have effective controls, Agency headquarters was not aware that its field offices had:

--Failed to complete required investigations at certain registrants.

--Failed to implement the priority system established in August 1972, which classifies registrants into categories to focus the greatest investigative effort on those registrants with the highest diversion potential. (See pp. 13 to 14.)

Effective indepth drug accountability investigations at registrants require sufficient scope and efficient methodology. Agency guidelines and procedures for conducting such investigations could be improved. (See p. 15.)

The guidelines are vague as to the requirements of some important investigative areas. (See pp. 17 to 20.)

TRAINING OF COMPLIANCE INVESTIGATORS

The only formal training program provided to compliance investigators is for 6 weeks following appointment. Until improvements were made recently, the program did not adequately prepare the investigators for their duties. (See p. 25.)

RECOMMENDATIONS

The Attorney General should direct the Drug Enforcement Administration to:

--Adopt procedures providing criteria and instructions for setting and administering quotas.

--Document sources and methods for establishing quotas and provide postevaluation of their efficacy.

--Make studies leading to the establishment of appropriate inventory reserves for each controlled substance.

--Monitor quotas to assure that manufacturers do not exceed inventory requirements.

--Adjust quotas approved for manufacturers based on the actual beginning inventory reported for the start of the quota year.

--Establish procedures to insure that regional offices investigate registrants according to established priorities.

--Revise investigative guidelines to provide for detailed procedures for conducting compliance audits.

--Require the systematic use of working papers to evidence the investigative work performed.

--Make sure that periodic formal training is provided to compliance investigators.

CHAPTER 1

INTRODUCTION

Preventing the diversion of legally manufactured controlled substances--narcotics and dangerous drugs (stimulants, depressants, and hallucinogens)--into the illicit market is a primary responsibility of the Drug Enforcement Administration (DEA), Department of Justice. Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et. seq.)--referred to as the Controlled Substances Act (CSA)--authorizes the Attorney General to regulate the manufacturing, distributing, and dispensing of controlled substances. The Attorney General has delegated this authority to the Administrator of DEA.

CSA prescribes, in part, certain requirements for establishing and administering a regulatory system to control the manufacture, distribution, and dispensing of controlled substances. The overall objective of the regulatory system is to prevent diversion of controlled substances while assuring an adequate supply for legitimate medical, research, and industrial needs.

Under CSA, controlled substances are divided into five schedules on the basis of their potential for abuse, accepted medical use, and accepted safety under medical supervision. Schedule I includes subtsances without accepted medical use or safety and with high abuse potential. Schedule II includes accepted substances with high abuse potential. Schedules III through V include accepted substances with decreasing abuse potential. The placement of a drug in any one of these schedules determines the nature and level of control that is exercised to prevent its abuse and diversion. Schedule I and II controlled substances are more strictly controlled than schedule III through V substances.

REGULATORY CONTROLS

DEA is responsible for enforcing and administering the regulatory controls prescribed by CSA and the Code of Federal Regulations (21 C.F.R. 1301). CSA and regulations require in part that:

--Registration: All manufacturers, distributors, and dispensers of controlled substances register with DEA and are referred to as registrants.

--Quotas: For each basic class of controlled substances in schedules I and II, DEA establish (1) a production quota for the industry, (2) a manufacturing quota for

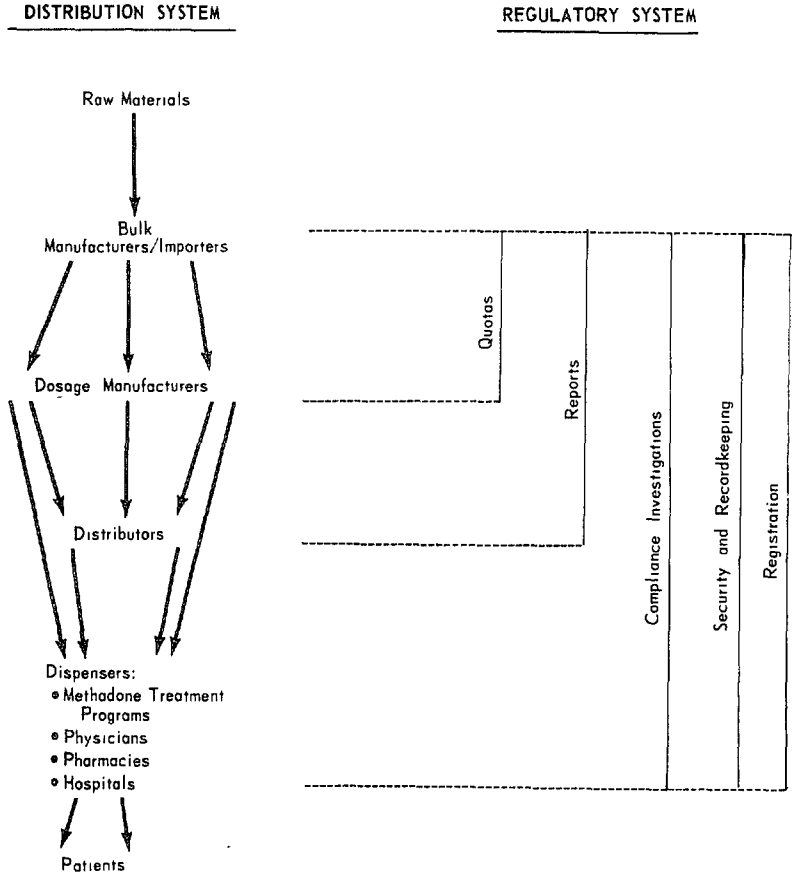
each bulk manufacturer, and (3) a procurement quota for each each dosage manufacturer.

--Security: Registrants comply with certain security requirements.

--Recordkeeping and reports: Manufacturers and distributors (1) sell schedule II drugs only upon receipt of an approved DEA order form, (2) keep records, and (3) submit monthly accountability reports to DEA.

--Investigations: DEA conduct periodic compliance investigations of registrants. Under its scheduled investigation program, DEA's plan is to make at least one compliance investigation every 3 years at manufacturers, distributors, and methadone treatment programs. At the retail level of the distribution system, which includes practitioners, pharmacies, hospitals, and teaching institutions, DEA conducts compliance investigations on a complaint/lead basis and cooperates with individual State authorities in their regulatory control.

The following diagram depicts the distribution and regulation of schedule II controlled substances.



The number and types of registrants as of July 1, 1974, are shown below.

Type	Number
Manufacturers	514
Distributors	1,834
Dispensers (pharmacies, practitioners, hospitals, methadone treatment programs)	491,227
Other (researchers, laboratories, importers, teaching institutions, and others)	5,103
Total	498,678

ILLICIT DEMAND

Effective administration and enforcement of the controls over the manufacture and distribution of controlled substances are necessary because of their abuse potential and illicit demand. Substantial quantities of legitimately produced controlled substances have been diverted, as evidenced by the number of reported thefts and pilferages from legitimate sources of supply. During fiscal year 1974 there were over 7,900 reported thefts involving 33 million dosage units, of which over a third were narcotics, as shown below.

Narcotic	Quantity (dosage units)
Opium	540,787
Morphine	637,593
Codeine	4,065,375
Methadone	362,418
Pethedine	1,789,411
Oxycodone	1,084,552
Dilaudid	1,937,460
Miscellaneous	986,030
Total	11,403,626

According to DEA, the greatest source of diversion of controlled substances is at the pharmacy/practitioner level. However, considerable quantities have been diverted at other levels of the distribution system. For example, during fiscal year 1974, manufacturers and distributors reported 623 thefts totaling about 2.6 million dosage units. Thefts from manufacturers and distributors accounted for about 8 percent of the total thefts reported and dosage units diverted.

Controlled substances have also been diverted by some registrants through willful noncompliance with CSA and Federal regulations. For example, DEA and State investigations of a wholesaler led to the arrest of the firm's vice president for illegal sales of controlled substances. Because there is substantial illicit demand for controlled substances and diversion can take place at all levels, regulation of registrants should be administered as effectively as possible.

PROGRAM ADMINISTRATION

The Compliance Investigations Division within DEA's Office of Enforcement is responsible for setting quotas, registering legitimate drug handlers, monitoring registrants' required reports, and overseeing the periodic investigations of registrants by the regional offices. Periodic compliance investigations of registrants are conducted by compliance investigators in the 13 DEA domestic regional offices. As of June 30, 1974, 179 DEA compliance investigators were assigned to the regional offices. In its regulatory and compliance activities, DEA spent about $7.8 million in fiscal year 1974 and plans to spend about $11.1 million in fiscal year 1975.

SCOPE OF REVIEW

Our review was directed toward the effectiveness of DEA's efforts in regulating the legal manufacture and distribution of methadone and opium and its derivatives. Except for methadone dispensed at the treatment program level, we did not review the regulatory system as it applies to the dispensing level of the distribution system, such as practitioners, pharmacies, hospitals, and teaching institutions.

Our review included (1) an examination of applicable laws, regulations, policies, and procedures, (2) an examination of appropriate records and reports at DEA and selected registrants, and (3) discussions with representatives of DEA and selected registrants.

Our review was made at DEA headquarters, Washington, D.C.; DEA Region 2, New York City; and the sites of selected registrants primarily in the New York metropolitan area. The registrants we visited included (1) the three importer-manufacturers of opium and its derviatives, (2) one bulk manufacturer, one dosage manufacturer, and one wholesaler of methadone, and (3) five methadone treatment programs.

CHAPTER 2

SETTING QUOTAS TO CONTROL PRODUCTION

To prevent overproduction of controlled substances with high abuse potential, CSA requires that quotas be established to provide for legitimate medical, industrial, and research needs; lawful export; and reserve stocks. DEA recognizes that quotas are useful to control the manufacture of substances which have a legitimate use but also a high potential for abuse. DEA believes that the purpose of quotas is to keep the flow of controlled substances "lean" in order to minimize diversion, while assuring adequate supplies for legitimate requirements.

DEA establishes, for each basic class of schedule II controlled substances, three types of annual quotas as follows:

--An aggregate production quota, which is the total quantity that should be produced nationwide to meet legitimate needs.

--A manufacturing quota for each bulk manufacturer, which is the quantity allowed to be produced.

--A procurement quota for each dosage manufacturer, which is the bulk quantity that may be purchased.

Further improvements are needed in DEA's procedures for establishing and monitoring quotas for methadone and opium derivatives. DEA did not

--have written procedures for setting and administering quotas,

--fully document the basis on which the quotas were set,

--make studies leading to the establishment of an appropriate inventory reserve amount for each controlled substance under quota, and

--monitor and adjust quotas as required by Federal regulations.

A discussion of weaknesses in DEA's procedures for setting methadone and opium-derivative quotas follows.

PROBLEMS IN ESTABLISHING AGGREGATE PRODUCTION QUOTAS

Aggregate production requirements for controlled substances and therefore the quotas set have not been based on a determination of medical and other legitimate needs, as required by CSA. When enacted in 1970, CSA contained an amendment to the Public Health Service Act (42 U.S.C. 242(a)) which requires the Secretary of Health, Education, and Welfare (HEW) to report each year the results of studies and investigations conducted to determine the quantities of controlled substances necessary to supply normal and emergency medical, scientific, and reserve requirements of the United States. HEW assigned the Food and Drug Administration (FDA) to prepare estimates of legitimate needs. These are to be used at the discretion of DEA to set production quotas. FDA, however, has not generally given DEA estimates on the legitimate medical and scientific needs for controlled substances.

DEA requested on February 5, 1974, that HEW provide such estimates for use in establishing 1975 quotas. On January 14, 1975, FDA gave DEA estimates for selected controlled substances. When DEA published the approved aggregate production quota for 1975 in the Federal Register on January 20, 1975, DEA indicated that the 1975 quotas would be adjusted in early 1975 based on FDA's estimates.

DEA expects an improved data base to assist in setting quotas, with full implementation of an automated reporting system called Automation of Reports and Consummated Order System (ARCOS). The objective of ARCOS is to enable DEA to maintain a perpetual inventory of (1) controlled substances under quota and (2) other selected controlled drugs from point of import or manufacture to point of sale, distributic , export, or disposition to the dispensing level.

In the past, DEA determined aggregate production requirements and set quotas based primarily on information from manufacturers requesting individual manufacturing and procurement quotas. As a result, quotas were established on the basis of market demand as reflected at the manufacturing level.

Bulk manufacturers include in their requests for individual quotas

--for the current year and prior 2 calendar years, actual or estimated data on quotas received, quantities manufactured, net sales and other dispositions, inventory reserve, and ending inventory and

--the quotas requested and the estimated sales and other dispositions for the year for which the quotas are requested.

Dosage manufacturers requesting procurement quotas provide the quotas requested, bulk quantities used in the prior 2 calendar years, and estimated usage for the current year. They are also requested to provide sales and inventory information. Based on sales and inventories reported by the manufacturers, DEA establishes the aggregate production quota as well as individual manufacturing and procurement quotas.

In computing the aggregate production quota, DEA (1) estimates production requirements, generally based on the total estimated sales of bulk and dosage manufacturers and trends in the market, (2) adds a 50-percent inventory reserve to the estimate, and (3) subtracts the estimated inventories available at bulk and dosage manufacturers at the beginning of the quota year. The result is the maximum amount of a controlled substance which may be produced in bulk form during a given year.

Problems in establishing aggregate production quotas for methadone

The production requirements for methadone through 1974 were computed by DEA using estimates of (1) the number of patients receiving maintenance treatment and (2) the average daily dose for such patients. In calculating the methadone requirement, DEA used unsupported and questionable data.

For example, in computing the quota for 1972, DEA representatives said they used an estimate of 25,000 patients in maintenance treatment; the Special Action Office for Drug Abuse Prevention (SAODAP) estimated there were more than 55,000 such patients in 1972. Similarly, in 1973, DEA used an estimate of 60,000 maintenance patients versus SAODAP's estimate of 73,000 patients. The SAODAP estimates were based on surveys of treatment programs and responsible State agencies.

DEA, in setting the 1973 aggregate production quota for metnadone, also used questionable inventory data. Each of the three bulk manufacturers reported its estimated beginning inventory to DEA on quota applications before DEA established the aggregate production quota for 1973. Had DEA used these estimates, the 1973 aggregate production quota of 3,339 kilograms would have been lower by 489 kilograms, or about 15 percent.

PROBLEMS IN ADMINISTERING MANUFACTURING QUOTAS

Need for formal procedures for setting quotas

Effective administration of quotas requires the preparation and use of written procedures sanctioned by the agency, documentation for the basis and details of the data used, and a postevaluation process. Although Federal regulations provide some general guidance in setting aggregate production and individual manufacturing quotas, DEA has not adopted any formal procedures for setting quotas.

A review of DEA's setting of individual manufacturing quotas through 1974 disclosed that DEA did not have written procedures or specific criteria to equitably allocate the aggregate production quota to bulk manufacturers.

For example, no documentation exists as to why the calendar year 1973 quota for methadone was established for one manufacturer at the precise quantity requested, for one manufacturer at a slightly smaller quantity than requested, and for one manufacturer at a quantity 20 percent lower than requested.

Discussion with DEA representatives and a review of pertinent files indicated that DEA expended very little effort in establishing and administering procurement quotas. DEA lacked (1) written instructions on reviewing applications and setting quotas, (2) any records of what factors were actually considered in approving quotas for any calendar year, (3) a control file indicating which firms were required to have procurement quotas, and (4) procedures for monitoring quotas.

Need to monitor manufacturing quotas

Federal regulations require adjusting individual manufacturing quotas when:

--The actual beginning inventory is determined and differs with the estimate on which the quota was based.

--Actual current inventories exceed 65 percent of the firm's estimated annual net sales and other dispositions as determined at the time of application and approval.

DEA has generally not monitored or adjusted quotas once they have been approved. For example, a bulk manufacturer of methadone reported to DEA at various dates inventories exceeding 65 percent of its estimated net sales and other dispositions. Although the manufacturer's inventory for methadone exceeded the maximum level allowed, DEA did not suspend

the manufacturer's quota until inventories were reduced to less than 60 percent of the net sales. The full implementation of ARCOS should allow DEA to improve its monitoring of manufacturers' activities. Under ARCOS, manufacturers' inventories will be monitored to assure observance of established levels.

DEA officials said that beginning with the 1975 quotas, they planned to adjust quotas based on the actual beginning inventory for the quota year. Further, when the aggregate production quotas were published in the Federal Register, applicants for manufacturing quotas were notified that DEA will adjust 1975 individual quotas, based upon 1974 end-of-year inventories reported by manufacturers.

Need to determine inventory reserves in determining manufacturing quotas

CSA provides that in establishing quotas allowance be made for an inventory reserve sufficient to assure uninterrupted supply. In determining manufacturing quotas, DEA allows each manufacturer an inventory reserve equal to 50 percent of its average yearly net sales and other disposals. This procedure is not based on an analysis of desired inventory levels for each controlled substance. The 50-percent figure was incorporated into the Federal regulations promulgated by DEA in 1970 and applies to all controlled substances under quota.

The major factors which justify a large inventory reserve--a lengthy production process and unstable sources of raw material--may not apply to all controlled substances. In some cases an inventory reserve of less than 50 percent may be sufficient to assure uninterrupted supply. For example, methadone is a synthetic drug that can be produced in a short time from raw materials easily obtained from domestic sources.

On the other hand, production complexities of some controlled substances or dependence on a foreign source of materials may warrant a reserve greater than 50 percent to insure protection against shortages. For example, the production of codeine and other opium derivatives depends on the importation of raw opium, in short supply in recent years.

CONCLUSIONS

The basic function of quotas is to limit the amount of controlled substances to the amount needed to meet legitimate needs and assure an uninterrupted supply. DEA has

the responsibility to insure that quotas function as intended.

To effectively fulfill this responsibility DEA must acquire and use reliable, complete, and accurate data within a framework of formal procedures and criteria for establishing, administering, and evaluating quotas. Further, quotas should be based on a determination of the legitimate medical reserve and other approved needs of controlled substances. HEW, however, has not generally given DEA the results of studies of estimated needs as legally required. DEA has requested that HEW fulfill its statutory responsibility, and HEW has provided estimates for 1975.

RECOMMENDATIONS TO THE ATTORNEY GENERAL

We recommend that DEA:

--Adopt procedures providing criteria and instructions for setting and administering quotas.

--Document sources and methods for establishing quotas and provide postevaluations of their efficacy.

--Establish quotas based on studies and evaluations of medical and other approved uses of controlled substances.

--Make studies leading to the establishment of appropriate inventory reserves for each controlled substance.

--Monitor quotas to assure that inventory requirements are not exceeded by manufacturers.

--Adjust manufacturers' quotas based on the actual beginning inventory reported for the start of the quota year.

AGENCY COMMENTS

DEA made the following responses.

--Quotas for opium and opium derivatives have been a function of availability rather than one of production control, because foreign opium production has not met legitimate demand for several years.

--Until 1973, treatment-program demand had not stabilized and experience was insufficient to reasonably estimate methadone requirements.

--Intensive efforts are underway to develop (1) a measuring system to accurately reflect controlled substance inventory reserves throughout the distribution system and (2) effective coordination with the Department of Health, Education, and Welfare for projection of developing needs.

--Written procedures for quota setting, centered on ARCOS, are being developed both as guidelines and as regulations.

--Verification of inventory and other information to back up quota requests is being required in selected cases.

--The quota system will require continuous refinement and development in the future.

--Further refinement of the 50-percent inventory reserve provision depends on the accumulation of historical data for at least 2 years under ARCOS.

CHAPTER 3

COMPLIANCE INVESTIGATIONS

An important safeguard for preventing the diversion of legitimately produced substances is DEA's compliance investigation of registrants' operations. DEA periodically conducts investigations of registrants to insure compliance with CSA requirements and to identify and act against those who divert controlled substances through willful noncompliance and criminal activity. Investigations are also initiated upon complaints and other leads. To effectively prevent diversion, improvements are needed in DEA's compliance inspections.

During a regulatory compliance investigation at a registrant's facilities, the adequacy of physical security is reviewed and an indepth accountability investigation is made of selected controlled substances. Investigations of registrants are to be so thorough that if violations are uncovered, sufficient evidence is obtained to support forceful action against the violator, if necessary. Further, the results of investigations are to be considered by DEA in its annual reregistration.

The numbers of compliance investigations conducted at registrants and the actions taken by DEA during fiscal year 1974 follow.

	Number and type of investigations			Actions taken		
Registrant	Regulatory	Complaint	Total	Arrests	Seizures	Administrative actions
Manufacturers	138	6	144	2	2	79
Distributors	546	7	553	5	6	287
Pharmacies	-	117	117	22	9	97
Physicians	-	201	201	23	3	128
Other (methadone programs, researchers, etc.)	370	23	393	1	-	105
Total	1,054	354	1,408	53	20	696

Because investigations are an important function and because they are made at numerous sites involving varying degrees of complexity, it is necessary for DEA to provide controls to insure that investigations:

--Are made of all manufacturers and distributors of controlled substances and methadone treatment programs according to established priorities.

--Are of sufficient scope and use necessary methodology to detect (1) inaccuracies in records and reports or (2) failures to comply with recordkeeping and reporting requirements.

We believe DEA's practices can be improved in each of these areas to strengthen compliance investigations.

NEED FOR CONTROLS OVER INVESTIGATIVE PRIORITIES

DEA headquarters needs procedures for monitoring regional compliance inspection activities to insure that registrants are investigated according to established priorities.

Completing investigation of high-priority registrants

After CSA was enacted in 1970, DEA established priority guidelines requiring that a compliance investigation be conducted (1) annually at manufacturers of schedule I and II and distributors of schedule I controlled substances and (2) at least once every 3 years at all other manufacturers and distributors of controlled substances and at methadone maintenance treatment programs.

In August 1972, DEA issued revised guidelines that rescinded requirement (1) and required all such registrants to be investigated by December 31, 1972, and thereafter at least once every 3 years. DEA headquarters did not establish controls to assure that the required investigations were completed by December 1972. DEA representatives told us they relied upon the regions to implement this requirement.

DEA headquarters could not provide information on whether these high-priority registrants were ever investigated, nor could it provide a listing of the registrants involved. We reviewed records for 60 schedule I and II manufacturers and schedule I distributors who were registered before July 1, 1972, and found that compliance investigations had not been made at 21 of these registrants by December 31, 1972.

DEA officials said this ommission may have occurred because the compliance investigations program was new and lacked sufficiently experienced investigators. The officials,

however, said that all registrants originally requiring annual visits have been investigated at least once since the end of 1972 under DEA's scheduled investigation program.

Implementation of the investigative priority system

The August 1972 guidelines also established a selection and rating system for classifying registrants into priority categories to focus the greatest investigative efforts on those registrants with the highest diversion potential. The guidelines require that each DEA region classify registrants into categories ranging from I (highest priority) to IV (lowest priority). The regions were given criteria for classifying registrants. A registrant's category determines the number of substances for which an indepth accountability audit is made during a compliance investigation.

In addition, the guidelines require DEA regions to coordinate with DEA headquarters the selection of category I registrants. The regions, in submitting their semiannual work plans to DEA headquarters, are also required to include each registrant's category. The regions, however, are not required to report the basis for placing a registrant in a priority category.

DEA headquarters did not establish controls to assure implementation of the selection and rating system. DEA could not furnish us information on (1) the number and identity of registrants by category, (2) the date of the last investigation, and (3) the next scheduled investigation date. Even though operating instructions require DEA regions to coordinate with headquarters in the selection of category I (highest priority) registrants, headquarters could not furnish us either the number or identity of these registrants. DEA representatives said the information we requested could be obtained only by contacting the regional offices.

DEA's New York Region, which includes about 800 registrants subject to classification, has not implemented the selection and rating system. For example, the region's work plan indicated that none of the 313 registrants scheduled for investigation during the 6-month period ended June 30, 1974, had been classified into priority categories.

DEA officials told us that the regions have overall responsibility for insuring the implementation and monitoring of the priority selection system. They said, however, that DEA headquarters, beginning in July 1974, began to monitor regional inspections of registrants more closely.

INVESTIGATIVE GUIDELINES NEED IMPROVEMENT

Effective indepth accountability investigations require sufficient scope and efficient methodology. We believe DEA could improve its compliance investigations by:

--Revising guidelines to provide detailed systematic procedures clearly describing each important segment of the investigation, the purpose of thorough coverage, and criteria for making required evaluations.

--Requiring working papers which show investigative work performed to aid in supervisory review and in conducting future investigations and followup action at registrants.

While DEA's guidelines for making compliance investigations provide some assistance to investigators, we believe they (1) omit areas of investigation that should be included, (2) lack clarity as to what is required and why an area must be covered, and (3) lack criteria essential for evaluation of complex technical areas.

Reports and quota applications provided to DEA are not verified

All schedule II manufacturers and wholesalers are required to periodically provide DEA with information on inventory, manufacturing, receipts, sales, and disposal activities. The manufacturers are also required to include on their quota applications similar information--summarized for calendar years--as well as projections of inventory and sales and disposals at future dates. Complete and accurate information is essential for proper administration of the regulatory system, especially for establishing quotas and monitoring inventories and transactions. Since compliance investigation guidelines do not require verification or evaluation of the reported information, they generally were not made at methadone and opium manufacturers.

The need for such verification can be illustrated by the substantial inaccuracies we found in the records and reports prepared by a bulk manufacturer we visited. The manufacturer reported production for methadone on four quarterly reports for calendar year 1972 totaling 169 kilograms. Actual production from raw materials totaled 101 kilograms or about 60 percent of the reported figures. The production overstatement resulted from

--the manufacturer reporting as production (1) quantities acquired by consolidating several lots that were not fully depleted into one lot and (2) purchases made from other bulk manufacturers, and

--the erroneous reporting of certain quantities being processed as finished product.

Ending inventories on quarterly reports for the periods ending September 30, 1972, and December 31, 1972, also were understated, because the figures were extracted by the manufacturer from inventory records which reflected certain finished inventory as work in process. The extent of the understatement was as follows:

Quarter ended	Ending inventory (in kilograms) Reported	GAO determined	Understatement
September 30, 1972	170	212	42
December 31, 1972	134	188	54

These matters were not uncovered by the DEA investigators during their indepth accountability investigation, since DEA investigative guidelines do not require the verification of information on a registrant's reports and quota applications. DEA officials told us that such verifications are made on a spot-check basis at the discretion of the investigator. Because of the need for accurate and reliable information in these reports, such verifications should be made standard practice.

Registrants' records not validated

Federal regulations require registrants to maintain records of receipts, manufacture, distribution, and inventories. Registrants such as manufacturers and distributors of schedule II substances are required to maintain these records separately from all other records. Investigative guidelines provide for examining the required records.

The guidelines, however, do not provide for verification that the records examined are complete and accurate. This could be achieved by tracing drug transactions recorded by CSA-required records into the registrants' official books of account and conversely from the books of account back to the recorded drug transactions. This procedure would provide some assurance that the records and documents DEA reviews are, in fact, the registrants' official ones. The investigation would be more reliable, because the books of account are normally verified by an independent certified public accountant and by the registrants' internal auditors.

In one example a problem area could have been avoided, had the investigators used the registrant's official books of account. The example involved the accountability audit of an opium importer-manufacturer's transactions. DEA investigators tabulated sales from the manufacturer's individual shipping orders. The resulting accountability computation disclosed unexplained overages and shortages. We found that the variances for three controlled substances may have resulted because sales orders recorded in the manufacturer's sales journal were not included in DEA's tabulation. The causes of these variances would have been evident if the tracing procedure we suggest had been used.

By confining its investigation only to those records required by CSA which the registrant claims are complete and accurate, DEA does not take full advantage of information that would provide increased assurance of complete and accurate accounting of the controlled substances being audited.

Under CSA, DEA is required to obtain written consent from a registrant to examine financial data and sales data other than shipment data. DEA officials believe that examining these records is unnecessary. We believe, however, that examining such records, particularly sales records, could result in a more thorough and effective compliance investigation, because it would provide a means of testing the reliability of a registrant's records.

Guidelines vague

Evaluation of manufacturing variances

Federal regulations require manufacturers to maintain records of theoretical and actual yields; quantities lost or gained during manufacturing; and, if known, causes of losses and gains. Investigative guidelines provide for a comparison of theoretical with actual yields of the various production processes, an evaluation of losses and gains, and a spot review of production records. However, they do not include criteria for evaluating variances or describe the different variances which should be identified and evaluated.

DEA's compliance investigations at three opium importer-manufacturers disclosed shortages in the manufacturing of codeine which ranged from 28.5 percent to 1.9 percent. The manufacturers explained to DEA that the variances were attributable to various causes, such as routine manufacturing losses, imprecise conversion factors, and inaccuracies in weighing processes. DEA investigators accepted the general explanations because the variances appeared to be consistent with the manufacturers' prior experiences.

The manufacturers' prior experience and general explanation of variances appear to be reasonable factors to be considered in analyzing variances. However, they are not an adequate substitute for a thorough analysis aimed at attributing variances to specific causes and verifying their reasonableness.

For example, a methadone bulk manufacturer attributed losses in one quarter to the packaging of methadone in an unusually large number of small shipping containers. DEA investigators accepted this explanation on the basis of personal judgment. The investigators, however, were not aware that the manufacturer frequently experiences three types of losses.

--Substantial losses are experienced in the initial bulk methadone manufacturing processes. Investigators did not identify or analyze these losses.

--The manufacturer sometimes combines several depleted lots of finished product into a single lot. These are not weighed before combining. The manufacturer records the actual weight of the combined lot as the new inventory balance. The manufacturer does not reconcile the difference between the weight of the depleted lots and the amount recorded as inventory for the depleted lots and thus does not record any losses which may have occurred before combining. For the two lots we reviewed, the actual losses, which were not recorded or reported, amounted to 100 grams and 130 grams, respectively.

--The manufacturer, as the need arises, places desired quantities of work-in-process into final manufacturing. The losses occurring from this process are not recorded; rather, the work in process is issued into final manufacturing at its recorded inventory balance. The actual weight of the finished goods is recorded as the opening balance. For the three lots we reviewed, unrecorded losses were 6.3 kilograms (7.2 percent of the lot), 5.9 kilograms (6.4 percent of the lot), and 4.7 kilograms (5.7 percent of the lot).

Procedures for taking physical inventory need improvement

DEA guidelines do not discuss the need for (1) verifying the weight of container contents, (2) analyzing samples to verify that the product in the container is

as labeled, and (3) closely observing storage locations to insure that all containers of the substance are included in the count. They require only that a physical count be made of the drugs selected for audit during the initial phases of an investigation.

DEA investigators confine their observation of storage areas to those inventory stocks which the registrant points them to and do not make independent observations to detect the presence of unreported inventory. The weakness of this procedure is illustrated by the following examples.

The physical inventories taken by DEA investigators at the sites of two registrants did not include all the methadone stored at each of these locations. A bulk manufacturer had 13 pounds of methadone in a container inside the finished goods vault. This methadone was not recorded on the manufacturer's inventory records and was not reported on its quarterly reports. In taking their physical inventory, DEA investigators counted all containers shown on inventory records but did not include the unrecorded quantity of 13 pounds. Although 13 pounds does not represent a significant percentage of the total methadone included in the physical inventory, this amount, which was not subjected to recordkeeping or reporting controls, could have a value in the illicit market of between $1 million and $2 million.

A dosage manufacturer did not maintain an inventory record of an undetermined quantity of various schedule II and schedule III controlled substances stored in a finished goods vault. The substances, accumulated over several years, were portions of samples taken for laboratory tests but not completely used. We found that 210 grams of methadone (one of the schedule II substances) had accumulated in this manner. DEA investigators did not include this material in their physical inventory count, nor did the manufacturer in its periodic reports.

Procedures for determining accountability at methadone treatment programs need improvement

DEA has issued instructions modifying the "Agent's Manual" and providing guidelines directed at investigations of methadone treatment programs. These special guidelines are necessary because of the difference in the operations of treatment programs relative to other types of registrants and the known or suspected diversion of methadone from some of these programs. We noted in DEA's

investigative practices at treatment programs certain weaknesses which we believe can be corrected by improving the guidelines.

The guidelines require that the program account for all methadone for the period selected for audit. The starting point of the audit is to be either

--the biennial physical inventory required by CSA of all registrants,

--the registrant's annual inventory,

--the physical inventory taken by DEA on its most recent investigation, or

--a zero balance.

DEA made accountability reviews at three of the five programs visited. DEA investigators used an inaccurate or arbitrary opening inventory figure at two of the three programs, because an acceptable figure, meeting the requirements of DEA guidelines, was not available. This procedure precluded an accurate determination of the programs' accountability.

Guidelines require investigators to review patient files to validate the dispensing of methadone, but do not provide criteria on the number of files to be reviewed. Of the three programs where DEA made accountability reviews, investigators reviewed all the patient records at two programs and none at one program.

Guidelines require tracing receipt records to DEA shipment order forms. Investigators rely upon the programs for information on the number and amount of purchases. This receipt verification procedure could be improved by determining whether all official order forms provided to the program can be accounted for by records at DEA headquarters.

Guidelines require investigators to evaluate the severity of shortages and overages disclosed by their accountability audit. However, they do not provide any criteria for making these evaluations or for taking regulatory actions.

Need for working papers

In conducting audits it is a generally accepted practice that working papers be prepared to provide (1) a systematic record of the scope and methodology of the investigation, (2) a record of information and evidence obtained, and (3) a basis for guidance and followup for subsequent investigations.

DEA has no written policies or procedures for working papers. The working papers we reviewed (1) did not document the scope and methodology of investigations to any significant extent, (2) did not fully support information included in reports of investigations, and (3) were generally unorganized and largely unintelligible. Thus, the adequacy of investigative work in important areas could not be determined and at one location the accountability audit was duplicated.

One opium importer-manufacturer stated that DEA investigators did not take a physical inventory during their compliance investigation. Although the investigation report indicates that a physical inventory was taken, DEA could not furnish us working papers evidencing this. Similarly, investigative work performed in most areas at this and one other opium importer-manufacturer site was not documented by working papers. We compared information included in DEA's report on investigation at one of these opium importer-manufacturers with the manufacturer's records and found unexplained differences in beginning and ending inventory, consumption, and distribution figures. DEA could not furnish the source of its figures or explain the difference between DEA's figures and the manufacturer's records.

The Office of Internal Audit, Department of Justice, pointed out in November 1972 that region 2 lacked policy concerning the keeping of working papers to support its compliance investigation reports and that such support data was essential to (1) address any questions that might later arise from the registrant and (2) assure supervisory investigators that the audits were made according to established policy and with sufficient coverage to justify the results shown. At that time, DEA representatives in region 2 agreed that working papers were important and would be maintained on all future compliance investigations.

The general inadequacy of working papers continues to be a problem. For example, regarding the compliance investigations of a dosage form manufacturer and a bulk methadone manufacturer started in May 1973, working papers (1) did not support all the investigative work performed or material required for reports and (2) lacked clarity, organization, and indication of supervisory review.

Need for supervisory review

A review of the scope, methodology, and adequacy of investigations is necessary for the proper supervision and evaluation of the investigators' performance. As discussed above, working papers providing a systematic record of the scope and methodology of investigations are not prepared. Consequently, this valuable tool is not available to supervisors. Furthermore, DEA records do not indicate the type and extent of supervisory reviews which may have been made.

Supervisory review is also necessary to insure that guidelines are being followed in conducting compliance investigations at registrants. DEA investigators in some important areas did not adequately follow investigative procedures, though fairly clear.

At a bulk manufacturer, for example, we found that (1) data on batch sheets (detailing the manufacturing process) were not validated as to records of raw materials used, theoretical versus actual yields, and manufacturing losses, (2) inventory transactions were not reconciled regarding work in process and finished goods, and (3) the disposition of rework was not traced through the manufacturer's records. Similarly, at a dosage manufacturer's site, verifications were not made of the amounts removed from work-in-process for testing or the amounts of finished goods actually used in tests.

DEA said that there are no formal written procedures or criteria for reviewing work accomplished, but reviews are in fact made informally from time to time during the course of an investigation at the discretion of supervisors.

CONCLUSIONS

Because of the illicit demand for controlled substances, it is essential that the legitimate sources of these substances be effectively monitored. As a monitoring tool there is a need for systematic, onsite inspections of a registrant's activities to determine if the registrant is complying with regulatory requirements.

DEA's compliance investigation procedures need to be improved to facilitate the identification of actual and potential sources of diversion. To accomplish its purpose, DEA must insure that investigations are made as needed and cover sufficient ground to detect violations.

RECOMMENDATIONS TO THE ATTORNEY GENERAL

We recommend that DEA improve compliance investigations by:

--Establishing procedures to insure that registrants are investigated by its regional office according to established priorities.

--Revising investigative guidelines to include detailed procedures for conducting compliance audits, clearly describing the objective of each important segment of the investigation and the criteria for making required evaluations.

--Requiring the systematic use of working papers evidencing the investigative work performed to aid in supervisory review and in future investigations and followup actions at registrants.

AGENCY COMMENTS

DEA stated that while deficiencies still exist in the regulatory program, most of the deficiencies pointed out in the report have been addressed. DEA stated that a new compliance manual section was issued on June 30, 1974, reflecting regulatory program development under CSA, and that there are now two levels of supervisory review of the work performed in the regions. In addition, DEA headquarters reviews all actionable investigations against registrants and reviews on a spot-check basis inactionable investigations. Also, DEA headquarters periodically visits the regions and receives status reports on accomplishment of projected work from the regions. As for requiring the systematic use of working papers, DEA stated there are sufficient reasons to leave this matter in developmental status for the present.

CHAPTER 4

TRAINING OF COMPLIANCE INVESTIGATORS

Effective performance of compliance investigations depends largely upon the quality of training received by investigators. In general, although investigators are well-educated and experienced, they have not had formal training in accounting and auditing. DEA's training program for investigators could be improved in certain important areas dealing with compliance investigations.

An important segment of compliance investigations conducted at registrants is an indepth drug-accountability investigation of a number of controlled substances selected in accordance with the priority criteria established by DEA. (See p. 14.) These investigations range from intricate manufacturer accountability systems to relatively simple treatment-program accountability systems.

EDUCATION AND EXPERIENCE OF INVESTIGATORS

Before employment by DEA, most compliance investigators have completed college and have experience in areas which are somewhat related to their duties as compliance investigators. However, very little of their education and experience is in accounting or auditing--skills which would be useful to compliance investigators performing indepth drug-accountability investigations.

Qualifications for the position of compliance investigator include 4 years of college with a bachelor's degree, or a minimum of 3 years of general experience, or an acceptable combination of education and experience. Our review of personnel files of the 25 compliance investigators assigned to DEA's New York Region in April 1974 disclosed that:

--18, or 72 percent, had college degrees, with 6 completing some postgraduate study. Six other investigators had at least 1 year of college.

--The college major was varied and included pre-med and education. Eight of the 18 college graduates majored in business administration or marketing; none of the 18 majored in accounting or auditing.

--Prior experience was also of a wide variety and included investigative experience with the New York City Police Department and private companies. Of

the 25 employees, 5 had been previously employed as DEA special agents, 4 had been Civil Service Commission investigators, 3 had been employed in military intelligence, and only 2 had experience as auditors and accountants.

In conducting an indepth accountability investigation, compliance investigators deal mainly with accounting-type records, reports, and transactions. The procedural aspects of the investigation are essentially audit oriented--a systematic review, verification, testing, and questioning of data. The general lack of accounting and auditing expertise may hinder investigators in effectively performing this segment of a compliance investigation.

TRAINING PROGRAM FOR INVESTIGATORS NEEDS IMPROVEMENT

DEA's training program evaluation system has disclosed significant weaknesses in its program for compliance investigators. Improvements have been made. Earlier classes of the training program attended by 150 investigators were considered inadequate. DEA, however, did not provide additional training to these investigators or establish a formalized continuous training program to insure that investigators develop and maintain the skills, knowledge, and abilities needed in their job.

Shortly after appointment, compliance investigators attend a formal 6-week instruction program at DEA's National Training Institute (NTI) in Washington, D.C. DEA personnel are used as instructors in courses related to their assigned duties. This is the only formal training program provided to compliance investigators.

The program includes 240 hours of scheduled instruction and case studies. Eighty-six of these are titled "Drug Industry and Compliance Operations, Principles and Techniques" and are listed in the following categories.

	Number of hours
Manufacturers	48
Retail operations	14
General instruction	12
Registration	10
Wholesale operations	2
Total	86

The remaining 154 hours of scheduled instruction cover such matters as legal principles, DEA policies, and pharmacology.

DEA has established a system for evaluating the effectiveness of the training program in terms of the course content, instructors, and usefulness of courses in performing compliance investigation duties. Evaluations are based upon analyses of students' written critiques; discussions with students, counselors, instructors, and class coordinators; and personal observations by a monitoring staff. Written critiques are obtained from students at the midpoint and the end of the 6-week program and again 6, 9, and 12 months after completion of the program.

From November 1971, when the training program was initiated, to February 1974, 6 classes were conducted and 173 persons completed the program.

Records of DEA's evaluations of the training program's effectiveness consist of (1) end-of-course evaluations for four of the six classes and (2) one evaluation of field feedback responses covering four classes. These evaluation records indicated inadequacies in the first five classes of the training program regarding audits of manufacturers. Examples follow:

> "Students were unanimous in complaining that they failed to receive adequate instruction in conducting audits. * * * All of the problems, * * *, were on audits of a pharmacy. Students were given no practical training and no testing on auditing of wholesalers and manufacturers."
>
> --April 1972

> "One instructional area meeting with quasi-unanimous disapproval was Manufacturer Audit Problems. * * * Audit Problems were obviously prepared in haste and were full of errors. Absolutely no pertinent instruction was given students prior to being asked to do this type of audit."
>
> --June 1972

> "* * * manufacturer audits, as usual, received a quasi-unanimous negative assessment in Class #5. Students and Counselors alike felt that inadequate emphasis had been placed on this vital aspect of a Compliance Investigator's training."
>
> --March 1973

DEA's records indicate that actions were taken to improve the training program after each of the first 5 classes, attended by 150 investigators in total, had been completed. Evaluation reports disclose that significant improvements were detected over previous classes.

The evaluation of field feedback responses was made in April and May 1973. The investigators were asked to view their training in the light of its application to their personal experiences in the field and to comment in four areas--(1) most beneficial aspects, (2) least beneficial aspects, (3) aspects of no use to fieldwork, and (4) suggestions for improvements. As with the end-of-course evaluations discussed above, this evaluation showed inadequacies in the training program provided to the first five classes regarding conduct of audits, particularly at manufacturers.

Further indications of inadequacies in the training program were pointed out in a March 1973 memorandum from the New York Region Directorate to DEA headquarters. This memorandum states:

> "In the past, audits of practitioners have been stressed at NTI. However, in the field, the investigator has little time for a practitioner audit. The more complex manufacturer and distributor audits have been glossed over and sufficient attention was not paid to this extremely important aspect of training. Even now, the audits during the training school at this level are not practical since they apparently do not represent the true picture of a complex audit."

Although DEA has instituted actions to improve its training program, it has not taken actions to provide further training to the approximately 150 investigators (comprising 87 percent of the investigative staff as of February 1974).

DEA officials told us that, in addition to the 6-week training program, investigators receive on-the-job training as well as periodic informal training by the regions. However, on-the-job training is no substitute for a well developed, formalized, continuous training program. Also, DEA has not provided criteria and guidelines to its regions for providing training to investigators, nor does DEA evaluate or monitor the training that may be provided by the regions. Further, the New York Region said it had no training program for compliance investigators.

CONCLUSIONS

To effectively carry out its compliance program, DEA must have investigators who are properly prepared to perform compliance audits of manufacturers and distributors. Audits of manufacturers are difficult and require specialized training. DEA recognizes that the first 5 compliance-investigation training sessions attended by about 150 investigators were weak in the area of manufacturer audits. Action was taken to improve future training sessions. However, DEA has not developed a program for identifying the training needs of compliance investigators, nor for providing the continuous training needed to maintain their proficiency in conducting compliance investigations.

RECOMMENDATION TO THE ATTORNEY GENERAL

We recommend that DEA improve its training program to insure that periodic formal training is provided to compliance investigators.

AGENCY COMMENTS

DEA agreed that much more remains to be done in the training of compliance investigators. As a result, DEA stated that formalized on-the-job training and advance training for compliance investigators is being developed. In addition, DEA plans to provide specialized supervisory training to begin in July 1975.