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The Honorable Charles B. Rangel
 House of Representatives



Dear Mr. Rangel:

Your letter of May 9, 1974, requested that we study issues relating to the supply and demand for crude opium and opium derivatives. In discussions with your office, it was agreed that we would provide an initial report on the first three issues in your letter. The effect that Turkey's recent decision to resume the growing of opium will have on future supplies was not addressed in this report. The remaining issues will be dealt with in a later report. It was also agreed that, due to the urgency associated with your request, we would not attempt to independently determine the legitimate U.S. demand for crude opium and its derivatives.

This report discusses the following issues:

- What is the present and 5-year projected, legitimate demand for crude opium and opium derivatives in the United States?
- What is the process by which the Government determines the legitimate demand, and how adequate is the process in terms of accuracy and industry control of input data?
- What is the present and 5-year projected supply from present sources?

As your office later requested, we have also projected when demand will exceed supply.

We found that:

- The demand for codeine, which accounts for about 90 percent of the demand for all opium derivatives, is increasing and is expected to increase for the next 5 years. Industry spokesmen project an increase which averages 13 percent per year with the greatest increase in 1974. The view of the Department of Health, Education, and Welfare (HEW), presented in September 1973, was that the national need for opium would not decrease. (See pp. 1 to 3.)
- The Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801) provides for annually determining legitimate U.S. needs for controlled substances, including opium and its derivatives. We found, however, that:

1. HEW has yet to issue an annual report containing the results of studies done to determine the legitimate medical and

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scientific needs for opium and its derivatives, as required by the act.

2. The Drug Enforcement Administration (DEA), in February 1974, for the first time formally requested HEW to prepare estimates of U.S. needs for controlled substances to assist it in setting production quotas and import requirements for 1975.
3. Neither HEW nor DEA is making its own studies or surveys to determine the legitimate medical and scientific needs for opium and its derivatives. DEA, however, has contracted with the National Research Council for a review of synthetic alternatives to opium derivatives. (See pp. 3 to 6.)

--The present and projected supply of crude opium consists of 238 metric tons authorized to be released from our strategic stockpile during 1974-76 and about 232 metric tons to be imported from India each year for the next 5 years. The recent decision of the Government of Turkey to resume the growing of opium should drastically alter the entire supply picture. (See pp. 7 to 9.)

--Demand could exceed supply as early as the fall of 1976 and probably before 1978. (See pp. 9 to 11.)

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As requested by your office, we did not obtain formal agency comments. However, we discussed the results of our review with HEW and DEA officials and considered their comments in preparing this report. We plan no further distribution of this report unless you agree or publicly announce its contents.

Sincerely yours,



[Deputy

Comptroller General
of the United States

Enclosure

ISSUES CONCERNING THE SUPPLY AND
DEMAND FOR LICIT OPIUM IN THE
UNITED STATES AS OF JULY 1, 1974

WHAT IS THE PRESENT AND 5-YEAR PROJECTION
OF THE LEGITIMATE DEMAND FOR CRUDE OPIUM AND
OPIUM DERIVATIVES IN THE UNITED STATES?

The demand for crude opium and its derivatives according to Government and drug industry sources is not expected to decrease over the next 5 years. Industry spokesmen project an increase which averages 13 percent a year over the next 5 years. Federal officials stated that the Government has no quantitative estimate of demand but HEW predicts that the national demand for opium and its derivatives will not decrease due to an increase in the number of persons receiving medical care and an increase in physicians' prescribing opium derivative drugs.

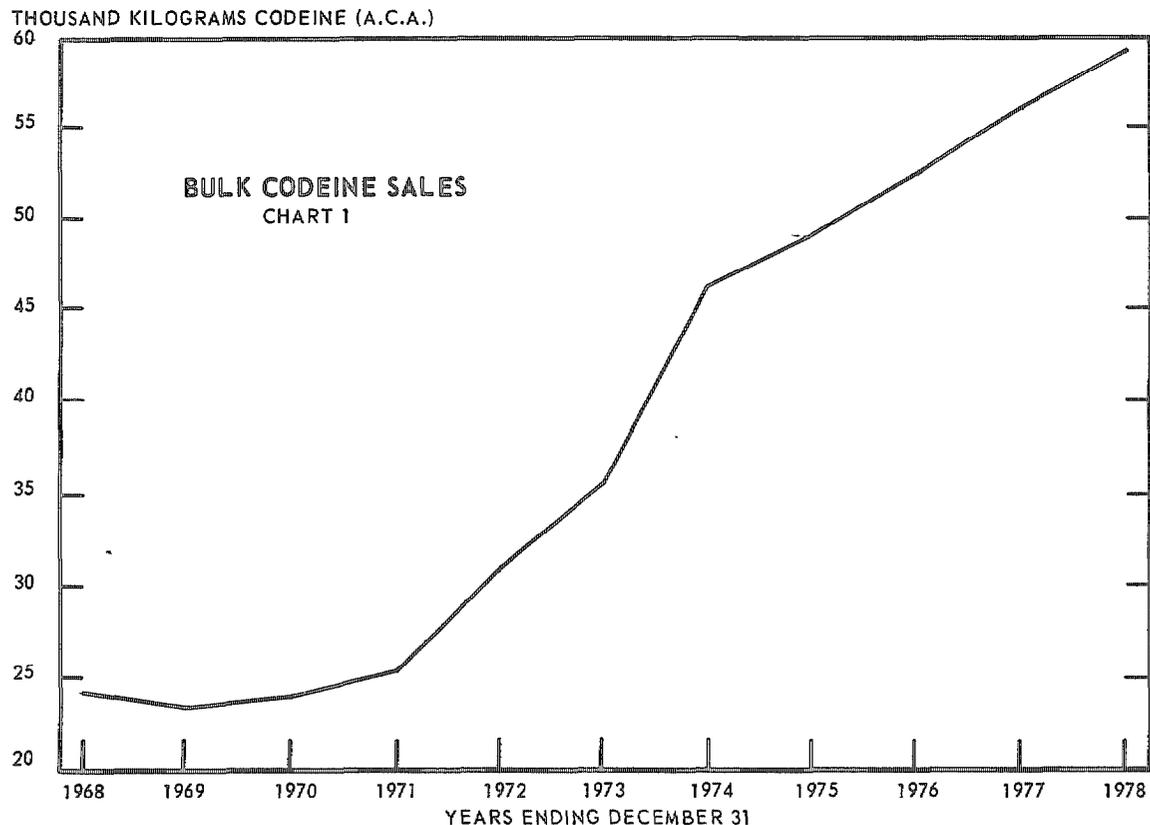
The demand for crude opium and its derivatives in the United States is affected at three levels--importer and processor, dosage formulator, and retailer and practitioner. Only three companies in the United States are licensed to import and process crude opium. Thus, at this level, demand for crude opium is primarily a function of sales of opium derivatives which these three companies produce. The manufacture of codeine accounts for about 90 percent of the opium imported and gives a good indication of opium demand; the balance of imported opium is used primarily for morphine, for which demand is relatively stable. Therefore, our discussion will focus exclusively on the codeine market.

The processing companies sell the bulk codeine they produce to approximately 65 companies, called formulators, which market codeine-based medications in various dosage forms as analgesics (pain suppressants) for mild to moderate pain or antitussives (cough suppressants). These formulators base their demand for codeine on the popularity their brands of medication have experienced in sales to private hospitals, Federal and State institutions, and drug wholesalers and retailers.

At the retail level the purchase of drugs containing codeine (with the exception of some nonprescription, over-the-counter sales of codeine-based cough suppressants) are predicated upon the prescribing habits of practitioners. Thus, demand is ultimately determined by practitioners' determinations of the best medication available to treat patients and consumer-preference purchases of brand-name, codeine-based cough suppressants. Industry officials said that past prescription and over-the-counter sales weigh heavily in their forecasting of future demands.

We discussed demand for codeine with (1) representatives from two importer and processor companies and three formulator companies and (2) Government officials and private physicians. The responses to our inquiries supported the views expressed by the Director of the National Institute on Drug Abuse, HEW, in September 1973 congressional testimony before the House Armed Services Committee. The Director said that opium derivatives are the primary source of medication providing satisfactory analgesic and antitussive effects and that domestic requirements had increased. Some reasons cited for increased demand of codeine-based drugs were reports by the Food and Drug Administration (FDA) concerning the lack of effectiveness of the synthetic analgesic propoxphene (Darvon), the expanded use of medical services in the United States due in part to medical insurance plans and programs such as Medicare and Medicaid, and the increased longevity of the U. S. population. Industry officials gave these same reasons in explaining their forecasts of increasing sales.

The three processing companies provided us with data on consolidated bulk codeine sales for 1968-73 and on projected demand for 1974-78. This data is shown in chart 1. The supply and demand data is expressed in terms of anhydrous codeine alkaloid (A. C. A.). This measure acts as a common denominator allowing comparison, in terms of codeine content, of all substances--from crude opium to finished preparations--on a consistent basis.



The demand projections for 1974 and beyond show a continued expansion for the codeine market. HEW believes that future trends will prove to be more stable with a leveling demand growth pattern; however, it agrees that the demand for codeine-based medications is not likely to decline in the near future.

WHAT IS THE PROCESS BY WHICH THE GOVERNMENT DETERMINES THE LEGITIMATE DEMAND, AND WHAT IS THE ADEQUACY OF SUCH PROCESS IN TERMS OF ACCURACY AND INDUSTRY CONTROL OF INPUT DATA?

The Federal Government is responsible for annually estimating legitimate medical and scientific needs for opium and opium derivatives and for limiting imports of opium and production of its derivatives to meet these needs.

Both the Attorney General and the Secretary of HEW have certain statutory responsibilities under the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801) for determining legitimate U.S. needs for controlled substances. Under title III, section 1002(a), of the act, the Attorney General is charged with limiting imports of crude opium to amounts necessary to provide for medical, scientific, or other legitimate purposes.

The Attorney General, under title II, section 306(a) and (c), of the act, must determine the total quantity and establish aggregate production and individual manufacturing quotas for each basic class of controlled substances, including opium derivatives, listed in schedules I and II of the act to be manufactured each year to provide for the estimated medical, scientific, research, and industrial needs of the United States; for lawful export requirements; and for the establishment and maintenance of reserve stocks.

HEW's role in estimating needs for opium and opium derivatives is stated in title II, section 701(j), of the act. This section provides that the Secretary of HEW shall annually report the results of studies and investigations conducted to determine the quantities of crude opium, its derivatives, and other controlled substances which are necessary to supply the normal, emergency medical, scientific, and reserve requirements of the United States. HEW estimates of legitimate needs may be used at the discretion of the Attorney General in determining production quotas and import requirements. The Attorney General's responsibility for setting production quotas and import requirements for controlled substances has been delegated to the Administrator of DEA. HEW assigned the task of preparing estimates of legitimate needs to FDA.

Neither HEW nor DEA is making its own studies or surveys to determine the legitimate medical and scientific needs for opium and its derivatives. DEA, however, has contracted with the National Research Council for a review of synthetic alternatives to opium derivatives. DEA said that the results of the review should be available in the near future.

DEA's role in determining legitimate needs

DEA recognizes that quotas are a useful regulatory tool to control the manufacture of substances which have a legitimate use but which also have 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 sets several types of quotas for opium and opium derivatives.

Although the act does not expressly provide for an opium import quota, DEA has used quota procedures to carry out its responsibility to limit opium imports. In recent years, because the world supply of opium has been less than the demand, DEA has not had to use quotas as a means to limit opium imports. According to DEA officials, the U.S. opium importers have not been able to import enough opium in recent years to maintain adequate inventories.

As required by the act, DEA sets annual aggregate production and individual manufacturing quotas to limit production of controlled substances. Each of the three licensed importers processes crude opium into bulk opium derivative products such as bulk codeine. Each of these companies is given an individual manufacturing quota authorizing amounts of opium derivative products that it can manufacture in bulk form each year. (Only firms which manufacture controlled substances in bulk form receive individual manufacturing quotas from DEA.) The sum of the individual manufacturing quotas is the "aggregate production quota" which is the total amount that can be produced nationally.

Federal regulations provide that DEA set procurement quotas for opium derivatives. DEA gives procurement quotas to all dosage-form manufacturers of controlled substances. Each of the approximately 65 dosage formulators of codeine drugs receives a procurement quota from DEA authorizing maximum purchases of bulk codeine from the opium processors.

In establishing quotas for controlled substances, DEA uses a variety of data, including

- quota amounts requested;
- inventory data;

- quantities manufactured, purchased, and imported;
- actual sales and other disposals;
- availability of raw materials;
- abuse and diversion potential; and
- nationwide prescribing and dispensing surveys by private firms.

Drug manufacturers supply most of this data on quota applications. Although quota applications do not have to be certified, the same historical data is reported on other accountability reports which are required by law, including a statement of certification. According to DEA, in the past it has found no reason to doubt the accuracy of data and requests submitted by industry and quota applications have generally been accepted and approved as requested.

As part of its statutory responsibility for regulating controlled substances, DEA periodically audits drug manufacturers and wholesalers. DEA policy is that audits will be conducted at least once every 3 years. DEA, therefore, has the opportunity to verify the accuracy and reasonableness of quota data submitted by the companies.

DEA, in setting quotas to provide for legitimate needs, depends primarily on data supplied by drug manufacturers rather than data from retailers and practitioners. DEA also looks to HEW for estimates of legitimate medical demand for controlled substances.

HEW's role in determining medical and scientific needs

The statutory requirement for HEW to undertake studies and investigations to determine the legitimate medical and scientific needs for controlled substances and to report the results of such studies to the Attorney General has been in effect since 1970. HEW has not issued such a report concerning opium and its derivatives, although it has issued reports on other controlled substances.

In a February 1974 letter, DEA requested that HEW provide the required annual report on the estimated needs for controlled substances. HEW responded that these estimates would be provided by May 1, 1974. As of July 1, 1974, the report had not been prepared. An FDA official indicated that, due to severe staff limits, work on estimating the need for opium and its derivatives had not yet begun.

An FDA official said that, to fulfill its statutory responsibility for providing estimates on the legitimate need for opium and its derivatives,

ENCLOSURE

FDA plans to (1) work closely with DEA in reviewing data from drug manufacturers, (2) use its own New Drug Application 1/ files, and (3) analyze the results of nationwide prescribing and dispensing surveys which are conducted by private companies.

1/ A New Drug Application, when approved by FDA, permits a drug manufacturer to market a new drug.