July 2, 1969

MEMORANDUM TO THE ATTORNEY GENERAL

I would like to urge that we move the Presidential package on narcotics and dangerous drugs as quickly as possible. I believe it is essential that it be the subject of the leadership briefing next Tuesday, July 8. The package is ready and awaiting your final review.

I believe we should move this package for the following reasons:

1. This legislative session of Congress is running short. This is a major piece of legislation and will require extensive hearings in both the House and Senate. If these hearings are not completed this session it will jeopardize the possibility for enacting this measure in this Congress. Delay, of course, is what our opponents want and our delay will strengthen their ability to tie up the legislation before the Congress.

2. The press is beginning to make inquiries both at the Department and at the White House regarding the status of this Presidential package. We have been saying that it is imminent for several weeks and will not be able to use that response much longer.

3. In an effort to expedite the processing of this legislation we were able to accomplish substantial compromises on the part of HEW and Treasury. I am somewhat embarrassed that we have not been able to submit this legislation to Congress sooner because I was able to get real cooperation with the top officials of HEW in resolving our differences in an effort to get the bill before the Congress. I am now concerned that further delay could result in the resolved issues being reopened.

4. Lou Nichols has told me he is willing and anxious to get ABA support for this measure. However, I did not want to release the bill to Nichols prior to your discussion of it with the leadership. Nichols wants to circulate a final copy of the bill that will go to his executive committee as soon as possible so that he may obtain a resolution in support of it at the Dallas convention of the ABA.

5. Ken Cole of the White House staff called today to ask if we were ready for a leadership briefing. He indicated that next week would be a good week for this message and accompanying legislation to be processed through the White House machinery.

John W. Dean

Form DJ-150
(Ed. 4-26-65)

UNITED STATES GOVERNMENT DEPARTMENT OF JUSTICE

Memorandum

TO : The Attorney General DATE: MAR 13 1969

FROM : Will Wilson
Assistant Attorney General
Criminal Division

WW:PW:emc
12-01

SUBJECT: Controlled Dangerous Substances Act of 1969

The subject bill has been proposed by both the Criminal Division and the Bureau of Narcotics and Dangerous Drugs to bring together and to bring into harmony the various federal statutes relating to narcotics, marihuana and other dangerous drugs. The bill had the wholehearted support of the Criminal Division. However, it does contain some controversial features which must be taken into account.

I. The penalties provided in the bill are generally lower with respect to narcotics and marihuana than is presently the case

Under current statutes first offenses relating to trafficking in narcotics and marihuana are punishable by a minimum mandatory term of 5 years (maximum 20 years) without possibility of probation (in the case of narcotics parole is also excluded). While there are no simple possession offenses relating to narcotics and marihuana, offenses attributable to simple possession are nevertheless felonies for which first offenses are punishable by imprisonment for from 2 to 10 years, subject to the usual probation and parole provisions. Simple possession of other dangerous drugs is a misdemeanor and offenses relating to traffic in such drugs are subject to maximum 5 year terms -- again subject to the usual probation and parole provisions. The bill provides a maximum penalty of 12 years for a first offense relating to traffic in narcotics with no minimum and 5 year maximum for a first offense relating to traffic in all other substances including marihuana. It also provides that simple possession of any substance shall be a misdemeanor. The entire sentence structure is something of a novelty, but it seems clear that the most controversial features are the absence of mandatory minimum terms for first offenses relating to traffic in narcotics and marihuana (which will be discussed separately), the reduction of the penalties relating to marihuana and the misdemeanor possession offenses as they relate to narcotics and marihuana.

As noted, the current maximum penalty for traffic in dangerous drugs is 5 years. Included in the dangerous drug category are LSD and STP, two of the most dangerous hallucinogenic drugs now current among drug abusers. Marihuana is also an hallucinogenic. In its natural state it is clearly less dangerous to the user and to the community than either LSD or STP, and in its more refined stages (THC or hashish) it is no more dangerous than those substances. These facts underlie the current criticism that the marihuana penalties are unrealistic and unnecessarily harsh. The marihuana statutes were enacted at a time when no other similar substances were under federal control. Since then, similar and even more dangerous substances have been brought under control and are subject to less severe penalties. In terms of a bill of this nature there is no rational justification for treating marihuana differently from any other hallucinogenic and we have not attempted to do so. Moreover, considering the character of defendants usually apprehended in such cases and the fact that organized crime seems rarely to be involved in marihuana and dangerous drug offenses, as distinguished from narcotic offenses, we think a maximum penalty of 5 years for a first offense and 10 years for subsequent offenses is in reasonable proportion to the seriousness of the offenses involved.

With regard to simple possession, we note that this does not make any change in the law insofar as the dangerous drugs are concerned. It does make two changes insofar as narcotics and dangerous drugs are concerned. As a matter of legal fact simple possession of narcotics or marihuana is not an offense under the federal laws. Therefore, this provision creates an offense not previously found in the federal law and can be said to represent a tightening of federal strictures and a realignment of the narcotic and marihuana controls with those applicable to other dangerous drugs. In point of fact, however, simple possession of narcotics and marihuana raises, in each case, a presumption that possession was acquired in violation of the tax statutes and hence is punishable as a felony. To this extent it is apparent that the penalties assessable for simple possession are being reduced. This can be justified, we think, for the following reasons. (1) We are eliminating the tax features and, therefore, there will be no offense to which the present presumption could attach. (2) Since possession with intent to distribute is covered elsewhere as a felony, the simple possession count is intended to relate only to those in possession of such small amounts as to indicate that possession was for personal consumption only. (3) With

respect to possessor-users who are primarily the victims of the traffic, the sanctions imposed should be calculated to deter drug abuse and to make the user amenable to rehabilitative treatment. Harsher treatment appears unwarranted and may tend to harden the attitude of the drug abuser rather than incline him toward rehabilitation.

II Elimination of mandatory minimum penalties for first offenders

As noted previously, traffickers in narcotics and marihuana are now subject to mandatory minimum penalties of 5 years for a first offense. Traffickers in other dangerous drugs are subject to maximum penalties of 5 years, without any prescribed minimum.

The bill provides a maximum term of 12 years for first narcotic offenders and 5 years for all other offenders without any minimum. The mandatory minimum sentences have been in controversy since they were imposed in 1956. They were enacted in response to an apparent reluctance on the part of some judges to impose meaningful sentences on major narcotic law offenders. It would be difficult to demonstrate that they have had any substantial beneficial effect. No statistics are currently at hand but even casual observation of the sentences imposed indicates that 90% or more of all narcotic and marihuana sentences are the minimum prescribed; the likelihood that they would tend to be less if the law would permit is very great. On the other hand, we can easily demonstrate that judges do sentence in excess of the minimum required where members of organized crime and other major traffickers are involved. Also, the mandatory minimum sentences have created some rather severe and uncomfortable problems. (1) They apply indiscriminately to all offenders. Addict street peddlers and major wholesalers and smugglers are subject to the same sentences. The courts are naturally reluctant to sentence small-time addict-peddlers and smugglers of infinitesimal quantities of narcotics and marihuana to 5 year and longer terms and frequently strain to suppress evidence or find technical defects in otherwise valid prosecutions. United States Attorneys faced with similar considerations frequently resort to subterfuges and legal fictions in order to charge offenses to which the mandatory minimums are not applicable. Defendants are, of course, aware that they are being charged and are pleading guilty to offenses which they did not in fact commit

in lieu of offenses properly applicable, and this, we think, is a contributing factor in the growing lack of respect for law enforcement. (2) Since most defendants are not in the organized crime or major supplier categories, they are aware, or at least their attorneys are aware, that no advantage can accrue to the defendant by entering a plea of guilty, no matter how strong the government's case. Whether or not the average defendant goes to trial the minimum sentence must be 5 years and for all practical purposes will not exceed 5 years. As a result the only real demonstrable result of the enactment of mandatory minimum penalties has been the tremendous increase in the number of narcotic and marihuana cases which go to trial. Most of the trials are short and most result in conviction, but they manage to consume a considerable amount of court time which might otherwise have been devoted to more meritorious litigations. (3) Lastly, Bureau of Prison officials have consistently maintained that persons sentenced to mandatory minimum terms present the hardest disciplinary problems within the institution and are the prisoners least likely to respond to rehabilitative efforts. The Bureau of Prisons has stated on numerous occasions that such prisoners have no incentive to cooperate and are devoid of any optimism regarding their situation and are thus unresponsive to rehabilitative programs.

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Under current law (21 U.S.C. 176b) anyone over the age of 18 who provides heroin to a person under 18 is punishable for a term of from 10 years to life and may at the discretion of the jury be put to death. The statute was added in 1956 and has rarely, if ever, been utilized.

Aside from the fact that under the recent case of United States v. Jackson, 390 U.S. 570, the death penalty is probably unconstitutional, the statute presents some practical difficulties. Cases involving actual sales are usually cases in which the purchase is accomplished by a government agent; therefore, we rarely come into possession of actual evidence of a sale to a minor. In the rare instances where there is such evidence the defendant is himself under 18 or, if older, is a peer of the purchaser. The bill would eliminate this statute and substitute instead a provision which would authorize double the usual penalty for any adult who sells any drug to a minor. This would in each case of a sale of heroin to a minor provide a sentence at least as severe as the minimum now provided (10 years) and would add to the law an enhanced penalty for those who sell other drugs to minors. On balance, we think this a more realistic provision

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The bill proposes initially to identify the drugs in each Schedule. Recognizing however that scientific advances may develop new drugs or new insights into old drugs, the bill authorizes the Attorney General, with the advice of a scientific board, to add drugs to the Schedules, switch drugs from one Schedule to another or to drop a drug from control.

This, of course, is subject to the objection that, in theory at least, an Attorney General could legalize traffic in heroin or marihuana. A short answer may be that to do so would be in violation of our treaty obligations under the Single Convention on Narcotic Drugs, 1961. Alternatively Schedule I drugs could be frozen or be made subject to a provision that they could not be dropped below Schedule II without the assent of Congress.

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respect to offenses within their investigative jurisdiction.

While the Criminal Division has no objection to the proposal, others may object to so broad a power on the basis that it is unnecessary.

VI Professional Criminal Statute

Proposed Section 409 is a provision which enables the Court to double the penalty otherwise authorized on a finding that the person convicted has been involved in a continuing criminal enterprise involving violations of the Act.

The provision calls for a post-trial hearing, to which the rules of evidence are not applicable, on issues regarding whether the defendant occupied a position of management with respect to the offense involved, whether he played a substantial role in a continuing criminal enterprise or whether he has under his control substantial income or resources not demonstrated to have been derived from lawful sources.

We have no quarrel with the provision in theory. Indeed such a provision will aid immeasurably in countering attacks on the bill as being "soft." However, we retain some reservation as to whether the criteria established are sufficiently clear and certain so as to pass constitutional muster.

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While the Criminal Division has no objection to the proposal, others may object to so broad a power on the basis that it is unnecessary.

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TO : The Honorable John W. Dean III DATE: May 7, 1969
Associate Deputy Attorney General

FROM : Michael R. Sonnenreich
Deputy Chief Counsel
Bureau of Narcotics and Dangerous Drugs

SUBJECT: Department of Health, Education, and Welfare's staff papers regarding the "Controlled Dangerous Substances Act of 1969"

The arguments expressed in the staff papers by Mr. Theordore Ellenbogen on May 1, 1969, are quite similar to the proposal made, in draft form, by the law firm of Royall, Koegel, and Wells on April 17, 1969. I direct your attention to my memorandum to you of April 23, 1969, regarding that draft.

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(2) The regulatory and licensing controls over manufacturers, distributors, and dispensers is not a part of a law enforcement function and is separable from other law enforcement efforts.

(3) Specifically, physicians and researchers should not be licensed or monitored by the Department of Justice as this somehow creates a control over their actual medical practice or research.

(4) The Department of Health, Education, and Welfare is being pre-empted by the Department of Justice from its rightful education and research functions.

These appear to be the major bones of contention expressed in the proposed letter to Mr. Mayo from the Secretary of Health, Education, and Welfare. These points have been discussed with staff members of HEW time and time again. These generalized assumptions have been made again and again in response. In an effort to examine these assumptions logically, a brief discussion of each one follows.

It is my personal belief that these assumptions have become a rallying cry, with little thought given as to what they really mean. The truth of the matter is that under the old system prior to Reorganization Plan No. 1 of 1968, effective law enforcement was being hampered by constant bifurcation of authority and conflicting goals and purposes among the different Departments. The arguments advanced in the proposed letter regarding the Reorganization Plan No. 1 of 1968 are purely conjecture and at this point really should not be considered a necessary item for discussion. The proposed legislation is not a vehicle for reorganizing the Bureau of Narcotics and Dangerous Drugs. The proposed bill will expand the Attorney General's powers but not change the existing organizational structure (save for eliminating the tax provisions). Comments should be limited to substantive discussions making the proposal more effective and meaningful. It should not be used as a vehicle for reopening organizational changes and interdepartmental squabbles. It is important to focus on the bill itself and not raise bygone battles already lost.

A. Control of drugs under the proposed act

The constantly reiterated statement that the control of dangerous drugs under the proposed bill is purely a scientific and medical determination is not necessarily a true one. While no one would question that a preliminary determination of abuse potential is the necessary trigger that places in motion any decision for subsequent control, it is, however, only a trigger. It is a determination made by the Scientific Advisory Committee, a group of qualified scientists drawn from a list prepared by the National Academy of Sciences. It is the function of this Committee to evaluate scientific data concerning a particular dangerous drug and determine its potential for abuse. The input at this level comes in not only from the Department of Health, Education, and Welfare but from the academic community and from other agencies, State and local. In addition, actual street abuse of the drugs in question comes from agent investigations which are conducted and carried out by this Bureau. In short, all the basic information, medical, scientific, and actual abuse itself flows to the Committee from many diverse sources. The Committee itself, as an independent body, makes its recommendations. Once such recommendations are made, it is a policy determination as to whether or not a drug should be controlled. At that point in time, since the control of the drug will require enforcement, it is necessary to evaluate that recommendation, along with practical problems of enforcement, to determine whether the drug should be placed under control. This is not something that the Secretary of Health, Education, and Welfare is as qualified to perform as is the Attorney General.

The Department of Health, Education, and Welfare is not enforcement oriented as has been clearly pointed out in the staff papers. Yet the control of a dangerous drug is an enforcement matter since such control results in investigations and regulations to insure against illicit diversion and illicit trafficking. The control of a particular drug also can raise antitrust considerations, as well as international questions. All these factors must be brought together and decided upon. The Attorney General is best able to make such a judgment and in point of fact, has been doing so at the present time. 1/

The Secretary of Health, Education, and Welfare has an important role to play in making available the expertise of his Department to the Scientific Advisory Committee so that it can make better informed, scientific judgments. It is for this reason that two consultants to the Committee are appointed by the Secretary. So too, the Secretary of State has an important role to play in advising the Attorney General of the effect the control of a given drug might have on our international obligations and relations. Other Departments, such as the Departments of Treasury and Defense, will also on occasion have some input for the Attorney General before he makes a decision for control. However, since the ultimate effect of control is enforcement or nonenforcement, the ultimate policy decision should be the Attorney General's.

B. Licensing of the legitimate industry

The major controls established by this Act over the legitimate industry are essentially as follows:

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(2) Records be kept as to the flow of these drugs.

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(3) Manufacturing quotas be established as to Schedules I and II drugs to insure an adequate supply for medical, scientific, and industrial purposes, while deterring over-supplying which might create potential diversion.

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As you are well aware of the provisions of this Act, it is unnecessary to explain in detail what each provision accomplishes. Suffice to say that the regulation of the industry is one of identifying the persons engaged in the legitimate traffic of these drugs and requiring some form of recordkeeping so that we know where the drugs are going, where they came from, and who received them. The licensing provisions and the import and export provisions of this bill do not control the manufacturing practices or the health standards required by the Food and Drug Administration. These provisions in the proposed legislation are directed at identifying potential diversion and preventing such diversion. Such provisions are buttressed further by stronger administrative inspection authority. This scheme is nothing less than preventative law enforcement; the keeping of legitimate drugs out of the hands of illicit traffickers and the policing of the industry to insure that there are adequate safeguards to prevent such diversion. The existing registration system for the Drug Abuse Control Amendments is not adequate and is not working. Although no industry likes more Federal regulation, if we are to have effective law enforcement, we must close the loopholes and require a better accounting, with the ability to revoke and suspend the licenses of those who violate the law.

The enforcement aspects with regard to the import and export provisions is not only of concern to the Bureau but also of concern to the Antitrust Division of the Department of Justice. The existing quota system as it exists raises antitrust problems and the Attorney General is the most proper official to render decisions in this area. Necessarily, he must be able to control the quotas as an enforcement tool. There is apparently a misunderstanding on the part of the Department of Health, Education, and Welfare as to the establishment of these quotas. The determination of this country's medical needs will, of course, be made by the Department of Health, Education, and Welfare as the proposed legislation intends. However, the ultimate establishment of these quotas shall be made by the Attorney General.

The existing regulatory structure as to depressant and stimulant drugs has not stopped diversion and has not given us the ability

to identify all handlers of drugs in a meaningful way. To effectively protect the public and to effectively and efficiently wage a campaign against illicit traffic and illicit diversion of these drugs, the basic enforcement decisions and ability to control dangerous drugs must remain together within the Department of Justice. The Attorney General should make the policy determinations for controlling drugs which principally involves a law enforcement decision as well as a scientific decision, and he must have the ability to exercise effective controls over the legitimate industry to insure against diversion.

C. The regulation of research

The proposed "Controlled Dangerous Substances Act of 1969" would require the licensing of practitioners which include physicans and researchers. Such licensing is tied directly to whether or not such persons are authorized or permitted to engage in such activities by their respective states. The Bureau, from experience, feels that such a license is needed as it is well known that doctors have abused drugs and have abused their privilege of dispensing narcotic and dangerous drugs. With regard to researchers, the existing Drug Abuse Control Amendments exempts these people from the registration requirements. This is a glaring loophole in the law and an obvious potential source of diversion. It is necessary to require that these people be licensed so that, from a law enforcement point of view, an effective monitoring capability over the total flow of these drugs can be achieved. 2/

Persons licensed generally under Schedules II through IV under our proposed legislation can conduct research without any further filing. As to Schedule I substances, which are the most dangerous and/or most subject to abuse, a separate research license is required. Such a license would be granted by the Attorney General if the Secretary of Health, Education, and Welfare adjudged the individual to be a legitimate researcher.

2/ The existing system for the filing of a researcher's qualifications with the Food and Drug Administration under its investigational new drug procedures is insufficient from a law enforcement point of view. While such a procedure might be useful for determining whether or not a given researcher can experiment on a given drug, it is in no way restrictive or required as the researcher, intrastate, need never file his qualifications with FDA.

Our greatest concern in this area, of course, is the nonprofessional researcher or young "experimenter." These drugs are far too dangerous to allow such persons to conduct research with them, even at the animal or in vitro stages of experimentation. To insure against diversion we must control who shall be permitted to conduct research with these substances. It is not just a scientific question but, again, one involving enforcement.

D. The Department of Health, Education, and Welfare's role in drug education and research

There is an apparent misconception on the part of the Department of Health, Education, and Welfare that there is an intent to preempt the drug abuse education and research conducted by the Federal government and vest it with the Attorney General. Categorically, the Bureau of Narcotics and Dangerous Drugs has always maintained that the primary responsibility of these programs rest within the Department of Health, Education, and Welfare, generally, and the National Institute of Mental Health in particular. Theirs is the major effort in drug education and research, along with the function of receiving and distributing Federal grant and research money for such studies. Nothing in the proposed bill is intended to change this role.

The Department of Justice, through the Bureau of Narcotics and Dangerous Drugs, has a minor, but important, role to play regarding research and education. The Bureau, as part of its preventive enforcement program, conducts education programs of a limited nature. As to education, the Bureau sees its role as that of a catalyst to prompt State and local drug abuse control programs. The Bureau further makes speeches, conducts seminars, and provides information to Federal, State, and local agencies as well as the population in general on the dangers of drug abuse.

As for research, the Bureau maintains its own laboratories and conducts necessary research and evaluation of drugs found to be abused on the street. Through its limited contract funds, it authorizes outside research efforts directly pertaining to drug abuse information or findings which are considered immediately necessary to augment its law enforcement goals. The identification of the unknown abuse substances on the street or a short term studies in a particular geographic area to determine why and how abuse is growing are naturally functions necessary to effective law enforcement and must be retained by the Bureau. Such short term programs can best be handled by the Bureau, leaving to the National Institute of Mental Health the broader, bigger, and more long term projects in this area. There is no intent in the proposed

legislation to down grade the predominant role of the National Institute of Medical Health in the area of drug abuse research or is there any intent to down grade the general educational functions of the Department of Health, Education, and Welfare.

Conclusion

In summation, I feel that the re-examination of Reorganization Plan Number 1 undertaken by the staff of the Department of Health, Education, and Welfare is neither necessary nor understandable as a concomitant result of commenting on the proposed "Controlled Dangerous Substances Act of 1969." The control of dangerous drugs and the licensing of the manufacturers, distributors and dispensers of such drugs should remain with the Attorney General and not be transferred. The role of the Department of Health, Education, and Welfare in the area of education and research has never been questioned and it is felt perhaps that the staff persons examining the proposed legislation have over-reacted, fearing what is, in reality, a nonexistent erosion of their Department's role in this area.

Form DJ-150
(Ed. 4-26-65)

UNITED STATES GOVERNMENT DEPARTMENT OF JUSTICE

Memorandum

TO : Honorable John W. Dean, III
Associate Deputy Attorney General

DATE: April 23, 1969

FROM : Mr. Michael R. Sonnenreich
Deputy Chief Counsel
Bureau of Narcotics and
Dangerous Drugs

SUBJECT: Proposed "Controlled Substances Act of 1969" submitted by Royall, Koegel and Wells.

I have examined the draft of April 17, 1969, of a proposed "Controlled Substances Act of 1969" submitted by the law firm of Royall, Koegel and Wells to the Attorney General. Mr. John A. Wells of that firm has discussed with the Office of Chief Counsel, Bureau of Narcotics and Dangerous Drugs, the concern of his client, Hoffmann-LaRoche, Inc., over the inclusion in the Department's proposed "Controlled Dangerous Substances Act of 1969" the drugs librium and valium.1/

I feel this proposal is unacceptable and deficient for the reasons mentioned below:

The draft is an attempt at maintaining the status quo ante of the organizational structure prior to the Reorganization Plan No. 1 of 1968 and seeks to maintain and carry forward the Drug Abuse Control Amendments of 1965 as they relate to the control of the legitimate industry. This proposal would bifurcate enforcement authority by placing the methods for controlling dangerous drugs and narcotics under the Secretary of Health, Education, and Welfare and would also place all research functions within the Department of Health, Education, and Welfare. Further, the Advisory Committee would be responsive to the Secretary of Health, Education, and Welfare and not to the Attorney General. Such a system is unacceptable in that the controlling of these drugs is an enforcement and not solely a scientific function. The scientific function is performed by the Scientific Advisory Committee and would perform the identically same function whether it be under the Attorney General or the Secretary of H.E.W. However, street abuse information and collection of information from such places as Poison Control Centers, Coroners' offices, and police records are all supplied

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by agents of the Bureau. By having it under the Attorney General, this "street" information can be gathered quickly and submitted to the Scientific Advisory Committee, which will also gather scientific information and consult with the Department of H.E.W. This flow of information controlled by one Department (that being Justice) will insure that these substances will be controlled swiftly when there is a need for such control. A bifurcation of this authority would render the control of these drugs purely a matter of scientific inquiry, which it is not. Enforcement policy also plays a substantial role in determining whether drugs should be controlled once the scientific determination is made that there is a potential for abuse. Control is a policy decision drawing upon scientific and enforcement information.

As to research, the Bureau has an important, albeit secondary, role to play in the area of drug abuse research. We have the laboratories and we have the support personnel. The research efforts of the Bureau are directed within a very narrow channel of inquiry and are basically aimed at short-range, fact-finding studies that will be useful to law enforcment and to provide background for specific problems confronting the Bureau itself in terms of specific drugs under control or intended for control. There is no question that the Department of Health, Education, and Welfare has the primary role in this area, but the majority report for the Reorganization Plan No. 1 of 1968 specifically transferred research functions to the Bureau, recognizing the need for this capability, and these functions should remain under the Attorney General (Appendix D of that report). The argument that this research capability would overlap and duplicate manpower requirements and scientific efforts is not correct; a better analysis would show that this research is complimentary rather than duplicative of the work performed by H.E.W. The Bureau many times needs quick responses to research questions. H.E.W. many times is unable to adjust quickly to meet such needs.

As to the regulatory and record keeping requirements in this proposal, they are entirely unsatisfactory and would merely perpetuate one of the glaring loopholes in the existing Drug Abuse Control Amendments. There is no question that the Department's proposed "Controlled Dangerous Substances Act of 1969" is much tougher in this area, requiring a licensing of persons dealing in hallucinogenic, depressant, and stimulant drugs, as well as further permitting a prelicensing inspection and more careful and complete records. We do know that over 90 percent of these drugs on the illicit market were legitimately manufactured and distributed, but diverted, and the Bureau feels that both from an enforcement and policy point of view our legislative scheme is more necessary, realistic, and workable.

The schedules of drugs as listed in this proposal is equally unacceptable, especially as they exclude from control librium, valium, and meprobmate. The Scientific Advisory Committee has recommended control of these drugs and the Bureau favors control of these drugs (see memorandum of March 13, 1969, from Director John E. Ingersoll to the Attorney General). The evidence we have recently obtained plus the hearings carried out to determine whether these drugs should be controlled indicate a real need for control. Further, the recommendation in this proposal that the administrative hearing procedure as set out in section 701 of the Food, Drug, and Cosmetic Act be retained is not acceptable to the Bureau and the Department in that our proposed legislation permits appeals from rulings controlling drugs under the Administrative Procedures Act of 1948. The Department has uniformly supported the provisions of the Administrative Procedures Act of 1948, both as to its rule making and adjudicative provisions. Section 701 is a cumbersome, elaborate procedure that is highly advantageous to the drug companies in that it can delay and effectively stay any recommendations for control for a long period of time. The Administrative Procedures Act guarantees the discontented party the right to appeal and adequately protects the industry against capricious and erroneous determinations for control.

In summation, I feel that the bifurcation of authority between the Department of Justice and the Department of Health, Education, and Welfare, along with some regulation of the industry as presently exists under the Drug Abuse Control Amendments (with the concomitant record keeping provisions), and the exclusion of librium, valium, and meprobamate from control, make this proposal unacceptable in the light of our discussions carried on within the Department of Justice. It is important that the Attorney General have authority to control these drugs and to <u>effectively</u> regulate the industry to prevent diversion, a law enforcement function. Unless there is a desire to destroy the concept and rationale of the Reorganization Plan No. 1 of 1968, I personally feel that this proposal submitted by Royall, Koegel, and Wells, cannot be accepted by the Department of Justic. There is no question that the Congress will discuss in great detail the Department of Justice's role in education and research. I firmly believe that the Department can adequately explain the need for its role in these areas. As to the need for the Attorney General to make the final decision for controlling a substance, I feel that there has been a mistaken pigeonholing of this concept as a medical and scientific determination, without recognizing that this is in fact a law enforcement decision which draws upon science, medicine, <u>and</u> law enforcement to reach the decision for control. I feel the Attorney General can make this policy decision for control more effectively than the Secretary of Health,

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Honorable John W. Dean, III
Associate Deputy Attorney General

April 23, 1969

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May 7, 1969

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to identify all handlers of drugs in a meaningful way. To effectively protect the public and to effectively and efficiently wage a campaign against illicit traffic and illicit diversion of these drugs, the basic enforcement decisions and ability to control dangerous drugs must remain together within the Department of Justice. The Attorney General should make the policy determinations for controlling drugs which principally involves a law enforcement decision as well as a scientific decision, and he must have the ability to exercise effective controls over the legitimate industry to insure against diversion.

C. The regulation of research

The proposed "Controlled Dangerous Substances Act of 1969" would require the licensing of practitioners which include physicans and researchers. Such licensing is tied directly to whether or not such persons are authorized or permitted to engage in such activities by their respective states. The Bureau, from experience, feels that such a license is needed as it is well known that doctors have abused drugs and have abused their privilege of dispensing narcotic and dangerous drugs. With regard to researchers, the existing Drug Abuse Control Amendments exempts these people from the registration requirements. This is a glaring loophole in the law and an obvious potential source of diversion. It is necessary to require that these people be licensed so that, from a law enforcement point of view, an effective monitoring capability over the total flow of these drugs can be achieved. 2/

Persons licensed generally under Schedules II through IV under our proposed legislation can conduct research without any further filing. As to Schedule I substances, which are the most dangerous and/or most subject to abuse, a separate research license is required. Such a license would be granted by the Attorney General if the Secretary of Health, Education, and Welfare adjudged the individual to be a legitimate researcher.

2/ The existing system for the filing of a researchers qualifications with the Food and Drug Administration under its investigational new drug procedures is insufficient from a law enforcement point of view. While such a procedure might be useful for determining whether or not a given researcher can experiment on a given drug, it is in no way restrictive or required as the researcher, intrastate, need never file his qualifications with FDA.

Our greatest concern in this area, of course, is the nonprofessional researcher or young "experimenter." These drugs are far too dangerous to allow such persons to conduct research with them, even at the animal or in vitro stages of experimentation. To insure against diversion we must control who shall be permitted to conduct research with these substances. It is not just a scientific question but, again, one involving enforcement.

D. The Department of Health, Education, and Welfare's role in drug education and research

There is an apparent misconception on the part of the Department of Health, Education, and Welfare that there is an intent to preempt the drug abuse education and research conducted by the Federal government and vest it with the Attorney General. Categorically, the Bureau of Narcotics and Dangerous Drugs has always maintained that the primary responsibility of these programs rest within the Department of Health, Education, and Welfare, generally, and the National Institute of Mental Health in particular. Theirs is the major effort in drug education and research, along with the function of receiving and distributing Federal grant and research money for such studies. Nothing in the proposed bill is intended to change this role.

The Department of Justice, through the Bureau of Narcotics and Dangerous Drugs, has a minor, but important, role to play regarding research and education. The Bureau, as part of its preventive enforcement program, conducts education programs of a limited nature. As to education, the Bureau sees its role as that of a catalyst to prompt state and local drug abuse control programs. The Bureau further makes speeches, conducts seminars, and provides information to Federal, State, and local agencies as well as the population in general on the dangers of drug abuse.

As for research, the Bureau maintains its own laboratories and conducts necessary research and evaluation of drugs found to be abused on the street. Through its limited contract funds, it authorizes outside research efforts directly pertaining to drug abuse information or findings which are considered immediately necessary to augment its law enforcement goals. The identification of the unknown abuse substances on the street or a short term studies in a particular geographic area to determine why and how abuse is growing are naturally functions necessary to effective law enforcement and must be retained by the Bureau. Such short term programs can best be handled by the Bureau, leaving to the National Institute of Mental Health the broader, bigger, and more long term projects in this area. There is no intent in the proposed

legislation to down grade the predominant role of the National Institute of Medical Health in the area of drug abuse research or is there any intent to down grade the general educational functions of the Department of Health, Education, and Welfare.

Conclusion

In summation, I feel that the re-examination of Reorganization Plan Number 1 undertaken by the staff of the Department of Health, Education, and Welfare is neither necessary nor understandable as a concomitant result of commenting on the proposed "Controlled Dangerous Substances Act of 1969." The control of dangerous drugs and the licensing of the manufacturers, distributors and dispensers of such drugs should remain with the Attorney General and not be transferred. The role of the Department of Health, Education, and Welfare in the area of education and research has never been questioned and it is felt perhaps that the staff persons examining the proposed legislation have over-reacted, fearing what is, in reality, a nonexistent erosion of their Department's role in this area.

Mr. John W. Dean, III
Associate Deputy Attorney General

June 24, 1969

Michael R. Sonnenreich
Deputy Chief Counsel

Recommendations by the Treasury Department concerning the Attorney General's authority under the proposed "Controlled Dangerous Substances Act of 1969."

As per your request, attached is a listing of those recommendations made by the Treasury Department that would limit the Attorney General's authority under the new proposed Controlled Dangerous Substances Act. Many of these matters were resolved by compromise; however, some of them have remained in the bill as a result of compromises. Please note that the first point in the attachment, relating to 26 U.S.C. 7607, now raises some difficult policy decisions for the Attorney General which are outside the scope of this bill and affect the existing memorandum of understanding between the Bureau of Customs and the Bureau of Narcotics and Dangerous Drugs which was transferred under the Reorganization Plan No. 1 of 1968.

Attachment

Changes Recommended by the Treasury Department

Affecting the Powers of the Attorney General

1. 26 U.S.C. 7607 was retained in Title VIII of the new bill (subsection (r)), to allow the Bureau of Customs to make arrests without warrants as to any offenses under the laws of the United States relating to narcotic drugs and marihuana. That portion of section 7607 that relates to the Bureau of Narcotics and Dangerous Drugs was repealed and replaced by section 701 of the new bill. This sweeping authority was continued for the Bureau of Customs on the understanding that the Memorandum of Understanding between the two Bureaus would be maintained in force and enforced. Without a clear delineation of functions, such a repealer would never have been contemplated from the view point of the Attorney General since, without a restrictive Memorandum of Understanding, such authority would give the Secretary of Treasury theoretical co-equal powers with the Attorney General in the field of narcotic drug and marihuana enforcement. This theoretical equality was never contemplated by the drafters of the bill, and the removal of existing guidelines now creates the possibility of parity.

2. In the preamble to the bill, the Treasury Department wanted a statement as to its role in the enforcement of those laws "affecting all importations" and the laws against smuggling. Such a statement would tend to freeze the Attorney General out of this area which is somewhat illogical since, as chief law enforcement officer, there would be times when the Attorney General would want to supervise investigations, not only internationally and domestically, but also at the ports and borders of the United States. This language was deleted and a compromise was made (see point 3 below).

3. The Treasury Department was insistent about including in the bill the following statement: "Nothing in this Act shall derogate from the authority of the Secretary of the Treasury under the customs and related laws." With great reluctance the term "and related laws" was inserted in the bill as a compromise measure. This phraseology is nebulous and does not carefully delineate the authority of the Secretary of the Treasury. The intent of the Treasury Department was clear as they suggested other language which would limit the Attorney General's authority by subtracting from his general law enforcement

authority those activities handled by the Secretary of Treasury under the customs and related laws (emphasis supplied). This language was included as a compromise only with the understanding that the Attorney General could direct investigations of the narcotic and dangerous drug laws wherever they occur within and without the jurisdiction of the United States including ports and borders, when, in his judgement, such investigations were necessary.

4. The Treasury Department would not accept a recommendation that their authority be limited to the ports and borders of the United States. They insist on the authority to conduct international and internal investigations if they relate to smuggling. This would detract from the Attorney General's authority in that there would exist two organizations involved in international intelligence gathering and domestic investigations, one of which is not controlled by the Attorney General. This situation is far different from the Memorandums of Understanding which were promulgated by the Federal Bureau of Investigations. In those understandings the authority of the Attorney General was paramount and other investigative agencies were given a sphere of investigation, not as a matter of right, but rather as a matter of comity.

5. The Treasury Department has also recommended that the Secretary be given equal authority with the Attorney General to conduct conferences with law enforcement executives from the various states regarding the drug abuse problem. This recommendation was stricken from the President's message as it would usurp the traditional role of the Attorney General as the principal Federal law enforcement officer. This does not mean that the Treasury Department as well as other departments such as Health, Education and Welfare, and Defense would not be consulted by the Attorney General. However, the focus and the initiative must center on the Attorney General.

6. The Treasury Department recommended an expansion of its law enforcement school to service law enforcement personnel other than the Bureau of Customs agents in the narcotics and dangerous drug area. This recommendation was also deleted from the message as it would be duplicative of the training schools being conducted by the Bureau of Narcotics and Dangerous Drugs and would create unnecessary competition at the State level.

7. The Treasury Department's redraft of the President's message would have restricted the Attorney General's drug strike forces to internal operations only. This recommendation was deleted from the message as the Attorney General has the authority to use such strike forces anywhere in the United States, as well as overseas when appropriate. In this regard, the Treasury Department also sought to establish its own strike forces. This was deleted also from the message as there is no apparent need, given the role of the Bureau of Customs, for such a specialized force. It is superfluous to the major work of that Bureau and would duplicate the Attorney General's efforts. Further, the Bureau of Customs does actively participate on the Organized Crime Task Forces which are under the supervision of the Attorney General.

8. The Treasury Department's redraft sought to include the Secretary of Treasury with the Secretary of State and the Attorney General in the area of international cooperation and liaison. The rubric used by Treasury in justifying its inclusion into this area was its enforcement of the smuggling laws. This recommendation was rejected on the basis that the Secretary of State, as our principal liaison with foreign governments, and the Attorney General, as our principal law enforcement official sufficiently cover our needs in this delicate area and the roles should not be muddied by the interjection of a third party in any negotiations.

Form DJ-96a
(Rev. 6-22-66)

DEPARTMENT OF JUSTICE

ROUTING SLIP

TO: NAME	DIVISION	BUILDING	ROOM
1. ~~Mr. Jack Pearce~~	~~Antitrust~~	~~Main Justice~~	~~3117~~
2. Mr. Durham	DAG	Star MAIN	4119
3.			
4.			

- ☐ SIGNATURE
- ☐ APPROVAL
- ☐ SEE ME
- ☐ RECOMMENDATION
- ☐ COMMENT
- ☐ NECESSARY ACTION
- ☐ NOTE AND RETURN
- ☐ CALL ME
- ☐ PER CONVERSATION
- ☐ AS REQUESTED
- ☐ NOTE AND FILE
- ☐ YOUR INFORMATION
- ☐ ANSWER OR ACKNOWLEDGE ON OR BEFORE _____
- ☐ PREPARE REPLY FOR THE SIGNATURE OF _____

REMARKS

Forwarded in accordance with our telephone conversation.

Hugh Durham

Held this up hoping to get a view from Paul Owens, whose opinions I respect and whose contribution I would have been glad to have. But he is tied up & I don't want to hold this longer

FROM: NAME	BUILDING & ROOM	EXT.	DATE
Mr. Hugh Durham	Rm. 4119	2114	5/22
J Pearce			

Although the comments are ostensibly addressed to weakening of drug control safeguards, their thrust is to preserve for a few domestic manufacturers exclusive rights to manufacture useful drugs, without any check on the price consequences of such action.

There is no reason to assume that the Department of Justice will allow importation of drugs on any basis permitting significant risk of diversion to illicit channels. The terms and conditions of any importation allowed will be controlled by the Attorney General. If stringent measures are needed to prevent diversion of imported drugs with legitimate uses, he can take such measures. He will not allow importation on terms likely to lead to diversion of drugs.

Nor is there substance to the proposition that foreign production would increase by more than the amount which might be allowed into the United States under proper controls, with consequent diversion to illicit channels. The amount to be imported would represent the addition to the legitimate market for foreign firms. There is no substantial reason to suppose that foreign manufacturers would be led to overproduce for the legitimate market available to them by an increase in the size of that market. Producers would not normally behave so. If any special care were needed to prevent a scramble for the market, leading to overproduction -- which we doubt -- this could be prevented by the

terms on which imports were allowed. Finally, as to limitation on international production, it is obvious that if some foreign production is allowed into the United States, it will to that extent replace domestic production, with the result that total world production will be no higher than it otherwise would be.

The comments as to domestic licensing seem to reflect a misunderstanding of the purpose of the bill. The primary responsibility of the Bureau of Narcotics, under the Attorney General, is drug control. The Bureau will not undertake direct price regulation. It may, however, take cognizance of evidence showing that prices are too high. The criteria for determining reasonableness of price relate to reasonable costs and reasonable profits. No explicit statement of criteria is needed. If evidence indicates that additional licensing will result in more-reasonable prices with no significant diminution in the effectiveness of drug control, the Bureau should be able to license the additional manufacturers. There is no reason to suppose that the Bureau will prejudice its primary objective of effective drug control by excessive licensing.

Since the Bureau will not undertake direct price regulation, there is no occasion for judicial review of the reasonableness of price controls. Nor is there good cause for judicial review of the Attorney General's determination to license additional manufacturers -- we do not think persons subject to license have a

right to enhanced prices resulting from limitations on entry into their field which requires routine judicial review of decisions to allow new entrants. The Attorney General, like other heads of Executive Agencies, can be restrained from arbitrary and capricious action, by a suit in equity or a petition for mandamus. This is a sufficient and appropriate control over the licensing function, in our view.

As to the amount of commerce involved, Government action should not unnecessarily lead to enhanced prices in either small or large revenue flows. Many of the substances involved are needed by numerous users: often they are needed when financial pressures on these users are very great. Government restrictions on manufacture and import of these substances should not burden these users and their families beyond the necessities of effective drug control. The provisions of the bill would give the Attorney General sufficient flexibility in his administration of drug controls to avoid imposing unnecessary financial burdens on persons requiring medication.

PROPOSED OMNIBUS DRUG LEGISLATION

The Department of Justice has prepared a draft bill, entitled the Controlled Dangerous Substances Act of 1969, which would codify and revise all Federal laws regulating narcotics and dangerous drugs. The proposed bill unfortunately would weaken some of the safeguards that now prevent the diversion of narcotics from the legal trade into illicit channels.

The Existing Law

Federal statutes now absolutely prohibit the importation into the United States (for other than scientific purposes only) of any narcotic drugs, including such opium derivatives as morphine and codeine, with the single exception that crude opium (and coca leaves, although they are not relevant to this discussion) can be imported under strict licensing controls for medical and scientific use. The statutes also provide for a system of licensing US manufacture of usable derivatives from the imported crude materials. Thus, narcotics on the US market are all domestically manufactured.

Supervision of the importation and manufacture of narcotics is now in the hands of the Attorney General, through the Bureau of Narcotics and Dangerous Drugs, as the result of a 1968 reorganization that transferred those functions from the Treasury Department.

Manufacture of useful derivatives from opium is conducted under provisions of the Narcotics Manufacturing Act of 1960 requiring that licenses be issued only to the "smallest number of establishments which will produce an adequate and uninterrupted supply of narcotic drugs . . . for medical and scientific purposes, consistent with the public interest." Other criteria for granting a manufacturing license are set forth in the statute, including due consideration of the applicant's education, moral character and reputation, the applicant's past drug manufacturing experience and the quality of his products, his technical competence and the existence in his establishment of adequate safeguards against diversion of narcotics into other than legitimate channels. In the words of the Senate Committee Report on the 1960 Act:

> Considering the importance of exercising close control of the production of these potentially dangerous drugs, it is the intention that the manufacture thereof be restricted not only to persons having the requisite technical competence, drug-manufacturing experience, and safeguards

> against diversion, but also to the smallest number of establishments that will produce an adequate and continuous supply of narcotic drugs for medical and scientific purposes.

The existing system of controlling importation and manufacture has worked. There have been no known incidents of diversion of narcotic drugs during the legitimate import or manufacturing stages. This is primarily due to the thoroughness of inspection and regulation that is possible with only a small number of establishments involved in the traffic, as well as the elaborate and costly security precautions taken by the licensees themselves.

Department of Justice Proposals

The Department of Justice proposals would weaken the present system of control in at least two respects -- first, by opening the door to importation of finished narcotic drugs, and second, by creating the possibility of an increase in the number of licensed manufacturers.

Importation. Whereas existing law forbids any importation of finished narcotic drugs, the new proposals would permit importation of narcotic drugs under regulations issued by the Attorney General. There is no point in making these changes unless it is contemplated that the power will be used and such importation permitted.

The security risks of expanded importation are clear. While crude opium, for example, is a relatively bulky substance, its morphine and codeine derivatives are concentrated, extremely valuable and far more subject to diversion enroute. Only limited security measures could be taken to protect them prior to their arrival at customs warehouses in this country. While crude opium arrives in a very few shipments originating at only two sources (the governments of Turkey and India, the two producing countries), private shipments would be many and would emanate from multiple sources abroad in response to the newly created demand in the United States.

If importation of finished narcotic drugs were permitted, the initial point of vulnerability to theft and diversion would be moved back up the line and could occur even before the drugs entered the U. S. For example, it would be much more difficult to protect morphine concentrates from diversion in the import trade than it is to protect bulky or crude opium. Competition for the new market here could spur an increase in the production of finished narcotics abroad, and much of the resulting production could eventually find its way into the illicit trade. To prevent that happening, the

U.S. would have to rely on greatly improved smuggling control and increased diligence of other countries' enforcement and security measures.

The proposed laws are directly opposed to our longtime policy of seeking limitation on the international production and manufacture of narcotics, evidenced by our State Department's recent expenditures to help reduce opium production in Turkey, and our participation in programs of the U. N. and other international agencies.

Manufacture. The new proposals would establish an additional criterion which the Attorney General must consider in licensing manufacturing establishments. Instead of issuing licenses to the "smallest number" of establishments that can supply the demand, as under the present law, the Attorney General would be required to issue licenses to a number of establishments "small enough" to avoid diversion while supplying demand for the finished narcotics "at reasonable prices." By introducing price considerations into the determination, the new proposals would force a compromise between economic and security considerations which can only weaken the security and control features of the present law.

Besides, the proposed law contemplates a poorly conceived price control device at best. It contains no standards whatsoever for determining what prices are reasonable or no method of judicial review under which a manufacturer could test his contention that the standards had not been complied with. Excessive price reductions with respect to these drugs could put pressure on costs and on the ability of a manufacturer to provide maximum security for his products.

The weakening of security which could result from an increase in a number of manufacturers could not be offset by any significant and meaningful economic gains. This is so because the industry is small with an annual volume of less than $15 million and remains at that size because the products are not promoted or advertised. There is no public interest behind increasing this volume through price reductions, and furthermore reductions in the cost of finished narcotic drugs would have little, if any, significance on the costs of the drugs and medicines which the consumer buys. An increase in the number of manufacturers in this small industry of more or less finite size would only serve to divide the limited production among a greater number.

Conclusion

The present system operated under the present law works well for narcotic drugs. It should not be changed solely for the purpose of bringing the law more into line with doctrinaire anti trust concepts in the face of the clear probability that more harm to the public interest would be accomplished than good.

John Dean —
What is status? In my opinion private lawyers make a good case. Reo. K.

STEPTOE & JOHNSON

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WEST VIRGINIA OFFICES
CLARKSBURG
UNION BANK BUILDING
CHARLESTON
KANAWHA VALLEY BUILDING

June 13, 1969

The Honorable George Revercomb
Associate Deputy Attorney General
Room 4206
Department of Justice
Tenth and Constitution Avenue, N. W.
Washington, D. C. 20053

Dear George:

In accordance with our telephone conversation the other day, I am enclosing a copy of the material which was left with the Anti-Trust Division in regard to the legislation affecting imports of narcotics. Your attention to this is deeply appreciated.

With best regards,

Sincerely,

Jack

Robert J. Corber

RJC/rm

Enclosure

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June 13, 1969

Lewis Bernstein, Esquire
Chief, Special Litigation Section
Antitrust Division
Department of Justice
Washington, D. C.

Re: Controlled Dangerous Substances Act

Dear Lew:

Following our talk with you and Jack Pearce we have prepared the enclosed to further explain our position on the antitrust aspects on the proposed price control and importation provisions that would affect the domestic manufacturers of opium derivatives.

We are also delivering a copy to George Revercomb, as we talked with him initially on the general question.

Sincerely yours,

Stephen Ailes

Enclosure

cc: George H. Revercomb, Esquire
Jack Pearce, Esquire

June 12, 1969

NARCOTICS LEGISLATION: ANTITRUST ASPECTS

The draft Controlled Dangerous Substances Act, in response to antitrust considerations, would eliminate the existing ban on importation of finished narcotic drugs and would authorize the Attorney General to license additional manufacturers of narcotics until prices of finished narcotics became "reasonable." The difficulties with the proposed changes are discussed below.

1. Control of narcotics traffic is weakened by the proposals.

The manner in which control is weakened is outlined in a separate memorandum recently submitted to the Department of Justice. We submit that the importance of adequate control far outweighs whatever economic benefits could result in the small, stable business of extracting opium derivates, from the antitrust modifications that have been proposed.

2. The proposed provision for price control does not contain adequate standards to guide the Attorney General in his determination of what is a "reasonable" price, or provisions for judicial review.

That the proposed law gives price control power to the Attorney General is quite clear. The Director of the Bureau of Narcotics and Dangerous Drugs could, and perhaps should

under this provision, determine what he considers to be reasonable prices for the products involved and order the industry to that level under threat of new competitors. He would make such a determination unfettered by any legislative instructions whatsoever.

An example of the guidelines and provisions for judicial review that should accompany a system of price control, in order to avoid the possibility of arbitrary action, is the Emergency Price Control Act of 1942. That legislation set forth standards to "control the Controllers" and a system of judicial review. Even in time of national emergency, nothing less was deemed satisfactory, or even in accordance with the constitution.[1/]

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1. Writing of the necessity of standards to govern OPA in setting price controls, David F. Cavers wrote in 1947:

> Whenever a legislature determines thus to direct the action of officials, it is confronted by the problem of how far to limit or channel the exercise of the authority it seeks to confer. If the legislature were to do no more than state a broad policy goal and empower the official to take whatever action he deemed appropriate to attain it, then the legislature would have so far abdicated its authority with respect to the problem as to have defeated, in the particular situation, the functioning of the constitutional scheme of government. Its failure to assume responsibility would in effect have transferred to the executive branch of the government authority which the Federal and State constitutions vest in the legislative. Moreover, this failure would vitiate the grant of authority, and persons adversely affected by its purported exercise could challenge the authority in the courts.

[Footnote 1 continued on page 3.]

Under existing legislation the Attorney General may consider in licensing new manufacturers certain specific criteria and "such other factors as may be relevant to and consistent with the public interest." 21 U.S.C.A. §506(a)(5). Antitrust considerations are certainly among those factors and should continue to be considered among all relevant public interest factors. In that manner specific antitrust abuses could be investigated if and when they arise.

3. No real benefits are to be derived from increased domestic or foreign competition in the manufacture of finished narcotics.

A. The industry is small, with total annual volume of about $13,000,000. Codeine is the principal product, accounting for over 90 percent of volume. It is sold principally to formulators of prescription drugs and cough preparations, ultimately appearing in such pain-relieving (analgesic) compounds as Empirin Compound with codeine and such cough preparations (antitussives) as Robitussin and Cheracol. Amounts are also sold to hospitals, pharmacists and physicians. It is estimated that about 30 percent of the bulk codeine is now used in cough preparations and 70 percent in analgesics. Far smaller amounts of morphine

[Footnote 1, continued from page 2]
Cavers cites Schechter Poultry Co. v. U.S. 495. "Problems in Price Control: Pricing Standards," 2-3. Office of Temporary Controls,

and medicinal opium are manufactured, as well as other less-known narcotics. Based on the last annual report of the Bureau of Narcotics and prices taken from the Drug Prices Red Book, the size of the industry for 1966 was as follows:

Codeine	31,400 kg*	at $360/kg	$11,300,000
Morphine	691	350	241,850
Med. Opium	3,976	50	198,800
Ethylmorphine	262	420	110,040
Hydocodone	486	750	364,500
Papaverine**	14,046	80	1,120,000
			$13,335,190

*(The average figure for 1960-67 is lower, 25,575 kg, and the figure was 22,257 for 1967. 1966 figures were used because 1967 not available for some drugs.)

**(The papaverine shown is principally synthetically produced by firms other than those licensed to extract opium and only small amounts are extracted from opium.)

B. The industry faces competition from synthetic substitutes, and is only part of a larger market. Increasingly, synthetic drugs can be and are substituted for opium derivatives in their medical uses. The opium derivative manufacturers supply only a part, and a diminishing part, of the relevant market for analgesics and cough preparations.

A striking example of the competition from synthetics is the case of pethidine (Demerol), an effective substitute for morphine. Introduced in the 1940's, pethidine has grown in use from 1,320 kg in 1945 to 12,884 kg in 1967, nearly a tenfold increase, at the expense of morphine. The use of morphine now is only about one-fifth of what it was immediately following World War II. Even in the 1960's,

long after the introduction of Demerol, the use of pethidine continues to grow from year to year, while sales of morphine further dwindle.

Codeine also faces strong competition from synthetics in both its analgesic and antitussive end uses.

In cough syrups, the principal synthetic is "dextromethorphan," manufactured under patent by Hoffman-LaRoche and found in such preparations as Vicks "Formula 44." The recommended single dosage of the codeine and dextromethorphan syrups is approximately the same, about 10-15 milligrams. Therefore, relative production figures for the two substances are an indication of market share. Dextromethorphan has been on the market about five years, and marketing personnel in the industry estimate that its consumption has risen from perhaps 10,000 kg in 1964 to 25,000 kg in 1968. Since the total use of codeine in cough syrup is estimated at only about 10,000 kg for 1968,[2/] dextromethorphan appears to now have over two-thirds of that market and has accounted for all of the growth in the market since its introduction.

Codeine's synthetic competitors for analgesic use are Lilly's Darvon and Sterling's Talwin. The common dosage form of Darvon contains one grain of its effective ingredient,

2. Use of codeine in exempted preparations, i.e., cough syrups, was 8,084 kg in 1967, according to BNDD figures.

propoxyphene hydrochloride. The comparable dosage of codeine is one-half grain. It is estimated that 60,000 kg[3/] of propoxyphene hydrochloride was used for Darvon in 1968, compared with approximately 20,000 kg of codeine used for all analgesics. Since one kilogram of codeine does the work of two kilograms of the synthetic, in terms of dosage units sold Darvon has a greater market share than codeine by a ratio of about three-to-two (i.e., one and one-half times as many Darvon doses are sold).

Talwin is manufactured by Sterling Drug Company. For 1968 its sales are estimated at $8,000,000 to $10,000,000. The common dosage is one-half grain of the analgesic ingredient, which is directly comparable to codeine. About 1,500 kg of Talwin's analgesic ingredient were used in 1968. Although these figures alone would portray Talwin as a minor factor in the market, a new 50 milligram tablet has recently been approved by FDA (all previous sales have been in injectible form) and trade publications estimate that 1969 sales for Talwin will be in the area of $40,000,000, indicating the use of 5,000 to 7,000 kg of the analgesic ingredient, or roughly one-quarter to one-third the amount of codeine used for analgesics.

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3. Drug publications indicate a dollar volume of $60,000,000 for Darvon, which is sold in capsules containing 65 mg of propoxyphene hydrochloride, for $7.00 a hundred. This is the basis for the 60,000 kg figure.

Taken together, Darvon and Talwin can reasonably be expected to account for more than twice the market share of codeine in the prescription analgesics in 1969.

A major factor in the market growth of the competitive synthetics is that, unlike codeine, they may be advertised and promoted. Dextromethorphan cough syrups are promoted directly to the public, and Darvon and Talwin (being prescription drugs) are promoted to doctors. For many years the Bureau of Narcotics has prohibited promotion of codeine and other narcotic preparations. (Memorandum of Commissioner of Narcotics, November 12, 1946.) Federal policy has been to discourage the use of the opium derivatives; and it has been determined that intense promotion and price competition would not further that policy.

C. The industry is stable in size. Additional manufacturers or importers will simply redivide the existing market. The competition from synthetics and the public interest factors prohibiting promotion of its products, are two strong factors that keep the industry stable in size. Any growth has been due primarily to increases in population and the availability of medical care. As noted, the use of morphine is sharply down over the last 20 years. The use of medicinal opium is at best holding its own. Average use of codeine for the period 1946-53 was 20,120 kg per year; while from 1960-67 the average figure

was 25,575 kg. This is an average annual increase of only 2%, over the 14 years separating the midpoints of the two periods of comparison.

Because of high fixed costs, the market will only support a small number of manufacturers economically. If the number becomes too large, and certainly if there were unlimited supplies of imported finished narcotics, one or more of the presently licensed manufacturers would probably be forced to leave the market. Further, economic pressure to cut costs, would make the important security measures that now require substantial outlays of both capital and operating funds more and more difficult to maintain. Finally, new applicants for licenses would in all likelihood be limited to firms with a special interest, since no others would be attracted to a small, tightly regulated industry with little growth prospect. Specifically, only drug companies that now purchase large amounts of bulk codeine could be expected to apply. The antitrust problems resulting from their vertical integration and distribution of codeine to their competitors could be far more serious than any potential problems under the present system.

Notwithstanding that the total industry has not grown appreciably, there have been significant shifts in the market shares of the three manufacturers during the past 30 years. Manufacturing quota figures published by the

Bureau of Narcotics and Dangerous Drugs are not broken down by company, but the Bureau's files contain information necessary to determine the relative market shares over the years. Changes in market share result not only from purchasers changing suppliers, but also from the success or failure of particular end product lines and the impact of federal regulation.[4/] In addition, the introduction of a new end product by one of the principal customers can create demand for bulk narcotics of precise specifications, which the existing supplier may not produce.

D. Prices charged by the industry have been stable for 20 to 30 years despite inflation. Based on industry-wide price information, found in the Drug Topics Red Book and elsewhere, prices for the major finished narcotics, codeine, morphine and medicinal opium, have remained more or less level since the end of World War II and have increased only in the order of 10% since as long ago as 1933. The price of crude opium fluctuates widely, and manufacturers have not been aided by a general reduction in the cost of raw material, in holding the price line during this period. It has been made possible by increased efficiency and absorption of large increases in labor and capital costs. In terms of the general purchasing power

4. When dihydrocodeinone was banned from use in cough preparations some years ago, its use declined and with it the sales of its manufacturers.

of the dollar, the price of finished narcotics sold by the industry today is perhaps half of the World War II price.

E. Even if prices of bulk narcotics could be reduced, the consumer would not benefit. The value of the narcotic component represents a small part of the retail price of prescription drugs and cough preparations. Any reduction in the price of finished narcotics would benefit only the other drug firms and pharmacists who formulate and retail the end products, and would not be passed on to the public.

A clear example of this is the cough preparation Robitussin. Marketing personnel in the industry surveyed drugstores selected at random in eight U.S. cities and found that the retail price of the 4-ounce size varied from $1.49 to $1.50. The cost to the formulator of the codeine contained in each 4-ounce bottle is only 9.2 cents.[5/] The ratio of the cost of the codeine to the price of the cough syrup therefore varies between 3.7% and 6.1%. Even a substantial reduction of 25% in the cost of the codeine would make only a 2.3-cent difference in the formulator's costs. By no stretch of the imagination will this be passed on to the public, since the prices at retail vary by over $1.00 from store to store and are influenced not by the cost of codeine but by other factors, such as

5. Each bottle contains one grain of codeine per fluid ounce, at 2.3 cents per grain.

distribution costs and markup, that are of far greater magnitude. Robitussin is typical of the cough preparations in this regard.

The ratio of the cost of codeine to the total retail price of analgesic compounds averages approximately the same as the ratio for cough preparations. However, different dosage units are available among analgesics, ranging from one-fourt grain to one grain. The stronger the dosage, the greater the relative cost of the codeine; but the codeine cost is very rarely above 10% of the total, and is as low as 2% in some compounds. The price variations among different pharmacists are narrower with analgesics than with cough syrups, but prices at retail are still determined independently of the cost of codeine. For example, the typical retail price of 12 tablets of the one-eighth grain dosage of Burroughs-Wellcome's empirin compound with codeine is about $1.80, the same as the price of the one-fourth grain dosage, notwithstanding that one has double the amount of codeine. The retail price of the same number of tablets of the one grain dosage costs only $2.00, and contains eight times the codeine of the $1.80 prescription.

Other compounds show a different pattern, equally independent of the cost of codeine. The one-eighth grain dosage of Robins' phenaphen with codeine has a typical price of $1.60 for 12 capsules, while the one grain dosage

typically sells for $2.60. The difference in retail price is $1.00, but the difference in the cost of codeine is only 22.5 cents.

4. Conclusion

It follows from the above that any weakening of the system of control is too great a price to pay for economic benefits which are theoretical at best in the present situation.

PROPOSED OMNIBUS DRUG LEGISLATION

The Department of Justice has prepared a draft bill, entitled the Controlled Dangerous Substances Act of 1969, which would codify and revise all Federal laws regulating narcotics and dangerous drugs. The proposed bill unfortunately would weaken some of the safeguards that now prevent the diversion of narcotics from the legal trade into illicit channels.

The Existing Law

Federal statutes now absolutely prohibit the importation into the United States (for other than scientific purposes only) of any narcotic drugs, including such opium derivatives as morphine and codeine, with the single exception that crude opium (and coca leaves, although they are not relevant to this discussion) can be imported under strict licensing controls for medical and scientific use. The statutes also provide for a system of licensing US manufacture of usable derivatives from the imported crude materials. Thus, narcotics on the US market are all domestically manufactured.

Supervision of the importation and manufacture of narcotics is now in the hands of the Attorney General, through the Bureau of Narcotics and Dangerous Drugs, as the result of a 1968 reorganization that transferred those functions from the Treasury Department.

Manufacture of useful derivatives from opium is conducted under provisions of the Narcotics Manufacturing Act of 1960 requiring that licenses be issued only to the "smallest number of establishments which will produce an adequate and uninterrupted supply of narcotic drugs . . . for medical and scientific purposes, consistent with the public interest." Other criteria for granting a manufacturing license are set forth in the statute, including due consideration of the applicant's education, moral character and reputation, the applicant's past drug manufacturing experience and the quality of his products, his technical competence and the existence in his establishment of adequate safeguards against diversion of narcotics into other than legitimate channels. In the words of the Senate Committee Report on the 1960 Act:

> Considering the importance of exercising close control of the production of these potentially dangerous drugs, it is the intention that the manufacture thereof be restricted not only to persons having the requisite technical competence, drug-manufacturing experience, and safeguards

against diversion, but also to the smallest number of establishments that will produce an adequate and continuous supply of narcotic drugs for medical and scientific purposes.

The existing system of controlling importation and manufacture has worked. There have been no known incidents of diversion of narcotic drugs during the legitimate import or manufacturing stages. This is primarily due to the thoroughness of inspection and regulation that is possible with only a small number of establishments involved in the traffic, as well as the elaborate and costly security precautions taken by the licensees themselves.

Department of Justice Proposals

The Department of Justice proposals would weaken the present system of control in at least two respects -- first, by opening the door to importation of finished narcotic drugs, and second, by creating the possibility of an increase in the number of licensed manufacturers.

Importation. Whereas existing law forbids any importation of finished narcotic drugs, the new proposals would permit importation of narcotic drugs under regulations issued by the Attorney General. There is no point in making these changes unless it is contemplated that the power will be used and such importation permitted.

The security risks of expanded importation are clear. While crude opium, for example, is a relatively bulky substance, its morphine and codeine derivatives are concentrated, extremely valuable and far more subject to diversion enroute. Only limited security measures could be taken to protect them prior to their arrival at customs warehouses in this country. While crude opium arrives in a very few shipments originating at only two sources (the governments of Turkey and India, the two producing countries), private shipments would be many and would emanate from multiple sources abroad in response to the newly created demand in the United States.

If importation of finished narcotic drugs were permitted, the initial point of vulnerability to theft and diversion would be moved back up the line and could occur even before the drugs entered the U. S. For example, it would be much more difficult to protect morphine concentrates from diversion in the import trade than it is to protect bulky or crude opium. Competition for the new market here could spur an increase in the production of finished narcotics abroad, and much of the resulting production could eventually find its way into the illicit trade. To prevent that happening, the

U.S. would have to rely on greatly improved smuggling control and increased diligence of other countries' enforcement and security measures.

The proposed laws are directly opposed to our longtime policy of seeking limitation on the international production and manufacture of narcotics, evidenced by our State Department's recent expenditures to help reduce opium production in Turkey, and our participation in programs of the U. N. and other international agencies.

Manufacture. The new proposals would establish an additional criterion which the Attorney General must consider in licensing manufacturing establishments. Instead of issuing licenses to the "smallest number" of establishments that can supply the demand, as under the present law, the Attorney General would be required to issue licenses to a number of establishments "small enough" to avoid diversion while supplying demand for the finished narcotics "at reasonable prices." By introducing price considerations into the determination, the new proposals would force a compromise between economic and security considerations which can only weaken the security and control features of the present law.

Besides, the proposed law contemplates a poorly conceived price control device at best. It contains no standards whatsoever for determining what prices are reasonable or no method of judicial review under which a manufacturer could test his contention that the standards had not been complied with. Excessive price reductions with respect to these drugs could put pressure on costs and on the ability of a manufacturer to provide maximum security for his products.

The weakening of security which could result from an increase in a number of manufacturers could not be offset by any significant and meaningful economic gains. This is so because the industry is small with an annual volume of less than $15 million and remains at that size because the products are not promoted or advertised. There is no public interest behind increasing this volume through price reductions, and furthermore reductions in the cost of finished narcotic drugs would have little, if any, significance on the costs of the drugs and medicines which the consumer buys. An increase in the number of manufacturers in this small industry of more or less finite size would only serve to divide the limited production among a greater number.

Conclusion

The present system operated under the present law works well for narcotic drugs. It should not be changed solely for the purpose of bringing the law more into line with doctrinaire anti trust concepts in the face of the clear probability that more harm to the public interest would be accomplished than good.