

Title 21 - FOOD AND DRUGS

Chapter II - Bureau of Narcotics and Dangerous Drugs,
U.S. Department of Justice

PART 320 - DEPRESSANT AND STIMULANT DRUGS;
DEFINITIONS, PROCEDURAL AND
INTERPRETATIVE REGULATIONS

Meprobamate: Exemption of Certain Combination Drugs

By an order published in the Federal Register on June 6, 1970, the Director of the Bureau of Narcotics and Dangerous Drugs ended the stay of the effective date of the final Order published in the Federal Register on December 6, 1967, (32 F.R. 17473), listing meprobamate as a drug subject to control under the Drug Abuse Control Amendments of 1965. This Order is to take effect July 6, 1970.

Notice is hereby given that the Order published June 6, 1970, is hereby supplemented in that the following combination drugs will not be controlled and thereby do not have to meet the requirements of Section 511(c) and (e), and the recordkeeping requirements of Section 511(d)(1) of the Federal Food, Drug, and Cosmetic Act:

Milprem - 200	Meprobamate 200 mg. Conjugated Estrogens - equine 0.4 mg.	Wallace Pharmaceuticals
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Milprem - 400	Meprobamate 400 mg. Conjugated Estrogens - equine 0.4 mg.	Wallace Pharmaceuticals
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Milpath - 200	Meprobamate 200 mg. Tridihexethyl Chloride 25 mg.	Wallace Pharmaceuticals
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Milpath - 400	Meprobamate 400 mg. Tridihexethyl Chloride 25 mg.	Wallace Pharmaceuticals
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Miltrate - 10	Meprobamate 200 mg. Pentaerythritol tetra- nitrate 10 mg.	Wallace Pharmaceuticals
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Miltrate - 20	Meprobamate 200 mg. Pentaerythritol tetra- nitrate 20 mg.	Wallace Pharmaceuticals
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Title 21, Chapter II, Subsection 320.8(b) of the Code of Federal Regulations is hereby amended by adding the above listed combinations to the end of that subsection. Since this supplement to the order published in the Federal Register on June 6, 1970 is non restrictive, it will become effective on July 6, 1970.

DATED: JUN 29 1970



John E. Ingersoll
Director
Bureau of Narcotics
and Dangerous Drugs

Title 21 - FOOD AND DRUGS

Chapter II - Bureau of Narcotics and Dangerous Drugs
U.S. Department of Justice

PART 320 - DEPRESSANT AND STIMULANT DRUGS;
DEFINITIONS, PROCEDURAL AND
INTERPRETATIVE REGULATIONS

Meprobamate: Proposed Delisting as Drug Subject to Control

By an order published in the Federal Register on June 6, 1970, (35 F.R. 8822), the Director of the Bureau of Narcotics and Dangerous Drugs ended the stay of the effective date of the final order published in the Federal Register on December 6, 1967, (32 F.R. 17473), listing meprobamate as a drug subject to control under the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Abuse Control Amendments of 1965. The order of June 6, 1970, made control of meprobamate effective on July 6, 1970.

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(v), 511, 701, 52 Stat. 1055, as amended, 79 Stat. 227 et seq; 21 U.S.C. 321(v), 360a, 371), and under the authority vested in the Attorney General by Reorganization Plan No. 1 of 1968 (33 F.R. 5611) and redelegated to the Director, Bureau of Narcotics and Dangerous Drugs (28 CFR 0.100) (33 F.R. 5580), the Director proposes that §320.3(c)(1) be amended by delisting meprobamate.

All interested persons are invited to submit their views in writing regarding this proposal. Views and comments should be submitted, preferably in quintuplicate, addressed to the Office of Chief Counsel, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Room 611, 1405 Eye Street NW., Washington, D.C. 20537, within 30 days following the date of publication of this notice in the FEDERAL REGISTER, and may be accompanied by a memorandum or brief in support thereof.

DATED:

JOHN E. INGERSOLL,
Director
Bureau of Narcotics and
Dangerous Drugs.

Title 21 - FOOD AND DRUGS

Chapter II - Bureau of Narcotics and Dangerous Drugs
U.S. Department of Justice

PART 320 - DEPRESSANT AND STIMULANT DRUGS;
DEFINITIONS, PROCEDURAL AND
INTERPRETATIVE REGULATIONS

Meprobamate: Stay of Effective Date of Order Listing
Drug as Subject to Control

In the matter of listing meprobamate as a drug subject
to control under the Drug Abuse Control Amendments of 1965:

By an order published in the Federal Register on
June 6, 1970, (35 F.R. 8822), the Director of the Bureau
of Narcotics and Dangerous Drugs ended the stay of the
effective date of the final order published in the
Federal Register on December 6, 1967, (32 F.R. 17473), listing
meprobamate as a drug subject to control under the Federal
Food, Drug, and Cosmetic Act, as amended by the Drug Abuse
Control Amendments of 1965. The order of June 6, 1970,
made control of meprobamate effective on July 6, 1970.

It is hereby ordered,

That the end of the stay of the effective date
listing meprobamate as a drug subject to control under
the Drug Abuse Control Amendments of 1965, ordered by the
publication in the Federal Register of June 6, 1970 is
rescinded.

DATED:

JOHN E. INGERSOLL,
Director
Bureau of Narcotics and
Dangerous Drugs

Free Hemo of compliance

invol. } A) crim. penalty - 1 yr jail for illegal possession
(7) } 5 yrs illegal sale
B) civil penalty

180 (2) change labeling requirements - 180 days

immov. ③ keep records - who ship to, etc.

already doing a
new made quarterly for inspect.

immed ④ take inventory - but this they have on we can defer -

⑤ limit of prescriptions to 5 times

⑥ Must register with DROO - sol already done

The Honorable
John W. Mitchell
The Attorney General

John E. Ingersoll
Director
Bureau of Narcotics and
Dangerous Drugs

Control of Meprobamate

You have asked for a discussion of our decision to control meprobamate and whether or not a stay of our final control order should be made. Set out below are the reasons why I feel that the final order should not be stayed and should take effect on July 6, 1970. I have also set out below possible alternatives for staying the order should you decide that this is appropriate.

Reasons for Controlling Meprobamate

(1) Historically, the initial proposal to place meprobamate under the control of the Drug Abuse Control Amendments of 1965 was published in the Federal Register on January 18, 1966. Subsequently, an order was published in the Federal Register on March 19, 1966, placing meprobamate under control. Control was stayed by the objections of Carter-Wallace, Inc., which requested a hearing on the matter. This hearing began on June 27, 1966, and ended on September 16, 1966, covering 4,891 pages of testimony. As a result of the hearing, on April 13, 1967, the Commissioner of Food and Drugs published findings of fact and conclusions of law in the Federal Register and ordered that meprobamate be placed under control. Carter-Wallace requested that this order be stayed pending judicial review of the Commissioner's decision by the U.S. Court of Appeals for the Fourth Circuit. Argument was heard before the Fourth Circuit on October 31, 1968, and their decision affirming the decision of the Commissioner of Food and Drugs was handed down on November 4, 1969. On April 17, 1970, Carter-Wallace filed a petition for a writ of certiorari to the U.S. Supreme Court. On June 1, 1970, the U.S. Supreme Court denied the petition. On June 6, 1970, I had published in the Federal Register an order ending the stay of effectiveness of control of meprobamate. This order is to take effect on July 6, 1970.

Linda Fardley

On reviewing the history of the control decision, there is no indication that anyone at the Food and Drug Administration agreed that meprobamate should be tried concurrently with Librium and Valium; and in fact, the drugs were tried consecutively--first meprobamate, and then Librium and Valium. There was a recognition at that time that meprobamate was a different drug from that of the drugs Librium and Valium. Because it is not similar, it was tried separately from those two drugs. The arguments raised by counsel for Carter-Wallace to the contrary cannot be substantiated. It should further be noted that other drugs which also have a depressant effect on the central nervous system were controlled at the same time and are under control now. These drugs are:

- (a) Chloral hydrate;
- (b) Placidyl, produced by Abbott;
- (c) Valmid, produced by Eli Lilly;
- (d) Doriden, produced by Ciba; and
- (e) Noludar, produced by Hoffmann-La Roche.

Therefore, counsel's discussion of the "uniqueness" of meprobamate vis a vis Librium and Valium should be read in the context of these other drugs that were controlled at the same time and are presently under control. To allow a stay in the case of meprobamate would mean that any time drugs are controlled together the ultimate listing of these drugs would depend on the last drug controlled in point of time. This does not make sense from a public health point of view.

(2) In light of the current Librium-Valium Hearings, the stay would set an unwanted precedent. This is not, as Carter-Wallace says, a unique situation. It will occur time and time again as other commercially usable drugs are brought under control. Assuming that Hoffmann-La Roche appeals to the U.S. Supreme Court and the Court affirms control of Librium and Valium, if the Controlled Dangerous Substances Act still has not been passed, we would have to grant the same stay to Hoffmann-La Roche as that requested by Carter-Wallace. This same situation would arise in our attempts to control any other drug that has similar properties or usage.

(3) In answer to the argument that Carter-Wallace's detail men are put at a great competitive disadvantage, we would point out that, prior to determining that a drug should be controlled, both antitrust and competitive factors are considered. At this stage of the meprobamate case, considerations of economic competition cannot be given much weight, since such considerations would then apply to the other drugs that were controlled at the same time. Further, this argument could be presented, and will be presented if the precedent is set, by any firm which manufactures a drug to be controlled for which there is a similar uncontrolled product on the market. Most importantly, although as a matter of course we consider the economic effects of Federal regulation on the legitimate drug industry, our primary responsibility is to the health and welfare of the American public. The timing of exhaustion of administrative and judicial remedies should not be the pivotal point in determining the listing of a drug as subject to control when other drugs are undergoing the control process.

(4) The Bureau has been receiving increasing numbers of reports from medical literature and from law enforcement agencies that meprobamate is being more and more abused. On a comparative basis with Librium and Valium, the reports concerning the abuse of meprobamate are much more numerous and much more serious in nature. For example, during the Miami, Florida, phase of Operation Eagle at least one defendant was found to be in possession of quantities of meprobamate, both in prescription bottles and in clear bottles. This defendant was also found to be in possession of such other drugs as benzocaine, belladonna, suspected cocaine, suspected opium, and quantities of assorted amphetamines and barbiturates, plus a large quantity of hypodermic syringes and needles.

(5) The order notifying the public that meprobamate will be controlled as of July 6, 1970, has already been published (June 6, 1970). In light of this publication, the Bureau and the Department would be put in an embarrassing position by staying control with no logical reason. This point is especially cogent when one considers that this matter has been under litigation for four and one-half years.

(6) We are dubious about Carter-Wallace's statement that they will fight for passage of the Controlled Dangerous Substances Act if we stay effectiveness of control. In fact we see the matter as being quite the contrary, in that controlling meprobamate would give Carter-Wallace greater incentive to have the bill passed, thereby bringing "competitive" products under control--i.e., Librium and Valium.

Should a Stay Be Granted

Should you decide that meprobamate should not be controlled at the present time, we can place an order in the Federal Register rescinding our order of June 6, 1970. We will also notify the manufacturers, wholesalers, and pharmacy associations of this order so that they need not change their labeling requirements, storage techniques, and inventory controls. We would have to state in the rescinding order that this is a unique situation, and interpret the initial control decisions over meprobamate, Librium, and Valium as being intended to have controlled the three drugs simultaneously. We will further have to specifically negate any intent that the effective date of control of chloral hydrate, Placidyl, Valmid, Doriden, and Noludar was to have been the same as that of meprobamate, Librium and Valium.

D/CC/MRSonnenreich/le/4644/7-1-70

UNITED STATES GOVERNMENT

DEPARTMENT OF JUSTICE

Memorandum

TO : Dr. Roger Egeberg
Assistant Secretary for Health
and Scientific Affairs
Department of Health, Education,
FROM : and Welfare

DATE:

John E. Ingersoll
Director, Bureau of Narcotics
SUBJECT: and Dangerous Drugs

Staff Revision of H.R. 13743

Pursuant to the conversation between yourself, Creed Black, John Dean, and myself on Wednesday, June 10, 1970, I am setting forth the major problem areas in the Staff Revision that I feel require change. Also included as Attachment A is a detailed critique of the Staff Revision of H.R. 13743, and as Attachment B is proposed alternate language for sections 201 and 604 of the Administration's Controlled Dangerous Substances Act, S. 3246.

(1) Title I of the Staff Revision covers rehabilitation programs relating to drug abuse. The Administration, both through the Attorney General and yourself, has recommended to the Congress that this bill deal only with the law enforcement aspects of the problem, and that rehabilitation programs be kept separate and apart from this legislation. Further, as to substantive rehabilitation legislation, you have testified before the Special Subcommittee on Alcohol and Narcotics in the Senate on March 24, 1970, that the Department of Health, Education, and Welfare does not feel new legislation is needed in this area, and that the Administration emphasis is on State action more than Federal action.

(2) Aside from some definitional problems which are set out in Attachment A, the authority to control in Part B of Title II is unacceptable to the Department of Justice. We are opposed to the establishment of a Commission which will merely add another layer of bureaucracy to the control determination. Further, as written there is no authority in the legislation to allow the addition of new drugs but only the removal of drugs from schedules and the "transfer" of drugs from one schedule to another. We further object to the administrative procedures built into section 201 which would require

proposals initiated by the Commission or the Attorney General to be carried out under a procedure virtually identical with the existing procedure in section 701 of the Federal Food, Drug, and Cosmetic Act, which we have consistently opposed, while allowing the petition of any other interested party to have a procedure under the Administrative Procedures Act. This bifurcation of administrative procedures does not make a great deal of sense. Further, it raises a question as to whether or not these are in fact adversary proceedings. Lastly, the management and control of administrative hearings to control drugs should remain vested where they are now, with the Bureau of Narcotics and Dangerous Drugs in the Department of Justice.

(3) There is a real question as to whether or not there is a need for an additional schedule other than the four schedules presently in S. 3246. The impetus behind this move to create a new schedule is clearly industry fostered and in reality serves several specific drug companies. This also has the effect of having criminal sanctions equal for schedule IV and V drugs, which we think inappropriate since the dangerousness of the drugs listed in schedule IV appears greater than that of the drugs in schedule V, and the drugs in schedule IV are prescription items as opposed to those in schedule V which are over-the-counter.

For the reasons mentioned above, we would oppose the creation of the Commission on Dangerous Drug Classification in section 203 of the Staff Revision, as well as the procedures used to control drugs under section 201.

(4) We are very strongly opposed to Part C of the Staff Revision, which would create a licensing of manufacturers by the Secretary of Health, Education, and Welfare, and a registration of manufacturers, distributors, and dispensers by the Attorney General. The requirement that the Secretary license manufacturers appears superfluous, and the criteria used for such licensing requirements by the Secretary are redundant in terms of the existing licensing requirements of the Federal Food, Drug, and Cosmetic Act.

Further, the exemptions from registration and licensing perpetuate the same existing loopholes that we are trying to close in the existing Drug Abuse Control Amendments of 1965. Because the procedures set out in the Subpart are

so opposite to the Administration's consistent position in S. 3246, it is the Department of Justice's feeling that this entire section would have to be struck and Title III of S. 3246 substituted in its place. From a law enforcement point of view, this perpetuates the problems found in the Drug Abuse Control Amendments, and creates a bifurcation of authority between the Secretary of Health, Education and Welfare and the Attorney General in an area that is strictly law enforcement.

(5) Part D, dealing with importation and exportation, is also an area of great concern to the Department of Justice. S. 3246, the Administration's proposal, updated the existing law and is presently acceptable to the drug industry. The substitution of authority in section 401 of the Secretary for the Attorney General is unacceptable. This function of regulating importation was performed by the Bureau of Narcotics in the Treasury Department and has been carried out by the Bureau of Narcotics and Dangerous Drugs since the Reorganization Plan No. 1 of 1968.

The Staff Revision has pulled key segments of Title IV of S. 3246 and incorporated them into the Staff Revision. Because of the antitrust considerations and the delicate balance that has been achieved with those members of the drug industry who are involved in such importation, the Department of Justice would require that the language of S. 3246, where applicable to non-narcotic drugs, be substituted for the language of the Staff Revision.

(6) Part E dealing with offenses and penalties is equally unacceptable to the Department of Justice. The wording of the substantive offenses for Prohibited Acts A, B, and C are a matter of particular importance to the Department of Justice, which is responsible for enforcing these laws in the district courts of the United States. The substantive offenses were carefully worked out in S. 3246, and those provisions are acceptable to the Department of Justice. In the matter of establishing penalties in terms of years, the Administration has taken the position that, within given parameters, certain penalties are acceptable. While the penalties set out in the Staff Revision are by and large greater than those in S. 3246, they are nonetheless within the parameters established by the Department of Justice.

It should be noted again that the penalty differentiation of ten years for sale of schedule III drugs and one year for sale of schedule IV drugs, which include chloral hydrate and meprobamate, does not seem reasonable. Also, the Department of Justice has taken the position that the section dealing with attempts should be more properly described in terms of "endeavors," which has a legal meaning which the Department of Justice favors.

(7) Subpart F creates several problems from the point of view of the Department of Justice. Section 602 restricts the Attorney General's powers to preempt State law in the granting of immunity for possession of dangerous drugs and for the withholding of names. The Staff Revision misreads the intent of S. 3246, which was to allow the Attorney General not only to grant this restricted use immunity for persons engaged in Federal research, but also for any researchers conducting scientific investigations with these substances. We would oppose subsections 602(c) and (d) for the above reasons, and would also oppose the Secretary of Health, Education, and Welfare having the power to preempt State research activities in his limited sphere. [Section 3, Part E, Title I of the Staff Revision.]

We further fail to see the need for the Secretary to have administrative hearing powers under this bill except for the licensing of manufacturers, which we oppose, and would therefore recommend his exclusion from section 604.

With regard to section 605 dealing with subpoena powers, once again we feel it inappropriate for the Secretary of Health, Education, and Welfare to have such subpoena powers, since administrative hearings conducted under this Act will be performed by the Attorney General through the Bureau of Narcotics and Dangerous Drugs, as will accountability investigations of manufacturers, distributors, and dispensers. Therefore, the Secretary should be excluded from the subpoena power provisions of the Staff Revision.

With regard to subsections 609 (c)(2), (3), and (4), dealing with administrative inspections and warrants, these subsections are felt to be contradictory to the recent Supreme Court rulings in this area. [See Colonnade Catering Corp. v. United States, 90 S.Ct. 774 (1970).] For that reason alone, the administrative inspection warrant provisions in S. 3246 should be maintained.

Conclusion

We consider the above points to be of major significance in our review of the Staff Revision of H.R. 13743. Attachment A goes into greater detail as to some of the more technical provisions of the bill which we find unacceptable. On balance, the Staff Revision as drafted is unacceptable to the Department of Justice and would require a major rewrite to bring it into line with Administration goals and policies. For these reasons, we believe this Revision should be strongly opposed by the Administration.

PINK SHEETS

began broadening its sales base in 1968 via the acquisition of Jaru Art Products, a decorative accessories mfr. whose goods are sold nationally. 42 Products had \$1.7 mil. sales in 1968 -- \$2.7 mil. with Jaru -- but volume jumped to \$9.6 mil. in 1969 due to inclusion of sales from the dates of acquisition of the acquired firms. Total volume for all "42" companies would have exceeded \$15 mil. for the full 1969 calendar year. Pre-tax profits gained 26.6% from \$106,000 in 1968 to \$134,000 in 1969, but after-tax earnings fell from \$40,000 (7¢ a share) to \$37,000 (5¢).

The company was formed in 1956 from a business started in 1942 under the same name. It showed good sales growth, going from \$1.1 mil. in 1959 to \$3.3 mil. in 1963. But volume fell each of the next three years, to \$1.5 mil. in 1966, before resuming its upward trend. Pre-tax profits followed the same pattern, and rose from \$58,000 in 1959 to \$192,000 in 1963 before bottoming out with a \$100,000 deficit in 1966. Net profit climbed from \$33,000 in 1959 to \$102,000 in 1961. It declined to a \$49,000 deficit in 1966. Highest earnings since were \$58,000 in 1967.

¶ The 1969 acquisitions were LA-based Merchants Pet Supply, Market Pet Supply, Seabury & Co. advertising specialists, Alvi of California ceramics mfr., plus Halo Candle of San Francisco. In 1970, 42 Products has acquired an interest for stock in LA-based Malco Distributors, hair-goods racker. 42 Products said it took a major step forward in 1969 by "completely restructuring" its cosmetics-toiletries subsidiary. Named div. president was William Randall, former president of Sea & Ski. Two major sales groups also were established to spearhead the introduction of a "parade of new products," 42 stated.

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(T&G) MITCHELL'S FLA. BLAST AT HOUSE INACTION on narcotics-drug abuse legislation will produce no turnabout in Interstate's Health Subcmte., which may report its bill late this (June 22-26) week. The attorney general's rebuke was delivered to the bar assn. of the home state of Demo Rep. Rogers, subcmte.'s sparkplug and leading critic of the Nixon Administration bill.

¶ Rogers' office pointed out that the subcmte. held 11 days of hearings on the legislation and, through June 18, met 14 days in executive session. "The Justice Dept. bill was drawn so sloppily," a Rogers staffer said, "that it would have allowed anyone to walk across an internatl. border carrying heroin without violating federal law." He also pointed out that the Health Subcmte. made repeated efforts to have Mitchell testify, without success, and that Justice's chief lobbyist, John Dean III, asked the subcmte. to delay action one week because he was going to Europe.

¶ The latest subcmte. draft still vests abuse drug control authority in a "Commission on Drug Classification," appointed by the president, but reduces membership from nine to five -- one each from H-E-W and Justice plus three public members.

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(T&G) EDWARDS URGES FAIRER U.S. SCIENTIFIC BALANCE between applied and basic knowledge. The FDA chief told the Assn. of Food & Drug Officials of the U.S. (AFDOUS) June 17 that FDA's future is tied to the need for a natl. realignment of scientific priorities. He implied that FDA's applied scientific needs should be considered equally with NIH's basic research requirements. Edwards indicated he would take the public route to seek more funds for FDA. In a speech the day before, Edwards asked the Grocery Mfrs. Assn. to support a higher budget.

¶ In his AFDOUS speech, Edwards indirectly criticized the Fountain subcmte. hearings the week before. "The new leadership of FDA is trying to build on the best of the past. We see little gain in pounding away at acknowledged errors, whether of omission or commission," he said. In apparent response to Fountain's lecture

"PINK SHEETS"

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EXAMPLE CASES INVOLVING DIVERSION FROM RESEARCHERS AND BY
PERSONS PASSING THEMSELVES OFF AS RESEARCHERS

This summer BNDD investigated a graduate student at a large midwestern state university. The student was working on a university research project. On the side he was using the university laboratory to make dangerous drugs. This researcher went so far as to use funds provided by a Federal grant to purchase his dangerous drug precursor material. Our agents arrested him in his lab for illegal possession of dangerous drugs. Prosecution is pending.

A current case of diversion of Methamphetamine powder involves a major west coast university professor's research project. Students employed on the research project simply doubled orders directed to a drug wholesaler in Chicago. The amounts involved were one pound quantities, enough to make about 50,000 normal 5 milligram dosage units.

In late 1967, Bureau agents conducted an investigation of the head of the chemistry department at a community college in the Pacific Northwest. Investigation disclosed that the professor was using his position to obtain precursor chemicals and was using the college laboratory on weekends in an attempt to manufacture Methamphetamine. This operation was stopped before sufficient evidence was obtained for prosecution and the professor left the college. In the Spring of 1968, this former professor informed one of our undercover agents that he could manufacture large quantities of Methamphetamine. He was subsequently arrested by local authorities for possession of heroin and marihuana.

Wm. P. 1/18/68
A cooperating chemical supply firm furnished BNDD with information regarding suspicious orders for Methamphetamine from a customer. Investigation by Bureau agents determined that the customer, who had given a fictitious firm name and represented himself as a researcher, was in fact a young college chemistry student in the Metropolitan New York City area. Sizeable quantities of controlled drugs and chemical precursors were taken from the boy's home along with invoices reflecting that this youth had successfully obtained Methamphetamine from three major chemical supply firms on several occasions.

In 1967, an individual who worked for a large west coast firm set up a research laboratory at his residence and obtained an FDA research license. He purchased cultures to be used in the manufacture of LSD. An agent of the former BDAC met this individual and was furnished a one-gram sample of DMT. The DMT sample was to show good faith on the researcher's part until he was able to manufacture LSD which he was to sell to the agent. Subsequent negotiations between the researcher and the agent fell through with no other drugs being supplied by the researcher. The U.S. Attorney declined prosecution on the one-gram DMT exhibit because of the small quantity.

In mid 1967 our agents developed information that a chemist at a nationally known research foundation in southern California was using his position to obtain lysergic acid which he used to manufacture LSD. He made the LSD and supplied it to illicit traffickers who actually made sales to our undercover agents. He used foundation funds to purchase his materials.

Memorandum

TO : Mr. Creed Black
Assistant Secretary for Legislation

DATE: June 20, 1970

FROM : Theodore Ellenbogen, Consultant *TE*

SUBJECT: Committee Staff Revision (6/9/70) of H.R. 13743 (Staggers-Springer), the "Controlled Depressant and Stimulant Drugs Act of 1969." Principal Issues of HEW Concern.

Attached in anticipation of your meeting with Mr. Dean, is the requested summary of the principal issues raised by the 6/9 Staff Revision of H.R. 13743, insofar as those issues are of common concern to HEW and the Justice Department. Title I of the bill "Rehabilitation Programs Relating to Drug Abuse", which involves primarily amendments to the Public Health Service Act and the Community Mental Health Centers Act, will therefore be considered in this memorandum only insofar as it involves issues that are also of present concern to Justice, although HEW needs to develop positions on all of Title I. (I doubt that, in view of the Committee's jurisdiction and the pendency of related bills before the Committee, on which hearings were held, there is any use to urge the Committee to confine this bill to title II, which is the revised version of the original H.R. 13743.)

1. Authority to schedule, reschedule, and deschedule drugs and other substances.



Under the original Staggers bill and S. 3246 the Attorney General has authority to add to, transfer between, or remove from any of the four statutory schedules a drug or other substance, subject only to the requirement that he first obtain the written advice of the Secretary of HEW and of a scientific advisory committee appointed by the Attorney General (from among nominees of the National Academy of Sciences) after consultation with the Secretary. The June 9 print on H.R. 13743, on the other hand, vests the classification function in a Commission on Drug Classification (Sec. 203, pp. 31-35). The Commission is to consist of one employee of this Department and one of the Department of Justice, appointed by, and serving at the pleasure of, the President, and three members from the public appointed by the President for staggered three-year terms.^{1/} The only qualifications prescribed for members are that they be persons who because of their education, training, or experience, are eminently qualified to serve on the Commission. Before taking action on classifying a substance, the Commission would have to obtain the written advice of the Attorney General and the Secretary.^{2/}

As you will recall, this Department has, in testimony on both sides of the Capitol, supported the Administration bill vesting classification authority in the Attorney General, but requiring him to obtain the written advice of this Department and of a scientific advisory committee to the Attorney General in that connection.

^{1/} In the 5/11 print, the Commission was to have 2 HEW, 2 Justice, and 5 public members, appointed for 6-year terms.

^{2/} The June 9 print has "streamlined" the Commission procedure in those cases in which a proposal for action is initiated on the Commission's own initiative or by petition of the Attorney General, see paragraph (4) beginning on page 22, line 25, and ending on page 24, line 7, of the print.

Logically, it would seem that regulatory authority with respect to classification, which is quasi-legislative, should be in the agency (or agencies) otherwise generally vested with administration of the regulatory scheme. Whether this consideration should yield to other considerations such as the feeling of the medical and scientific communities and the temper of the Congressional committee in charge of the bill is the issue that needs to be decided by the Administration. Also, how well such a Commission would function would depend on its particular membership, not least its public members.

Attachment B to Mr. Ingersoll's memorandum of 6/12 to Dr. Egeberg, while adhering to the position that classification authority be vested in the Attorney General, offers a revision that would limit HEW to "scientific and medical" recommendations (relating to classification) and would make the recommendation of HEW in any such case "determinative as to scientific and medical fact, but not as to legal sufficiency." (The provision for a standing scientific advisory committee in the original bill would be deleted and general authority for appointment of advisory committees by the Attorney General substituted.) The explanation indicates that it is intended that the Attorney General have the authority to make the final decision not only as to "legal sufficiency" but also as to policy to control or not to control a drug. If this compromise is considered, I see no need to limit the Secretary's "recommendation" to the Attorney General, for HEW has not only strictly medical and scientific expertise but also a very substantial interest in social policy, especially as it affects children and youth, particularly prevention and control of juvenile delinquency and youth crime. However,

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the binding aspect of HEW advice might at the same time be circumscribed along the lines of Mr. Ingersoll's draft language on that aspect.

2. Schedules -- New Schedule IV

S. 3246 and the versions of H.R. 13743 prior to the May 11 Subcommittee working print provided only for four statutory schedules (I, II, III, IV). Schedule IV, for which no substances were initially listed in H.R. 13743, was intended for over-the-counter narcotic preparations, although narcotics are not, so far, included in H.R. 13743 because of a conflict of jurisdiction with Ways and Means. Beginning with the May 11 print, the prints provided for five schedules, which is due to the fact that certain named drugs have been taken out of Schedule III as previously listed in the bill and placed under a new schedule IV, so that the over-the-counter drugs, if any, would become schedule V. In the operative parts of the print, the new schedule IV is generally associated with Schedule III under the same regulatory provisions, except that in the penalty provisions contained in Sec. 501(c) the new schedule IV is, somewhat anomalously, associated for penalty purposes with the over-the-counter Schedule, i.e., V. I have been told by Dr. Novitch and Dr. Dobbs that this breakdown of Schedule III into two differentiated schedules is not technically sound. Dr. Dobbs tells me that there is not available the necessary knowledge to differentiate between drugs in Schedule III and those in the proposed new Schedule IV with respect to their potential for abuse.

3. Authority to license and to register

S. 3246 and the original version of H.R. 13743 require every person who manufactures, distributes, or dispenses a controlled dangerous

substance, or proposes to do so, to obtain annually a registration, in effect a license, issued by the Attorney General in accordance with regulations promulgated by him. In the case of manufacturers of Schedule I or II substances, such registration may be issued only if the Attorney General determines that the registration is "consistent with the public interest." In the case of registration of distributors of such substances and of manufacturers or distributors of Schedule III or IV substances, the Attorney General is to register the applicant unless the issuance of the registration is "inconsistent with the public interest."

Practitioners (i.e., physicians, pharmacists, etc.) are to be registered to dispense Schedule II, III and IV substances if authorized to dispense them under their State law. Registration for research with Schedule I substances by a practitioner deemed qualified by the Secretary may, under a provision worked out between the Justice Department and HEW, be denied only because of suspension or revocation of the practitioner's State license or registration or because of a prior drug felony, or "on the ground that the applicant's past practice or proposed procedures furnish ground for the belief that the applicant will abuse or unlawfully transfer such substances or fail to safeguard adequately his supply of such substances against diversion from legitimate medical or scientific use."^{3/} This provision of the Administration bill as to researchers, as you will recall, is a compromise originally arrived at between the two departments, as compared with the Justice Department's

^{3/} In the light of questions raised concerning this last-mentioned provision, the above-quoted provision was changed in the recently introduced Mills-Byrnes bill (H.R. 17463) to read: "on the ground that the proposed procedures are inadequate to safeguard against diversion of such substances from legitimate medical or scientific use."

draft bill which would have authorized the Attorney General to deny registration to a researcher merely on the ground that registration was not "consistent with the public interest."

The June 9 staff revision of H.R. 137⁴³ has a radically different scheme. Whereas registration under the Administration bill is not a matter of right but rather (in effect) a license, registration by the Attorney General under the June 9 print is a matter of registrant's right, provided that the registrant is an eligible person as determined by a "laundry list" (Sec. 301) contained in the print, and provided that the registrant has not been convicted of a drug felony or lost his State or local license (see Sec. 303 (p. 44) and Sec. 301 (p. 35) of June 9 print).

In the case of a manufacturer, the June 9 print requires that he obtain a license (in effect an establishment and product license) from the Secretary which is issuable in accordance with regulations of the Secretary designed to (1) provide for maintenance of effective controls against diversion of controlled substances (covered by the license) from legitimate channels, (2) insure the quality, purity, and strength of such substances, (3) insure good manufacturing practices, and (4) insure such other factors, relevant to the prevention of drug abuse, as the Secretary deems in the interest of the public health and safety. The Secretary is authorized to issue (or renew) a license for a Schedule I or II substance only if he determines that a license is consistent with the public interest; he is required to issue or renew a license for a Schedule III or IV substance if the manufacturer complies with the general requirements of this section unless such issuance or

renewal is inconsistent with the public interest. The licensed manufacturer must also register with the Attorney General but, as already indicated, this is to be as a matter of right. Suspension or revocation of the Secretary's license will automatically cause suspension or revocation of the registration.

The June 9 print thus removes what is in effect broad licensing authority from the Attorney General, and vests licensing authority, but only with respect to manufacturers, in the Secretary. It in effect deprives the Attorney General of most discretionary authority with respect to registration, so that registration of eligible persons is in effect purely informational, as it is under Sec. 510 of the Food and Drug Act.

This change is, of course, a basic one and flatly opposed to the past Administration position. (See, however, the separable issues as to control of researchers, below.)

Assuming that the Administration position on this basic issue is adhered to, it does not follow that the "laundry list" -- which is designed to limit manufacture, distribution, dispensing, and administration of controlled substances to persons in a legitimate business or profession relating to drugs -- should necessarily be eliminated. A requirement of licensing by the Attorney General and the application of the requirement that the licensee be a person described in this list could go together.

4. Record Keeping

S. 3246 exempts from record keeping requirements of the Attorney General only practitioners who lawfully prescribe or administer but do not otherwise dispense controlled substances in Schedule II, III, or IV.

The June 9 staff revision of H.R. 13743, in Sec. 305, exempts (p.56) in the first place any practitioner licensed to prescribe or administer controlled drugs "unless when he dispenses or administers such substances to his patients they are charged therefor an amount in addition to regular charges for other professional services." This provision seems difficult to enforce if not unenforceable except as to physicians who separately charge for drugs they dispense.^{4/} A requirement of record keeping for physicians is a sensitive matter with the medical profession because it carries with it authority to inspect. With respect to exemption of researchers and teachers from record keeping under this section, see heading "Regulatory control of research and teaching" below.

5. Regulatory control of research and teaching

S. 3246 and the original version of H.R. 13743 --

(1) Require registration of Schedule I drug researchers with the Attorney General, as above described under the heading "Authority to license and to register;"

(2) (A) empower the Attorney General to authorize researchers in controlled substances to withhold the names and other identifying characteristics of persons who are the subject of such research, and immunize persons so authorized from being compelled in any Federal or State proceeding to disclose this information; and

(B) empower the Attorney General to authorize the possession and distribution of controlled substances by researchers in

^{4/} Present law (Sec. 511(d)(3)) exempts physicians from record keeping and inspection unless the physician "regularly engages in dispensing any such drug or drugs to his patients for which they are charged, either separately or together with charges for other professional services." I understand that this likewise has been difficult to enforce.

such substances and to immunize such persons from State or Federal prosecution for possession and distribution to the extent authorized by the Attorney General. (See S. 3246, pp. 32; 65).

In the 6/9 print, the authority of the Attorney General here described under (2)(A) and (B) is limited to research projects under contracts entered into by the Attorney General under his own research authority (Sec. 602, p. 89).

In addition, the June 9 print of H.R. 13743 --

(1) requires researchers in controlled substances, who dispense or administer such substances, to register with the Attorney General, but such registration, if the researcher is acting lawfully in accordance with State or local law, is a matter of right (Sec. 303, p. 44 et seq.);

(2) exempts the researcher from record keeping if the research is conducted at an establishment licensed or registered under the bill which keeps records with respect to such substances (p. 56);

(3) empowers the Secretary (A) to authorize the researcher to keep confidential the identity of the persons who are research subjects and to possess and distribute the drugs involved in the research, and (B) to protect the researcher from being compelled to disclose such information in Federal or State proceedings or from being prosecuted for such possession or distribution (p. 10, line 20, through p. 11, line 11); and

(4) exempts a manufacturer who receives an order from a researcher for research involving a Schedule I or II substance, and to be conducted in conformity with section 505(i) or 512(j) of the Food and Drug Act, from being subject to a production quota with respect to the

amount of the substance so required for research. In addition, the June 9 print (page 57, subsection (e)) provides that regulations under sections 505(i) and 512(j) of the Food and Drug Act, relating to investigational use of drugs, "shall include such procedures as the Secretary determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply."

Thus the June 9 print is designed to exempt researchers from most of the controls which under the Administration bill the Attorney General would exercise over them, and to vest in the Secretary such controls with respect to these substances as may be necessary to prevent diversion from bona fide research.

6. Education and Research Functions of HEW and Attorney General

Under section 602 of the Administration version of H.R. 13743 and under S. 3426 the Attorney General is authorized "to carry out educational and research programs necessary for the effective enforcement" of the bill and, in connection therewith, to (A) establish methods to assess the effects of controlled substances and to identify and characterize controlled substances with potential for abuse, and (B) enter into contracts for research or special projects bearing directly on misuse and abuse of controlled substances.

Under the June 9 print (Sec. 602) the Attorney General is authorized "to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning narcotic drugs, marijuana, and depressant or stimulant drugs. The 6/9 print, (pp. 88, 89) further provides that such programs may include 6

different types of studies or special projects, all of which are closely tied to law enforcement and training functions^{5/} except for the last one which authorizes studies or special projects to develop information concerning law enforcement aspects of drug abuse necessary to enable the Attorney General to advise the Commission on Drug Classification in the performance of its functions when requested pursuant to Sec. 201(e). On the other hand, the Secretary, who under existing law already has very broad authority for conducting and supporting drug abuse research and education, is given additional specific authority (stemming from an earlier Staggers bill, H.R. 11701) to (A) establish a National Addiction and Drug Abuse Research Center (to be part of NIMH, located in close proximity to its central research facilities, and to serve also as a regional research center) and (B) make project grants for establishment of additional regional drug abuse research centers (pp. 10, 11 of 6/9 print) and, under a new Sec. 253 (pp. 5 and 6 of the Community Mental Health Centers Act), to (A) support the collection, preparation, and dissemination of education materials on drug abuse, and the development and evaluation of drug abuse education programs directed at the general public, school-age children, and special high-risk groups, and (B) through NIMH undertake activities essential to a national drug abuse education program, including several specifically described activities, among them coordination of activities of such Federal agencies as he designates with respect to drug abuse education.

^{5/} The 6/9 print also directs the Commission on Drug Classification to study the effectiveness of the licensing, reporting, and related provisions of the bill and, on or before 1/1/72, at such times thereafter as it deems appropriate, make such recommendations to Congress as it deems feasible and necessary for additional restrictions (such as manufacturing quota restrictions).

7. Prescriptions

Section 309(a) of S. 3246 authorizes the Attorney General, whereas Sec. 308(a) of the 6/9 print authorizes the Secretary, to authorize (by regulation) the dispensing of Schedule II drugs in emergencies pursuant to oral prescriptions. An HEW determination under what circumstances dispensing under oral prescription should be permitted is consistent with HEW's (FDA's) present functions under the FD&C Act.

8. Order forms

The June 9 Staff Revision is a substantial rewrite of this provision of H.R. 13743. I see no reason for HEW to become involved with Justice or the Committee in discussion of the order form section. However, one thing should be clear in case the point comes up in HEW discussion with Justice. S. 3246 expressly exempts from the requirement of obtaining an order form (1) the administering or dispensing of Schedule I or II substances to a patient or research subject by a practitioner in the course of his professional practice, and (2) the "distribution or dispensing" of such substances by a pharmacist to an ultimate user pursuant to a prescription. The 6/19 print omits these exemptions because they are not needed; this is because the order form requirement (under both versions) applies only to distribution and because under the definition in the 6/19 print (Sec. 101(11)) the term "distribute" excludes administering or dispensing a substance (including over-the-counter dispensing). In S. 3246, the term "distribute" is defined, simply, as the act of delivering a controlled substance, so that it is broad enough, if taken literally, to include dispensing. (The recent Mills bill, H.R. 17463, goes further because "dispense" is there defined

as meaning "to distribute a controlled dangerous substance to an ultimate user, or ~~has~~ research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for such distribution," and to "distribute" is to (actually or constructively) transfer a substance; thus a dispenser, and possibly a prescriber, would be a "distributor.")

9. Imports

In addition to technically revising the import provisions of the original H.R. 13743, and also picking up (and perfecting) certain technical changes contained in the new Mills-Byrnes bill (H.R. 17463), the 6/9 Staff Revision (Sec. 401) vests in the Secretary, rather than the Attorney General, the authority for determining the amounts of Schedule I or II imports.

The theory of this change was, presumably, that the Secretary would be more competent to determine domestic needs for these substances. In the June 2 print that was consistent with Sec. 304, which vested in the Secretary, rather than the Attorney General, the authority for determining domestic production quotas on the assumption that he is fully competent to determine domestic needs in this field, as he now is supposed to do for basic narcotics under the Narcotics Manufacturing Act of 1960. In the 6/9 print, however, the authority to fix domestic manufacturing quotas has been placed in the Attorney General. The vesting of authority over Schedule I and II imports in the Secretary in the 6/9 print thus seems inconsistent both with ~~respect to~~ the production quota provision and with the vesting of authority in the Attorney General over imports and exports.

generally. However, if the Attorney General is substituted for the Secretary in the important provision, consideration might be given to amending Sec. 302 (a) of the Public Health Service Act -- which now requires the Secretary to study and report to the Attorney General (formerly Secretary of the Treasury) the quantities of crude opium, coca leaves, and other narcotic drugs necessary to supply the domestic requirements of the United States -- so as to include other Schedule I and II drugs.

10. Offenses and penalties

Title V of the 6/9 print is a substantial revision of title V of S. 3246. Apart from elimination of specific penalties relating to narcotic drugs -- which at this point are not covered by H.R. 13743 -- and certain substantive policy changes referred to in Mr. Ingersoll's memorandum, one of the main purposes of the revision, as I understand it, is to clarify the application of the penalty provisions -- especially the heavy penalties in Sec. 501 -- to specific acts, and to avoid overlap between those penalties and the lesser ones under Sec. 502 and 503. Except as noted below, the differences between the respective versions of the penalty provisions are not in my judgment such as to require comment here from HEW's standpoint. However, some general observations and some specific ones seem appropriate here.

First, since the dates of the Staff Revision and of Mr. Ingersoll's memorandum, two significant developments have occurred which it would seem appropriate for the Administration to consider quickly before reacting to the Staff Revision. The National Commission on the Reform of Federal Criminal Laws has rendered a voluminous report which I have

not yet seen but which, I suppose, contains at least guiding principles bearing on drug penalties. And the LeDain Commission's just issued interim report on Canada's drug laws, excerpted in today's New York Times, recommends that no one be subject to imprisonment for simple possession of psychotropic drugs. As an interim measure the Commission recommends that this offense be punishable, in a summary proceeding, by a maximum fine of \$100.

Secondly, from HEW's standpoint, it is important to note that both S. 3246 and the 6/9 print avoid mandatory minimum penalties (in cases other than continuing criminal enterprises) and preserve and strengthen first offender treatment in cases of simple possession.^{6/} However, one change made by the 6/9 print in toughening the S. 3246 version should give cause for concern. Under Sec. 806 (p. 54) of S. 3246, if a person over 18 sells or gives a controlled substance to a person who is under 18 who is at least 3 years younger than the other, the offender is subject to a prison penalty which (in the case of a first offense) may be up to twice that authorized for trafficking in other cases, and probation is not permitted. Under the 6/9 print (Sec. 505, p. 79), there need be no age differential between the offender and the "victim" and the section applies also to cases in which the victim is over 18 but under 21. This follows the approach of the 1968 penalty amendments to the Food and Drug Act. It seems to me that S. 3246 is far sounder

^{6/} Mr. Ingersoll's memorandum questions the policy of the provision of the 6/9 print which allows "first offender" treatment for simple possession to be accorded repeatedly if the offender is under 21. If the Administration is to recommend that no offender be accorded "first offender" treatment more than once, it needs to clarify the relationship between this limitation and expunction of the record of the proceeding which is provided for in another part of this section in the case of a below-21 offender who has successfully gone through the first-offender treatment procedure (including probation). How would the court, in a future case, be made aware of the prior proceeding?

in both respects. If, as believed by the President and Congress, a person between 18 and 21 is mature enough to vote, he is hardly in need of the special protection against traffickers that may be desirable for juveniles.

Third, the age differential requirement of S. 3246, which stems from a proposal on drug penalties made to the National Commission on the Reform of Federal Criminal Laws, by its reporter on that subject, recognizes that, generally, a substantially older person is likely to have greater influence on a youngster in victimizing him by inducing him to take such drugs than would one of the same age or younger than the "victim."

11. Administration and enforcement

The 6/9 print confers on HEW, for the purpose of carrying out its functions under the bill, the same authority to delegate functions, issue regulations, issue subpoenas, make administrative inspections (and obtain a warrant for that purpose if needed), etc., as is conferred on the Attorney General for carrying out his functions. This seems needed only if HEW is to be given more than the advisory function specified in S. 3246. (In that event, however, the 6/9 print leaves to inference the authority of the Attorney General under certain sections where no enforcement authority is specified.)^{7/}

12. Medical treatment of narcotic addicts

Section 4 of the 6/9 print requires the Secretary, after consultation with the Attorney General and with national organizations

^{7/} See Appendix A for comment re administrative inspections and the need for a warrant.

knowledgeable in the treatment of narcotic addicts, to "determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts," and to report thereon from time to time to Congress. This provision is evidently intended to furnish what would in effect be a mandatory guideline for the Bureau of Narcotics and Dangerous Drugs in determining the applicability of provisions of the narcotic laws referring to the "course of professional practice" or "legitimate medical practice." I doubt that "treatment" as here used, should be construed to include clinical investigation, such as methadone maintenance.

I feel somewhat uneasy about even HEW "determining" what is "appropriate" and thus orthodox medical treatment of addicts, with the implication that physicians who are unorthodox but act in good faith should be subject to penalties. I would be prepared to attempt to rephrase this provision if it is to stay in the bill.

13. Special advisory committees

a. S. 3246 (Sec. 801) provides for a committee, jointly appointed by the Secretary and the Attorney General, to study all aspects of marihuana use and, within 24 months, submit to the President and Congress a comprehensive report on its findings, together with its recommendations with respect to the degree of control to be exercised over marihuana use. The Director of NIMH and the Director of the National Institute of Law Enforcement and Criminal Justice are to be ex officio members of the Committee. In our testimony on the original Administration drug bill and on various bills for a Presidentially appointed study commission, we had endorsed the general idea but stated that we were

exploring with Justice the possibility of including in the Administration bill a provision for a study committee jointly appointed by the two Departments. The Justice Department furnished us, as well as staff of the Senate Juvenile Delinquency Subcommittee, a draft of such a provision. I gave Dr. Novitch a redraft, but we were told that it was too late for consideration. So far as I know, HEW never gave official clearance to the proposal. Substantially the Justice Department's draft was incorporated in S. 3246. The Staggers bill (H.R. 13743) and the 6/9 Staff Revision of it do not include this provision.

Since then, the House Committee on the Judiciary has reported, with amendments, the Koch bill (H.R. 10019) which in its amended form provides for a one-year comprehensive marihuana study by a commission consisting of two members from each House and 9 members appointed by the President. More recently, Congress has passed the Hill-Burton Amendments with the Dominick Amendment, which requires HEW to submit to Congress by 1/1/71 and annually thereafter a report on the health consequences of marihuana use. In view of these developments, as well as the fact that H.R. 13743, so far, does not cover marihuana (though it includes tetrahydrocannabinol), I believe that the marihuana study provision should not be urged upon the Commerce Committee. (If a policy decision to the contrary is made, I believe HEW should review the provisions of Sec. 801 of S. 3246 and suggest any changes in it that appear advisable.)

b. On the Senate floor, a section (Sec. 802) was added to S. 3246, providing for a Presidentially appointed 21-member Committee on Nongovernmental Drug Abuse Prevention and Control to (1) study the extent to which nongovernmental organizations are involved in prevention and

control of drug abuse or addiction and (2) advise on how best to foster and encourage such organizations. This was not an Administration proposal, though the Administration has voiced no objection and the Justice Department's approval of S. 3246 as passed by the Senate implies its endorsement of this provision.

I suppose that neither HEW nor Justice Department wants to urge inclusion of this provision in H.R. 13743. It is not included in any version of that bill.

APPENDIX A

Mr. Ingersoll's memorandum of June 12, 1970, in commenting on Sec. 609 of the June 9 print relating to administrative inspections, characterizes as "patently unconstitutional" Secs. 609(c)(2) through 609(c)(4), which appear on page 98 of the June 9 print and which are additions to the original bill's list of situations in which an inspection warrant issued by a judge would not be required. These are (1) inspections to determine whether a manufacturer's license should be granted or renewed (not to determine whether a license is to be revoked or suspended), (2) inspections to determine what, if any, manufacturing quota for a Schedule I or II drug should be assigned, and (3) inspection of records or other documents required by the 6/9 print to be maintained or kept (see, e.g., p. 55, line 55, through p. 54, lines 1 and 2, of the 6/9 print).

I would not wish to burden this memorandum with even brief comment on this claim -- especially since in the event of deletion of these provisions there would still remain clause (8) on page 99, dispensing with an inspection warrant in any situation where it is not constitutionally required -- were it not for the implications of any such claim as to inspection under other laws where an inspection is needed in order to determine whether a license should be granted or a product (e.g., a new drug) be approved, or to inspect records that the law requires to be established and maintained and available for inspection and copying. The three cases cited (Camara v. Municipal Court, 387 U.S. 523; See v. Seattle, 387 U.S. 541; Colonnade Catering Corp. v. U.S., 397 U.S. 72) in the

June 12 memorandum do not, as I read them, stand for the proposition cited. No such situation was involved in any of them. Indeed, as noted in the Colonnade case, the problems of licensing programs requiring inspections prior to operating a business (or marketing a product) were expressly reserved; in the See case, for resolution on a case-by-case basis under general Fourth Amendment standards of reasonableness. Such a statutory or regulatory requirement is but another way of stating, not that entry would be forced without a warrant, but that a license (or renewal) will be withheld until the applicant makes it possible to the administrator to ascertain whether the prerequisites for a license, which can be satisfactorily verified only by inspection, are satisfied.

The Colonnade case did not even rest on a constitutional holding. The court held only that, since a relevant statute merely imposed a fine of \$500 for an owner's refusal to permit inspection of premises, this should be construed as the only sanction for such refusal, and that in these circumstances the Federal inspection authorization should not be construed as authorizing the Federal agents, without a warrant, to break a lock in order to conduct the inspection and seizure. The court, indeed, clearly seemed to recognize the power of Congress to not only authorize inspections without a warrant under the Federal tax laws on liquor in view of their special history, but to authorize a forced entry. The division between the justices (6 to 3) was over whether Congress had intended to do so; the majority thought that Congress had not so intended.

In arriving at that construction, the Court said: "Where Congress authorizes inspection but made no rules governing the procedure which

inspectors must follow, the Fourth Amendment and its various restrictive rules apply. (Emphasis supplied) *** As respects the [liquor] industry, Congress has broad authority to fashion standards of reasonableness for searches and seizures. Under the existing statutes, Congress selected a standard that does not include forcible entries without a warrant. It resolved the issue not by authorizing forcible, warrantless entries, but by making it an offense for a licensee to refuse admission to the inspector."

I should like to add that Sec. 609 of the June 9 print (and the corresponding provisions, Sec. 703, of the original bill) do not necessarily authorize forcible entry any more than in the Colonnade case, at least in the absence of a warrant so specifying. See the statement in Camara that "the requirement of a warrant procedure does not suggest any change in what seems to be the prevailing local policy, in most situations, of authorizing entry, but not entry by force, to inspect."

Analysis of staff revision
of H.R. 13743 concerning
procedures for classifica-
tion of drugs

We cannot support the staff revision of § 201 of H.R. 13743, which sets forth procedures for classification of drugs and other substances.

The staff revision requires that the classifying authority (in the staff version, the Commission on Drug Classification) may by regulation, add, delete or classify drugs in the following manner:

1. Where a proposal originates with the Commission or the Attorney General, it must first be published in the Federal Register so that written comments may be received. Following a thirty day period for comments the Commission may, after considering the submission, publish the proposal. Another thirty day period must pass before the regulation becomes effective. ~~However,~~ ^{If}, prior to the expiration of the thirty day period, objection is made ^{by "any person adversely affected"} then the Commission must hold a public hearing at which any "interested" person may be heard. The Commission at the close of the hearings must make "detailed findings of fact" based "only on substantial evidence of record

at such hearing". The Commission then specifies the date on which the regulation shall take effect.

2. In cases where the proposal originates with someone ~~outside~~ other than the Commission or the Attorney General then decisions must be made on the record after opportunity for hearing in accordance with the formal requirements for ~~adjudications~~ ^{hearings} set forth in the Administrative Procedure Act.

The bill, as introduced would require the Attorney General to request advice from the ~~Secretary~~ ^{Secretary} of HEW and from a scientific advisory ~~from~~ committee. The committee would be selected from a list of qualified experts drawn by the National Academy of Sciences. The Attorney General would then act pursuant to the APA.

We have two fundamental objections to the staff revision:

1. Rule making power is placed in the hands of a mixed Commission of government officials and part-time members of the public with administrative support to be provided by the National Science Foundation. We believe the decisions to be made under the bill ~~would~~ ^{should} be made by full-time public officials. The problems inherent in administration by ~~Commission~~ are increased when, as contemplated here, a majority of the Commission

is composed of ^{computers} who are compensated on a per diem basis. This objection takes on even more weight when one considers the burdens imposed by the procedural requirements set forth in the staff revision.

2. The revision adopts requirements better suited to adjudications rather than rule making. It goes far beyond the APA provisions for rule making. Although this type of procedure has some precedent, it has been widely ~~criticized~~ ^{criticized,} where it exists.

In his leading work on Administrative Law, Davis ~~states~~, ^{opposes the use of trials} He states,

"In rule making, the method of trial has no place except when specific facts are at issue, and even then it should seldom be used when the disputed facts are legislative." A trial is not designed for determining issues of law, policy, or discretion. § 6.06.

The questions to be resolved under the bill are of precisely the kind that Davis notes are inappropriate for resolution through trial procedures. Questions as to whether the public interest requires certain action, whether a drug has a potential ^{are matters of discretion and policy and} for abuse, and so forth, are quasi-legislative in nature.