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DRUG ABUSE CONTROL AMENDMENTS OF 1965

JUNE 21, 1965.—Ordered to be printed

Mr. YARBOROUGH, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H.R. 2]

The Committee on Labor and Public Welfare, to whom was referred the bill (H.R. 2) to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs and counterfeit drugs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

PURPOSE

The bill provides increased controls over the distribution of barbiturates, amphetamines, and other drugs having a similar effect on the central nervous system. The controls are accomplished through increased recordkeeping and inspection requirements, through providing for control over intrastate traffic in these drugs because of its effect on interstate traffic, and through making possession of these drugs (other than by the user) illegal outside of the legitimate channels of commerce. The bill also increases the authority of the Department of Health, Education, and Welfare over counterfeit drugs.

A bill with the same objectives in the control of stimulant and depressant drugs was sponsored by Senator Dodd and unanimously approved by the Senate last year. That bill was S. 2628.

EXTENT OF PROBLEM

At the hearings last year, testimony showed that over 9 billion barbiturate and amphetamine tablets are produced annually in the United States. It is estimated that over 50 percent, or 4½ billion tablets, are distributed through illicit channels.

The human toll of drug abuse cannot be measured for it affects not only the abuser but his family and the community around him. Drug abuse is closely bound up with juvenile delinquency. It also contributes to the rising crime rate in the United States. Misuse of

these drugs has contributed to the rising accidents on the highways.

The illegal traffic in drugs is enormously profitable. Barbiturates and amphetamines having a retail value of approximately $670 sell in illicit channels for in excess of $250,000.

President's Advisory Commission on Narcotic and Drug Abuse

On January 15, 1963, President Kennedy established the President's Advisory Commission on Narcotic and Drug Abuse, with Judge E. Barrett Prettyman as Chairman.

The Commission met regularly in Washington during 1963 and obtained the views of all the major Federal agencies involved with drug abuse, including the Treasury Department, the Department of Justice, the Department of State, and the Department of Health, Education, and Welfare. The Commission also held special meetings in New York City and Los Angeles, cities in which drug abuse is particularly virulent. On these occasions the Commission obtained the views of State and local officials and experts, and visited public and private hospitals, research centers, rehabilitation centers, and correctional institutions. These meetings and visits were an essential part of the Commission's deliberations.

In addition, members of the Commission, or of the staff, made individual visits to various areas in the United States in which drug abuse is of high incidence, to study the particular problems of each area and to inspect treatment and rehabilitation facilities.

The Commission reviewed all the significant literature and reviewed all the material presented at the first White House Conference on Narcotic and Drug Abuse, convened in Washington in September 1962, and the report of the Ad Hoc Panel on Drug Abuse, convened by the Special Assistant for Science and Technology to prepare a background paper on the scientific and technical aspects of drug abuse for the White House Conference. The Commission had the benefit of the written recommendations and views of more than 100 experts and consultants. After a yearlong study of drug abuse, the Commission made a number of recommendations, including recommendations for legislation along the lines of this bill.

The Commission recommended that the legislation should not be limited to the barbiturates and amphetamines, but should extend to all nonnarcotic stimulant and depressant drugs capable of producing certain serious effects when abused.

The Commission recommended that the bill's definition of its coverage should not, however, interfere with legitimate medical usage and that the bill should exempt any drug within this definition that combines a small amount with other substances where the resultant drug is not itself liable to abuse.

President Johnson has directed the several agencies of the executive branch entrusted with responsibility in the control of drugs to take steps to bring the full power of the Federal Government to bear on the problem. In his health message to the Congress, the President recommended legislation in this field.

Scope of Coverage

The legislation would immediately place barbiturates and amphetamines in the category of drugs subject to its added controls. Since

other drugs now on the market and likely to be developed will require the same type of control because of their potential for abuse, the bill provides that the Secretary of Health, Education, and Welfare, after investigation, shall, by regulation issued after opportunity for hearing, designate these other drugs as depressant or stimulant drugs, thereby bringing them under the coverage of the bill. This means that such drugs will be subject to closer recordkeeping, inspection, and possession controls.

The committee expects that the Secretary, very soon after the enactment of the legislation, will proceed with the classification as depressant or stimulant of those drugs which are already causing serious problems, primarily certain tranquilizers.

The committee determined that it would not be desirable to specify drugs other than barbiturates and amphetamines as subject to the controls of the bill, but determined that the other classes of drugs are to be brought under control of the bill on a case-by-case basis by the Secretary of Health, Education, and Welfare under the standards prescribed in the legislation. In accordance with this determination, the committee omitted specific reference to peyote as a substance subject to the provisions of the legislation. It is expected that peyote will be subject to the same consideration as all other drugs in determining whether or not it should be included under the provisions of the legislation.

The committee amended H.R. 2 to permit the Secretary, at his discretion, to utilize an advisory committee of scientific experts to assist him in determining whether drugs should be included as subject to the provisions of this legislation. In the interests of flexibility in administration, the committee has not required that it be mandatory for the Secretary to seek the advice of non-Federal consultants in reaching decisions concerning the drugs subject to the provisions of the legislation. Nonetheless, the committee believes the use of outside consultants would be beneficial and encourages their use by the Secretary.

While the bill would apply to all depressant or stimulant drugs, it would not apply to basic chemicals intended and used for nondrug purposes. For example, firms that ship or receive unsubstituted barbituric acid or other potentially depressant or stimulant drugs for industrial nondrug purposes would not be subject to the recordkeeping and other requirements of the bill.

Barbiturates, Amphetamines, and Other Drugs

Barbiturates are central nervous system depressants having a wide variety of medical uses where a hypnotic or depressant effect is desired. When taken in excessive amounts, these drugs act as intoxicants. The person affected becomes drowsy and confused, unable to think clearly. He cannot coordinate his muscular action when he walks or stands and sometimes reaches the point of collapse. He experiences tremors of his hands, lips, and tongue, has difficulty in thinking clearly, and may become inarticulate. His emotional control is unstable, and his attitude sometimes hostile though he is usually too intoxicated to carry out any harmful intent. Persons even mildly under the effects of barbiturates are a great safety hazard if they drive cars. Like the alcoholic, the individual who consumes barbiturates to the point of intoxication is a menace to himself and

to others. Barbiturates are also widely used by narcotic addicts when they are unable to obtain "hard" narcotics.

Amphetamines and derivatives thereof are central nervous system stimulants. They are widely used to combat a variety of mild depressive states such as those attending the menopause, chronic organic diseases, and postoperative recovery, and are used for the treatment of narcolepsy, certain behavior disorders of childhood, and as temporary curbs of appetite in weight-control programs. In therapeutic doses, amphetamines produce a general state of mental well-being coupled usually with increase in activity. When used in excessive quantities, amphetamines cause, among other things, nervousness, insomnia, tremor, irritability, hypertension, loss of weight, and in some cases, psychosis and hallucinations.

Hallucinogens are drugs which affect the central nervous system in such a fashion as to cause the user to have a distorted sense of reality. The most prominent of the hallucinogenic drugs being abused today is d-lysergic acid diethylamide, more commonly referred to as LSD–25. This drug is sometimes used as an adjunct to psychotherapy and as a research tool in psychiatry. Its use by amateurs and drug abusers can cause some terrifying experiences for the victims. It is capable of producing prolonged psychiatric reactions in persons possessing a previous underlying personality problem, and can precipitate the acting out of anti-social-behavior patterns.

The term "depressant and stimulant drug" includes not only the barbiturates and amphetamines, but also any drug which contains any quantity of a substance which the Secretary after investigation has found to be, and by regulation designated as being, habit forming because of its stimulant effect on the central nervous system, or as otherwise having a "potential for abuse" because of its depressant or stimulant effect on the central nervous system or because of its hallucinogenic effect. It is necessary to cover these additional classes of drugs in the legislation because, as stated by the President's Advisory Commission on Narcotic and Drug Abuse, "Experience has proved that the drug abuser often turns to other drugs having similar effects when barbiturates and amphetamines become difficult to obtain."

These additional drugs, primarily tranquilizers, are, in general, central nervous system depressants. Chronic use of these drugs having a potential for abuse produces loss of coordination, impaired judgment, and drowsiness.

Potential for Abuse

The bill provides that the term "depressant or stimulant drug" includes, in addition to barbiturates and amphetamines, any drug which contains any quantity of a substance which the Secretary, after investigation, "* * * designates as having a potential for abuse * * *." The term "drug abuse" was defined for purposes of the report of the President's Advisory Commission on Narcotic and Drug Abuse, submitted November 1, 1963, as existing when an individual takes drugs under any of the following circumstances;

(*a*) in amounts sufficient to create a hazard to his own health or to the safety of the community; or

(*b*) when he obtains drugs through illicit channels; or

(*c*) when he takes drugs on his own initiative rather than on the basis of professional advice.

It is not intended by the committee that a drug's potential for abuse be determined on the basis of the drug's having a potential for isolated or occasional nontherapeutic purposes. The committee feels that a drug's "potential for abuse" should be determined on the basis of its having been demonstrated to have such depressant or stimulant effect on the central nervous system as to make it reasonable to assume that there is a substantial potential for the occurrence of significant diversions from legitimate drug channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community.

The Secretary of Health, Education, and Welfare should not be required to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to controls of the bill.

Possession

The bill prohibits the possession of depressant or stimulant drugs except those actually intended for personal use or for use by members of the person's household, or for administration to an animal owned by the possessor or by a member of his household. This provision has been carefully drafted so as to make it clear that the purpose is not to punish individual drug users or to permit the Secretary to institute enforcement action against a user solely for the use of these drugs. The possession provision makes clear that its purpose is to combat the illegal traffic in these drugs.

The quantity of such a drug found in one's possession bears, of course, on whether a bona fide intent to use the drug for one's self or one's household actually exists.

Subsection (c) of section 511, added to the Food, Drug, and Cosmetic Act by section 3(b) of the bill, makes possession of a depressant or stimulant drug unlawful if such possession is by a person other than those described in the preceding subsections of section 511 and is neither (1) for the personal use of the possessor or of a member of his household nor (2) for administration to an animal of such possessor or of a household member.[1] A clarifying amendment added by the committee provides that the Government shall, in a criminal prosecution for such possession, have the burden of proof to negate the fact that the defendant possessed the drug for his personal use or that of a member of his household or for administration to an animal owned by him or a member of his household. Where the drug is covered by a valid prescription fair on its face and issued by a licensed practitioner described in section 511(a)(4), the burden of proof on the Government to show that the possession is in fact for a different purpose and hence not within an exception from section 511(c) is heavier, and can be satisfied only by evidence adequate to overcome the inference, flowing from the prescription, that the possession was for the purpose for which the prescription was issued.

Recordkeeping and Inspection Generally

The committee has sought in this legislation to establish controls upon the distribution of depressant and stimulant drugs throughout

[1] Such possession is declared to be a prohibited act by sec. 301(q)(3) of the act, added by sec. 5 of the bill.

the chain of distribution, from the basic manufacturer to (but not including) the ultimate consumer. The legislation provides that each person included in the chain of distribution shall maintain records for not less than 3 years with respect to the drugs covered by the bill, and make the records available for inspection. This would permit Federal inspectors to conduct an audit program which would reveal diversion of the drugs from legitimate channels and thus would aid effective regulation.

The legislation provides specifically, "No separate records, nor set form or forms for any of the foregoing records, shall be required as long as records containing the required information are available." The purpose of this provision is to insure that the ordinary business records kept by legitimate businessmen will be considered as adequate records for the purpose of this legislation.

The committee is also satisfied that, as the committee contemplates the bill will be administered, the recordkeeping requirements in the bill will not require the maintenance of any special records not usually kept by hospitals observing the usual minimum standards. Insofar as drug purchases by hospitals are concerned, hospitals now maintain records thereof, whether in the form of invoices or otherwise; it would be no hardship to keep such records for the required 3 years. The hospitals also have a record of drugs disposed of, both in the form of prescription or patient order files and in the form of each patient's medical record chart. It is standard hospital practice to retain the patient chart, if not the patient's order file, for many years, thus easily satisfying the 3-year requirement of the bill.

Recordkeeping and Inspection of Pharmacies

Every pharmacist today is required to keep a complete record of all prescriptions which he fills, and for tax purposes keeps, or should keep, his invoices and other records for not less than 3 years. Therefore, the recordkeeping requirements contained in the legislation impose no requirements upon pharmacists which they do not already meet under other laws.

The legislation provides that the records required to be kept shall be subject to inspection by duly designated officers and employees of the Department of Health, Education, and Welfare. Under existing law, agents of the Bureau of Narcotics have full and complete authority to conduct inspections of pharmacists and their records. These inspections are not considered to breach any confidential relationships, nor should the inspections authorized under this legislation be considered as breaching any such relationship. The purpose of the inspections is to trace the flow of these drugs from manufacturer to consumer, and for the purpose of pinpointing areas of diversion. Inspections are an integral and essential part of the enforcement machinery of this legislation, and the bill therefore provides that the records maintained by pharmacists with respect to these drugs shall be subject to inspection by officers and employees designated for this purpose by the Secretary of Health, Education, and Welfare.

Pharmacists today maintain separate records on narcotics. If a pharmacist chooses, he may keep a separate prescription file with respect to drugs covered by this legislation. In those circumstances where such separate files are kept, the inspection authority granted

by this bill, insofar as concerns prescription files, will extend only to those separate files.

Coverage of Physicians

The bill provides an exemption from the recordkeeping and inspection requirements for any practitioner licensed by law to prescribe or administer depressant or stimulant drugs while acting in the course of his professional practice. An exception is made, however, in the case of any licensed practitioner who "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."

Persons covered by the preceding language involve only a very small percentage of physicians, dentists, and other licensed practitioners.

The key phrases in the interpretation of this exception are the words "regularly engages" and "for which they are charged." The committee intends by this exception to require recordkeeping and to permit inspection in the case of those physicians who maintain a supply of pharmaceuticals or medicinals in their offices from which they compound prescriptions for their patients for a fee. The committee has provided for recordkeeping and inspection in the case of retail pharmacies and feels that physicians who compound prescriptions in their own offices should be treated in the same fashion.

Of course, where a practitioner orders large quantities of depressant and stimulant drugs which he dispenses for profit and not for the treatment of his patients, he is acting illicitly rather than in the course of his professional practice and hence is outside the basic exemption from recordkeeping and inspection and is subject to the sanctions of the legislation.

Limitations on Refills of Prescriptions

One source of depressant and stimulant drugs for individuals involved in drug abuse is prescriptions which are unlimited, either as to duration or the number of refills permitted. There are, of course, instances where the needs of the patient are such that prescriptions of long duration are necessary, however, with respect to the drugs covered by this legislation, the unlimited prescription is not necessary. If a patient has taken these drugs for as long as 6 months, in general, the doctor treating the patient should at least be made aware that the patient is seeking to obtain the drugs after 6 months have passed.

There are instances where patients who have received a prescription for these drugs which is unlimited as to refills have the prescription refilled for years following the date the prescription was originally issued. The ready availability of drugs of the type covered by the bill can be dangerous to the patient, leading to his developing a dependence upon the drug. In some instances these prescriptions serve as a source of supply for these drugs in illicit channels.

The committee is reluctant to impose any controls whatsoever upon the manner in which doctors prescribe for their patients. On balance, however, the committee felt that some reasonable restrictions should be imposed upon prescriptions for these drugs and has therefore provided that prescriptions for drugs subject to the controls of this bill, whether issued before or after the effective date of this legislation, shall not be valid for more than 6 months, and may not be refilled more than five times. Of course, if a prescription is written and

refilling is not authorized by the physician, or is authorized by him to a lesser extent than under the bill, this legislation does not authorize any additional refills. However, if a prescription is written, or outstanding, which is unlimited in duration (or is for a period in excess of 6 months), or which is unlimited as to number of refills (or permits refills in excess of five), the bill will limit refills to not more than five, and will not permit any refills (whether or not the number of five has been reached) after 6 months have elapsed from the date of initial issuance).

Where a patient proposes to have a prescription refilled beyond 6 months, or after five refills, the doctor issuing the prescription originally may authorize refills, either in writing or orally (for example, by telephone), if the authorization is promptly reduced to writing and filed by the pharmacist. The reauthorization then becomes subject to the same 6-month and five refill limitations but may, again, be more closely limited by the physician.

Counterfeit Drugs

A counterfeit drug, like counterfeit money, is a fraud on the public. More important, however, is the imminent danger which it presents to the health of the user. Enormous profits can be made by counterfeiting legitimate drugs with minimal risks of penalties under the present law. For this reason, the activity has become widespread and sometimes is nationwide in scope.

The counterfeit drug is not manufactured under the controls or with the care that is taken for the legitimate drug it imitates, and there is no guarantee that the counterfeit drug contains the amounts, quality, and kinds of ingredients the legitimate drug contains. A consumer who is sold a counterfeit drug may have his health and even his life dependent on a product which has little or no resemblance to the drug prescribed by his physician, except for labeling or appearance. In turn, his physician may be misled in his intended therepeutic regimen by the different response of the patient to the drug from that anticipated.

Production and distribution of counterfeit drugs are bootleg operations. Special equipment for their production such as tableting dyes, tableting punches, and capsule marking machines are secreted and put to use surreptitiously.

After being produced under conditions designedly hidden from inspection by Federal, State, and local officials, counterfeit drugs are distributed by equally devious means. These have included shipment in unmarked cartons and containers. No matter the route, however, the ultimate consumer receives a counterfeit drug in place of a trustworthy medicine. He is defrauded, and his health is jeopardized.

Because of the clandestine methods by which counterfeit drugs are manufactured and distributed and the burden they impose on interstate commerce in legitimate drugs, their regulation as contemplated by this bill, whether they are in interstate commerce or not, is absolutely essential to the effective protection of the public health.

INCREASED ENFORCEMENT POWERS AND PROTECTION OF PERSONNEL

The bill provides authority for officers and employees of the Department of Health, Education, and Welfare, who are designated by the Secretary to conduct examinations, investigations, or inspections relating to depressant or stimulant drugs or counterfeit drugs, to (1) carry firearms, (2) execute and serve search warrants and arrest warrants, (3) execute seizures by judicial process, (4) make arrests without warrant in certain cases, and (5) detain goods and equipment temporarily pending the issuance of a libel of seizure.

Under existing law, agents of the Department do not have any of the foregoing powers. This greatly hinders the effective enforcement of the laws relating to depressant and stimulant drugs and counterfeit drugs.

Under existing law, agents of the Department who have information of violations of the Food and Drug Act are required to go to the local U.S. attorney and obtain the issuance of necessary process for seizures and for arrests, and then obtain the services of a U.S. marshal to execute the seizures and make arrests. This creates extreme difficulties when these agents are dealing with individuals as transient as those engaged in the illicit drug traffic. Frequently offenders escape apprehension between the time they have committed an offense and the time, usually days later, when the necessary procedures have been accomplished to obtain the services of a U.S. marshal.

This problem arises because the Food and Drug Act is designed primarily to deal with problems such as the adulteration or misbranding of foods, the safety and efficacy of drugs, and the safety of cosmetics and therapeutic devices. The problems dealt with by the Department under the act are frequently scientific or economic ones, and only in relatively limited areas are powers such as the power to make arrests and execute seizures necessary. These powers, however, are essential to the proper enforcement of laws dealing with depressant and stimulant drugs insofar as these drugs find their way into illicit channels and with counterfeit drugs.

It is anticipated that these powers will be used sparingly, and used primarily in dealing with persons illegally engaged in the distribution of these drugs.

STATE ACTIVITIES

The bill is not envisioned as limiting or taking the place of effective State controls where they exist or may later be provided. However, effective control of these drugs has not been achieved under existing State laws. In view of demonstrated inadequacies, the absence of any prospect of general improvement in State controls in the near future, and the urgency of the problem, there should be immediate provision for effective controls by the Federal Government. As more States secure adequate law, adequate enforcement personnel, and vigorous enforcement, the State role in control of the problem, particularly the control of intrastate commerce, should increase. Under the bill, traditional cooperative Federal-State work on food and drug problems could be employed, and the committee anticipates such cooperation.

The Cost

The cost of the legislation is estimated by Commissioner Larrick of the Food and Drug Administration at $10 million annually.

Section-by-Section Analysis

Section 1. Short title: Drug Abuse Control Amendments of 1965.

Section 2 contains findings as to the need for including both interstate and intrastate traffic in depressant and stimulant drugs within the scope of the bill.

Section 3(a) adds a new paragraph (v) to section 211 of the Federal Food, Drug, and Cosmetic Act, which defines "depressant or stimulant drugs" to mean (1) any drug which contains barbituric acid or its salts and any derivative of barbituric acid which the Secretary has designated as habit forming, (2) any drug which contains amphetamine or any of its optical isomers, or any salts of these, or any substance which the Secretary, by regulation, designates as habit forming because of its stimulant effect on the central nervous system, or (3) any drug which contains any quantity of substance which the Secretary, by regulation, designates as having a potential for abuse because of its depressant or stimulant effect on the central nervous system or because of its hallucinatory effect. (The so-called hard narcotics and marihuana are exempt from this last provision.) The designation of drugs (other than barbiturates and amphetamines) under the authority of section 3(a) would have to be through formal rulemaking procedures (with opportunity for hearing and judicial review) and, as explained below, opportunity for consultation of an ad hoc scientific advisory committee.

Section 3(b) adds a new section 511 to the Food, Drug, and Cosmetic Act, which does the following:

Prohibits the unauthorized manufacturing, compounding, processing, sale, delivery, or other disposition, of any depressant or stimulant drug. The seven classes of persons who are authorized to engage in these activities (plus carriers or warehousemen, who are authorized to deliver) are listed.

Prohibits possession of a depressant or stimulant drug; except by those referred to above, and except by an individual for his personal use, use by a member of his household, or administration to an animal owned by him or a member of his household.

Requires every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of depressant or stimulant drugs to prepare an initial inventory and keep accurate and complete record of manufacture, receipts, and distribution, and to maintain these records for 3 years, but no separate records, or distinct form of records, would be required. Exempts licensed practitioners, except those regularly engaged in dispensing depressant and stimulant drugs for a fee, from keeping records on depressant and stimulant drugs dispensed in the course of their professional practice.

Authorizes inspection and copying of the required records. And, for the purposes of verification of these records and enforcement of this section, authorizes inspection of premises and ve-

hicles, and of all equipment, material, containers, labeling, records, processes, controls, records, and other things bearing on whether a violation has occurred with respect to these drugs, and authorizes inspectors to inventory stocks of such drugs and take samples. (Financial data, sales data other than shipment data, pricing data, personnel data, and research data, which are exempted from inspection under the third sentence of sec. 704(a) of the basic statute, are also exempted from inspection under H.R. 2; it is not intended by this exemption to keep from inspection records that are required by the bill to be kept, whether these records be in the form of invoices or otherwise (H. Rept. 130, pp. 15 and 16).)

Provides that no prescription for a depressant or stimulant drug may be filled or refilled more than 6 months after the date of issue and that no refillable prescription may be refilled more than five times. However, prescriptions can be renewed, in writing or orally (if reduced to writing and filed by the pharmacist) by the prescribing practitioner, and then again refilled to the same extent as an original prescription.

Empowers the Secretary to exempt any depressant or stimulant drug from the bill's provisions when he finds that its regulation is not necessary for protection of the public health.

Requires the Secretary to exempt by regulation any combination of depressant or stimulant drugs with other drugs where the combination does not have the effect at which the bill is aimed, and to exempt drugs which may be sold over the counter without a prescription.

Permits the Secretary to appoint a scientific advisory committee in connection with the legislation to advise on questions, including questions involved in proposals to bring a drug within, or remove it from, the bill's provisions.

Section 4 amends section 510 of the act to require the registration of wholesalers, jobbers, and distributors of depressant or stimulant drugs. Manufacturers, compounders, and processors of depressant and stimulant drugs are required to indicate such fact when registering under section 510's general provisions or when they first engage in such activity at an establishment. The present exemptions from registration applicable to pharmacies, licensed practitioners, bona fide researchers and teachers, etc., will also apply to these new provisions.

Section 5 conforms the "prohibited acts" section (sec. 301) of the Food, Drug, and Cosmetic Act to the above-mentioned provisions by listing as a prohibited act any act declared unlawful, or any failure to observe a requirement, specified in those provisions, including refusal to permit inspectors to have access to records and make inspections authorized by the bill. This is a technical amendment to mesh the substantive provisions with the sanctions of the basic act.

Section 6 provides for seizure and condemnation of depressant and stimulant drugs with respect to which a prohibited act has occurred, and of equipment used in the production of depressant and stimulant drugs with respect to which a prohibited act by the producer has occurred. The section also provides for seizure of counterfeit drugs and paraphernalia used in their manufacture.

Section 7 provides for increased maximum penalties for persons over 18 who illegally dispense a depressant or stimulant drug to persons under 21, i.e., up to 2 years or $5,000 or both for the first offense, and 6 years or $15,000 or both for a subsequent offense, as compared to the maximum of 1 year and $1,000 for a first offense (not shown to involve an intent to defraud or mislead) and 3 years and $10,000 for a subsequent offense (or for first offenses committed with intent to defraud or mislead) otherwise applicable under the Food, Drug, and Cosmetic Act.

Section 8 authorizes the Secretary to permit inspectors conducting investigations relating to depressant and stimulant drugs or counterfeit drugs to carry firearms, to execute and serve search and arrest warrants, to make arrests without warrant where the offense is committed in the inspector's presence or, in the case of a felony, he has probable cause to believe that the person arrested has committed or is committing it, and to execute seizures with or without libels of information (subject, in the latter case, to prompt institution of libel proceedings). This section also makes it a Federal offense to assault or kill inspectors conducting investigations or inspections under the Federal Food, Drug, and Cosmetic Act.

Section 9(a) contains a finding that there is a substantial traffic in counterfeit drugs, that such traffic poses a serious health hazard, that, while such drugs are misbranded under section 502(i) of the Food, Drug, and Cosmetic Act, controls for suppression of the traffic are inadequate because of the difficulty of determining the place of origin and the fact that implements for counterfeiting are not subject to seizure, and that these factors require enactment of additional controls as to such drugs without regard to their interstate or intrastate origin.

Section 9(b) defines the term "counterfeit drug" to mean "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor, other than the person or persons who, in fact, manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

Section 9(c) prohibits the making, selling, disposing of, possessing, or concealing of equipment for counterfeiting drugs. It also prohibits the doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug. Persons acting in good faith and having no reason to believe that their acts, or the use of the equipment, would result in a counterfeit drug, or that the drugs in their possession are counterfeits, are exempted from the criminal penalties of the statute because of acts prohibited by section 9(c).

Section 10 provides that no provision of the bill shall displace State legislation not inconsistent with the bill, or authorize manaufacture, disposal, or possession of drugs contrary to State law, or prevent the enforcement of criminal penalities under State law for acts made criminal by the bill.

Section 11 establishes the effective date of the bill's several sections. Most of the provisions take effect on the first day of the seventh calendar month following the month of enactment. Sections defining the drugs to be covered authorizing advisory committees, granting greater protection to enforcement personnel, and the saving clause for State law would become effective upon enactment.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., March 12, 1965.

Hon. LISTER HILL,
Chairman, Committee on Labor and Public Welfare,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: On Wednesday, March 10, H.R. 2, the Drug Abuse Control Amendments of 1965, unanimously reported by the House Committee on Interstate and Foreign Commerce, passed the House by a vote of 402 to 0. The Department wholeheartedly endorses this legislation, without qualification, and seeks no amendments either substantive or technical.

The bill is similar, in most respects, to S. 2628, the Psychotoxic Drug Control Act of 1964, reported from your committee and passed by the Senate last year. This bill contains, in addition to the controls in S. 2628, new aids to combat the counterfeiting of drugs, additional enforcement powers for the Food and Drug Administration in restricting illicit drug traffic, and creation of an advisory committee to assist the Secretary in the selection of drugs to be brought under the new controls.

President Johnson requested enactment of this legislation in his health message, and repeated his support in last week's message on crime. You can be assured of this Department's wholehearted support for expeditious committee action on this bill.

Sincerely yours,

WILBUR J. COHEN, *Assistant Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., April 12, 1965.

Hon. LISTER HILL,
Chairman, Committee on Labor and Public Welfare,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of March 12, 1965, for a report on H.R. 2, the proposed Drug Abuse Control Amendments of 1965.

The bill is fully summarized and analyzed in the House report on the bill (H. Rept. 130). A shorter summary of its major provisions is enclosed herewith for your committee's convenience.

As we advised you in our letter of March 12—the same date as that shown by your request for a report—we wholeheartedly endorse and recommend enactment of this bill, which was unanimously reported to the House and was passed by a vote of 402 to 0.

With respect to barbiturates, amphetamines, and other stimulant and depressant drugs, this bill is the outgrowth of many years of study and action within the Congress and the executive branch. This history is too familiar to your committee to require reiteration here. This is, however, an appropriate occasion to acknowledge, once again, the major contribution made in this field by the investigations carried on through the years by the Senate Subcommittee on Juvenile Delinquency and by the unflagging efforts of its chairman, Senator Dodd, in framing, and insisting on consideration of, his bills to combat illicit traffic in barbiturates and amphetamines and other central-nervous-system depressant, stimulant, and hallucinogenic drugs which have been the subject of abuse or have a potential for abuse. As pointed out in our letter of March 12, H.R. 2 is similar in most respects to his bill on this subject in the 88th Congress (S. 2628, the proposed Psychotoxic Drug Control Act of 1964), which passed the Senate last year. It is also similar to the Senator's bill introduced this year, S. 438, the proposed Drug Control Act of 1965.

As pointed out in the House report on H.R. 2 (H. Rept. 130, p. 4), time did not permit consideration, by the House Committee on Interstate and Foreign Commerce, of S. 2628 after its Senate passage during the last Congress, but it was announced that this legislation would be the first order of business before that committee this year, and this was done on the basis of H.R. 2 which was introduced on the first day of this session. The House committee—and this Department in studying, reporting on, and testifying on H.R. 2—took full account of and benefited from these Senate bills.

We invite attention to the fact that H.R. 2 provides, in addition to the means for effective control of the traffic in depressant, stimulant, and hallucinogenic drugs, further means to combat the clandestine and dangerous manufacture and traffic in counterfeit drugs. The President has recommended legislation with respect to both of these categories of drugs (health message of Jan. 7, 1965; message on crime, its prevalence, and measures of prevention, dated Mar. 8, 1965).

We should also like to emphasize that the time available for further study since Senate passage of S. 2628 has enabled us to develop recommendations to give us important additional enforcement tools, and to protect our inspectors, which were submitted to and accepted by the House committee considering H.R. 2. We believe that these tools are necessary and will be especially valuable in copying with the underworld that engages in the traffic in these drugs and in the manufacture of counterfeit drugs.

Passage of this act will add new responsibilities to those already borne by the Department and will require careful planning to determine the necessary mode of organization and level of financial support. These needs are now under consideration by the Department but no official determination has yet been made.

In view of the extended consideration which your committee, in addition to the House committee and various committees in earlies Congresses, has given to legislation in this field, we hope that the present measure will be speedily enacted.

We are advised by the Bureau of the Budget that enactment of H.R. 2 would be in accord with the program of the President.

Sincerely,

ANTHONY J. CELEBREZZE, *Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., June 17, 1965.

Hon. RALPH YARBOROUGH,
U.S. Senate, Washington, D.C.

DEAR SENATOR YARBOROUGH: Recently you expressed to us your profound concern that the administration of H.R. 2, the Drug Abuse Control Amendments of 1965, could result in unwarranted competitive disadvantage to a firm manufacturing or distributing barbiturates which may be no more habit forming than drugs that are not brought specifically under the control of the act by name—certain tranquilizers, for instance.

We wish to take this opportunity to assure you that we are doing everything reasonably possible to plan for administering the act in a manner that will not result in that kind of economic injury. As you are aware, section 201(v) would authorize us to include additional drugs, not specifically named, in the coverage of the act by regulation. That section, and section 511(g), relating to advisory committees, would become effective 7 months prior to the other portions of the act. In view of the amendments made in the provisions relating to the advisory committee procedures, we have every expectation that this process can be expedited, and we have every reason to believe that regulations will be issued by the end of the 7-month period.

So that regulations in this area can be proposed at the earliest possible moment, the Bureau of Medicine of the Food and Drug Administration has for the past several weeks been studying its records to determine what drugs should be brought under the control of the act through the above-mentioned provisions. In that connection, they have given special attention to drugs other than barbiturates and amphetamines which were mentioned during the hearings on H.R. 2, including those referred to in the House committee's report. In addition, the Food and Drug Administration has requested the assistance of the Public Health Service and St. Elizabeths Hospital, both in this Department, in identifying additional drugs that should be brought under the coverage of the bill. Further, the Food and Drug Administration has been in consultation with committees of the American Medical Association and the National Academy of Sciences-National Research Council which are studying narcotics and drugs such as those to be covered by H.R. 2. We will make every effort to move without delay in the publication of proposed regulations following the enactment of the bill. Moreover, every effort will be made to proceed with dispatch in the conduct of hearings, if they are necessary, with respect to any drug which is proposed to be included under the act by regulation.

We share your desire to resolve these problems as far as possible by prompt action. It will be our intention throughout to make the administration of the act logical, reasonable, and expeditious.

Sincerely,

WILBUR J. COHEN, *Under Secretary.*

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER II. DEFINITIONS

SEC. 201. For the purposes of this Act—

(a)(1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the U.S. Department of Health, Education, and Welfare.

(d) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) *(1)* The term "drug" means [(1)] *(A)* articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and [(2)] *(B)* articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and [(3)] *(C)* articles (other than food) intended to affect the structure or any function of the body of man or other animals; and [(4)] *(D)* articles intended for use as a component of any articles specified in [clause (1), (2), or (3)] *clause (A), (B), or (C)*; but does not include devices or their components, parts, or accessories.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device; or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means instru-

ments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promotiong attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q) The term "pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is an "economic poison" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., secs. 135–135k) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

(t)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other

agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe," as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal.

(v) The term "depressant or stimulant drug" means—

(1) any drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid; or (B) any derivative of barbituric acid which has been designated by the Secretary under section 502(d) as habit forming;

(2) any drug which contains any quantity of (A) amphetamine or any of its optical isomers; (B) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (C) any substance which the Secretary, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(3) any drug which contains any quantity of a substance which the Secretary, after investigation, has found to have, and by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect; except that the Secretary shall not designate under this paragraph, or under clause (C) of subparagraph (2), any substance that is now included, or is hereafter included, within the classifications stated in section 4731, and marihuana as defined in section 4761, of the Internal Revenue Code of 1954 (26 U.S.C. 4731, 4761).

The provisions of subsections (e), (f), and (g) of section 701 shall apply to and govern proceedings for the issuance, amendment, or repeal of regulations under subparagraph (2)(C) or (3) of this paragraph.

CHAPTER III. PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703; or the failure to establish or maintain any record, or make any report, required under section 505 (i) or (j), or 507 (d) or (g), or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i)(*1*) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 506, 507, or 706.

(*2*) *Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.*

(*3*) *The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.*

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, 704, or 706 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that approval of an application with respect to such drug is in effect under section 505, or that such drug complies with the provisions of such section.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b), or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register as required by section 510.

(q)(*1*) *The manufacture, compounding, or processing of a drug in violation of section 511(a); (2) the sale, delivery, or other disposition of a*

drug in violation of section 511(b); (3) the possession of a drug in violation of section 511(c); (4) the failure to prepare or obtain, or the failure to keep, a complete and accurate record with respect to any drug as required by section 511(d); (5) the refusal to permit access to or copying of any record as required by section 511(d); (6) the refusal to permit entry or inspection as authorized by section 511(d); or (7) the filling or refilling of any prescription in violation of section 511(e).

* * * * * * *

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine*: Provided, however, That any person who, having attained his eighteenth birthday, violates section 301(q)(2) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who has not attained his twenty-first birthday shall, if there be no previous conviction of such person under this section which has become final, be subject to imprisonment for not more than two years, or a fine of not more than $5,000, or both such imprisonment and fine, and for the second or any subsequent conviction for such a violation shall be subject to imprisonment for not more than six years, or a fine of not more than $15,000, or both such imprisonment and fine.*

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall *(except in the case of an offense which is subject to the provisions of the proviso to subsection (a) relating to second or subsequent offenses)* be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a

color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c) or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article*; or (5) for having violated section 301(i)(2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.*

SEIZURE

SEC. 304. (a)(*1*) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply [(1)](*A*) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or [(2)](*B*) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trail to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which they are found: (A) Any depressant or stimulant drug with respect to which a prohibited act within the meaning of section 301 (p) or (q) by any person has occurred; (B) any drug that is a counterfeit drug; (C) any container of such depressant or stimulant drug or of a counterfeit drug; (D) any equipment used in manufacturing, compounding, or processing a depressant or stimulant drug with respect to which drug a prohibited act within the meaning of section 301 (p) or (q), by the manufacturer, compounder, or processor thereof, has occurred; and (E) any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs.

(b) The article, *equipment, or other thing proceeded against* shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, and pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d)(*1*) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided,* That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the

owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes [(1)] (*A*) that the adulteration, misbranding, or violation did not occur after the article was imported, and [(2)] (*B*) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 801(d) can and will be met: *Provided, however*, That the provisions of this sentence shall not apply where condemnation is based upon violation of section 402(a)(1), (2), or (6), section 501(a)(3), section 502(j), or section 601(a) or (d); *And provided further*, That where such exportation is made to the original foreign supplier, then clauses (1) and (2) of section 801(d) and the foregoing proviso shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 801(d) have been met. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim or any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to depressant or stimulant drugs or counterfeit drugs.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties for purposes of such case, which the court

from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

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CHAPTER V. DRUGS AND DEVICES

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REGISTRATION OF PRODUCERS *AND CERTAIN WHOLESALERS* OF DRUGS

SEC. 510. (a) As used in this section—

(1) the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;

(2) the term "wholesaling, jobbing, or distributing of depressant or stimulant drugs" means the selling or distribution of any depressant or stimulant drug to any person who is not the ultimate user or consumer of such drug;

[(2)] *(3)* the term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs *or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug* shall register with the Secretary his name, places of business, and all such establishments. *If any such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of any depressant or stimulant drug, such person shall, at the time of such registration, indicate such fact, in such manner as the Secretary may by regulation prescribe.*

(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs *or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug* in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment. *If such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of any depressant or stimulant drug such person shall, at the time of such registration, indicate such fact, in such manner as the Secretary may by regulation prescribe.*

(d) *(1)* Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs *or the wholesaling, jobbing, or distributing of any depressant or stimulant drug. If any depressant or stimulant drug is manufactured, prepared, propagated, compounded, or processed in such additional establishment, such person shall, at the time of such registration, indicate such fact, in such manner as the Secretary may by regulation prescribe.*

(2) Every person who is registered with the Secretary pursuant to the first sentence of subsection (b) or (c) or paragraph (1) of this subsection, but to whom the second sentence of subsection (b) or (c) or of paragarph (1) of this subsection did not apply at the time of such registration, shall, if any depressant or stimulant drug is thereafter manufactured, prepared, propagated, compounded, or processed in any establishment with respect to which he is so registered, immediately file a supplement to such registration with the Secretary indicating such fact, in such manner as the Secretary may by regulation prescribe.

(e) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section.

(f) The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section.

(g) The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

(h) Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 704 and shall be so inspected by one or more officers or employees duly designated by the Secretary at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter.

(i) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall be permitted to register under this section pursuant to regulations promulgated by the Secretary. Such regulations shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether drugs manufactured, prepared, propagated, compounded, or processed in such establishment, if imported, or offered for import into the United States, shall be refused admission on any of the grounds set forth is section 801(a) of this Act.

DEPRESSANT AND STIMULANT DRUGS

SEC. 511. (a) No person shall manufacture, compound, or process any depressant or stimulant drug, except that this prohibition shall not apply to the following persons whose activities in connection with any such drug are solely as specified in this subsection:

(1)(A) Manufacturers, compounders, and processors registered under section 510 who are regularly engaged, and are otherwise qualified, in conformance with local laws, in preparing pharmaceutical chemicals or prescription drugs for distribution through branch outlets, through wholesale druggists, or by direct shipment, (i) to pharmacies or to hospitals, clinics, public health agencies, or physicians, for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practitioners licensed by law to administer such drugs in the course of their professional practice, or (ii) to laboratories or research or educational institutions for their use in research, teaching, or chemical analysis.

(B) Suppliers (otherwise qualified in conformance with local laws) of manufacturers, compounders, and processors referred to in subparagraph (A).

(2) Wholesale druggists registered under section 510 who maintain establishments in conformance with local laws and are regularly engaged in supplying prescription drugs (A) to pharmacies, or to hospitals, clinics, public health agencies, or physicians, for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practioners licensed by law to administer such drugs in the course of their professional practice, or (B) to laboratories or research or educational institutions for their use in research, teaching, or clinical analysis.

(3) Pharmacies, hospitals, clinics, and public health agencies, which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs upon prescriptions of practitioners licensed to administer such drugs for patients under the care of such practitioners in the course of their professional practice.

(4) Practitioners licensed by law to prescribe or administer depressant or stimulant drugs, while acting in the course of their professional practice.

(5) Persons who use depressant or stimulant drugs in research, teaching, or chemical analysis and not for sale.

(6) Officers and employees of the United States, a State government, or a political subdivision of a State, while acting in the course of their official duties.

(7) An employee or agent of any person described in paragraph (1) through paragraph (5), and a nurse or other medical technician under the supervision of a practitioner licensed by law to administer depressant or stimulant drugs, while such employee, nurse, or medical technician is acting in the course of his employment or occupation and not on his own account.

(b) No person, other than—

(1) a person described in subsection (a), while such person is acting in the ordinary and authorized course of his business, profession, occupation, or employment, or

(2) a common or contract carrier or warehouseman, or an employee thereof, whose possession of any depressant or stimulant drug is in the usual course of his business or employment as such,

shall sell, deliver, or otherwise dispose of any depressant or stimulant drug to any other person.

(c) No person, other than a person described in subsection (a) or subsection (b)(2), shall possess any depressant or stimulant drug otherwise than (1) for the personal use of himself or of a member of his household, or (2) for administration to an animal owned by him or a member of his household. In any criminal prosecution for possession of a depressant or stimulant drug in violation of this subsection (which is made a prohibited act by section 301(q)(3)), the United States shall have the burden of proof that the possession involved does not come within the exceptions contained in clauses (1) and (2) of the preceding sentence.

(d)(1) Every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of any depressant or stimulant drug shall, upon the effective date of this section, prepare a complete and accurate record of all stocks of each such drug on hand and shall keep such record for three years. On and after the effective date of this section, every person manufacturing, compounding, or processing any depressant or stimulant drug shall prepare and keep, for not less than three years, a complete and accurate record of the kind and quantity of each such drug manufactured, compounded, or processed and the date of such manufacture, compounding, or processing; and every person selling, delivering, or otherwise disposing of any depressant or stimulant drug shall prepare or obtain, and keep for not less than three years, a complete and accurate record of the kind and quantity of each such drug received, sold, delivered, or otherwise disposed of, the name and address of the person, and the registration number, if any, assigned to such person by the Secretary pursuant to section 510(e), from whom it was received and to whom it was sold, delivered, or otherwise disposed of, and the date of such transaction. No separate records, nor set form or forms for any of the foregoing records, shall be required as long as records containing the required information are available.

(2)(A) Every person required by paragraph (1) of this subsection to prepare or obtain, and keep, records, and any carrier maintaining records with respect to any shipment containing any depressant or stimulant drug, and every person in charge, or having custody, of such records, shall, upon request of an officer or employee designated by the Secretary permit such officer or employee at reasonable times to have access to and copy such records. For the purposes of verification of such records and of enforcement of this section, officers or employees designated by the Secretary are authorized, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, to enter, at reasonable times, any factory, warehouse, establishment, or vehicle in which any depressant or stimulant drug is held, manufactured, compounded, processed, sold, delivered, or otherwise disposed of, and to inspect, within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished material, containers, and labeling therein, and all things therein (including records, files, papers, processes, controls, and facilities) bearing on violation of this section or section 301(q); and to inventory any stock of any such drug therein and obtain samples of any such drug. If a sample is thus obtained, the officer or employee making the inspection

shall, upon completion of the inspection and before leaving the premises, give to the owner, operator, or agent in charge a receipt describing the sample obtained.

(B) No inspection authorized by subparagraph (A) shall extend to (i) financial data, (ii) sales data other than shipment data, (iii) pricing data, (iv) personnel data, or (v) research data, which are exempted from inspection under the third sentence of section 704(a) of this Act.

(3) The provisions of paragraph (1) and (2) of this subsection shall not apply to a licensed practitioner described in subsection (a)(4) with respect to any depressant or stimulant drug received, prepared, processed, administered, or dispensed by him in the course of his professional practice, unless such practitioner 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.

(e) No prescription (issued before or after the effective date of this section) for any depressant or stimulant drug may be filled or refilled more than six months after the date on which such prescription was issued and no such prescription which is authorized to be refilled may be refilled more than five times, except that any prescription for such a drug after six months after the date of issue or after being refilled five times may be renewed by the practitioner issuing it either in writing or orally (if promptly reduced to writing and filed by the pharmacist filling it).

"(f)(1) The Secretary may be regulation exempt any depressant or stimulant drug from the application of all or part of this section when he finds that regulation of its manufacture, compounding, processing, possession, and disposition, as provided in this section or in such part thereof, is not necessary for the protection of the public health.

"(2) The Secretary shall be regulation exempt any depressant or stimulant drug from the application of this section, if—

"(A) such drug may, under the provisions of this Act, be sold over the counter without a prescription; or

"(B) he finds that such drug includes one or more substances not having a depressant or stimulant effect on the central nervous system or a hallucinogenic effect and such substance or substances are present therein in such combination, quantity, proportion, or concentration as to prevent the substance or substances therein which do have such an effect from being ingested or absorbed in sufficient amounts or concentrations as, within the meaning of section 201(v), to—

"(i) be habit forming because of their stimulant effect on the central nervous system, or

"(ii) have a potential for abuse because of their depressant or stimulant effect on the central nervous system or their hallucinogenic effect.

(g)(1) The Secretary may, from time to time, appoint a committee of experts to advise him with regard to any of the following matters involved in determining whether a regulation under subparagraph (2)(C) or (3) of section 201(v) should be proposed, issued, amended, or repealed: (A) whether or not the substance involved has a depressant or stimulant effect on the central nervous system or a hallucinogenic effect, (B) whether the substance involved has a potential for abuse because of its depressant or stimulant effect on the central nervous system, and (C) any other scientific question (as determined by the Secretary) which is pertinent to the determination of whether such substance should be designated by the

Secretary pursuant to subparagraph (2)(C) or (3) of section 201(v). The Secretary may establish a time limit for submission of the committee's report. The appointment, compensation, staffing, and procedure of such committees shall be in accordance with subsections (b)(5)(D), and the admissibility of their reports, recommendations, and testimony at any hearing involving such matters shall be determined in accordance with subsection (d)(2), of section 706. The appointment of such a committee after publication of an order acting on a proposal pursuant to section 701(e)(1) shall not suspend the running of the time for filing objections to such order and requesting a hearing unless the Secretary so directs.

(2) Where such a matter is referred to an expert advisory committee upon request of an interested person, the Secretary may, pursuant to regulations, require such person to pay fees to pay the costs, to the Department, arising by reason of such referral. Such fees, including advance deposits to cover such fees, shall be available, until expended, for paying (directly or by way of reimbursement of the applicable appropriations) the expenses of advisory committees under this subsection and other expenses arising by reason of referrals to such committees and for refunds in accordance with such regulations.

(h) As used in this section and in sections 301 and 304, the term "manufacture, compound, or process" shall be deemed to refer to "manufacture, preparation, propagation, compounding, or processing" as defined in section 510(a), and the term "manufacturers, compounders, and processors" shall be deemed to refer to persons engaged in such defined activities.

CHAPTER VII. GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

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EXAMINATIONS AND INVESTIGATIONS

SEC. 702. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

(c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department of Health, Education, and Welfare duly authorized by the Secretary to make such inspection.

(d) The Secretary is authorized and directed, upon request from the Commissioner of Patents, to furnish full and complete information with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

(e) Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this Act relating to depressant or stimulant drugs or to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 304;

(4) make arrests without warrant for offenses under this Act with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 304(a)(2), seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable ground to believe that they are, subject to seizure and condemnation under such section 304(a)(2). In the event of seizure pursuant to this paragraph (5), libel proceedings under section 304(a)(2) shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

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SECTION 1114 OF TITLE 18 OF THE UNITED STATES CODE

§ 1114. Protection of officers and employees of the United States.

Whoever kills any judge of the United States, any United States Attorney, any Assistant United States Attorney, or any United States marshal or deputy marshal or person employed to assist such marshal or deputy marshal, any officer or employee of the Federal Bureau of Investigation of the Department of Justice, any post office inspector, any officer or employee of the secret service or of the Bureau of Narcotics, any officer or enlisted man of the Coast Guard, any officer or employee of any United States penal or correctional institution, any officer, employee or agent of the customs or of the internal revenue or any person assisting him in the execution of his duties, any immigration officer, any officer or employee of the Department of Agriculture or of the Department of the Interior designated by the Secretary of Agriculture or the Secretary of the Interior to enforce any Act of Congress for the protection, preservation, or restoration of game and other wild birds and animals, any employee of the Department of Agriculture designated by the Secretary of Agriculture to

carry out any law or regulation, or to perform any function in connection with any Federal or State program or any program of Puerto Rico, Guam, the Virgin Islands of the United States, or the District of Columbia, for the control or eradication or prevention of the introduction or dissemination of animal diseases, any officer or employee of the National Park Service, any officer or employee of, or assigned to duty in, the field service of the Bureau of Land Management, any employee of the Bureau of Animal Industry of the Department of Agriculture, or any officer or employee of the Indian field service of the United States, or any officer or employee of the National Aeronautics and Space Administration directed to guard and protect property of the United States under the administration and control of the National Aeronautics and Space Administration, [or] any security officer of the Department of State or the Foreign Service, *or any officer or employee of the Department of Health, Education, and Welfare designated by the Secretary of Health, Education, and Welfare to conduct investigations or inspections under the Federal Food, Drug, and Cosmetic Act* while engaged in the performance of his official duties, or on account of the performance of his official duties, shall be punished as provided under sections 1111 and 1112 of this title.

For the convenience of Members of the House, section 111 of title 18, United States Code, which incorporates by reference a portion of section 1114 of that title, is set forth below:

§ 111. Assaulting, resisting, or impeding certain officers or employees.

Whoever forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person designated in section 1114 of this title while engaged in or on account of the performance of his official duties, shall be fined not more than $5,000 or imprisoned not more than three years, or both.

Whoever, in the commission of any such acts uses a deadly or dangerous weapon, shall be fined not more than $10,000 or imprisoned not more than ten years, or both.

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