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NARCOTICS MANUFACTURING ACT OF 1960

FEBRUARY 4, 1960.—Ordered to be printed

Mr. BYRD of Virginia, from the Committee on Finance, submitted the following

REPORT

[To accompany H.R. 529]

The Committee on Finance, to whom was referred the bill (H.R. 529) to discharge more effectively obligations of the United States under certain conventions and protocols relating to the institution of controls over the manufacture of narcotic drugs, and for other purposes, report favorably thereon with amendments and recommend that the bill as amended do pass.

I. PURPOSE

Your committee's bill, H.R. 529, is designed to give full effect to treaty obligations of the United States to limit exclusively to medical and scientific purposes the manufacture of narcotic drugs and to require that such manufacture be restricted to persons and premises that have been licensed for the purpose. It is also designed to amend the Narcotic Drugs Import and Export Act (21 U.S.C. 171–185) to bring the regulation of exports in conformity with current treaty obligations, and to permit the importation and exportation of certain narcotic drugs for scientific research purposes. Favorable reports were received on this legislation from the Treasury Department and the Department of State.

II. GENERAL STATEMENT

The present provisions for the control of the distribution and use of narcotic drugs, insofar as the Federal law is concerned, are contained in parts I and III of subchapter A of chapter 39 of the Internal Revenue Code of 1954. Although these provisions (generally known collectively as the Harrison Act) were enacted as a taxing measure, they have been generally effective in controlling the distribution and use of narcotic drugs. However, neither the Harrison Act nor the

Narcotic Drugs Import and Export Act affords a basis for specific quantitative limitation of the manufacture of narcotic drugs, particularly those of completely synthetic origin.

When the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs entered into force with respect to the United States of America July 9, 1933, our country accepted an obligation to limit to medical and scientific uses its manufacture of the narcotic drugs then covered by that convention, that is, the "natural" narcotic drugs falling within the category of derivatives of opium and coca leaves, such as morphine and cocaine. This obligation could be and was met indirectly by appropriate restrictions, under the Narcotic Drugs Import and Export Act, upon the importation of the crude material (opium and coca leaves), there being no domestic production of these raw materials in the United States.

However, beginning approximately with the year 1940, there were discovered and developed synthetic substitutes for the "natural" analgesic drugs in the morphine class. These synthetic narcotic drugs (such as mepheridine, methadon, etc.) bore no chemical relationship to morphine or opium, but were synthetically prepared from other chemicals rather readily obtainable, yet they were found to have a pain-relieving quality and, unfortunately, a drug-addiction liability comparable to morphine. In 1946 the Robertson amendment, now section 4731(g) of the Internal Revenue Code of 1954, was adopted as a procedure whereby any drug found by the Secretary of the Treasury to have addiction liability similar to morphine or cocaine, and so proclaimed by the President, could be classed as an "opiate" and be subjected to control of the Federal narcotic laws. A somewhat analogous procedure, in the field of international control, was provided by the 1948 protocol for bringing under international control drugs outside the scope of the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs. Thus any state party to the 1948 protocol which considers that a drug which is or may be used for medical or scientific purposes and which is not presently under control of the 1931 convention is liable to the same kind of abuse and productive of the same kind of harmful effects as the drugs covered by that convention may send a notification to that effect, with all material information, to the Secretary General of the United Nations who shall transmit it immediately to the other states parties to the protocol, the Commission on Narcotic Drugs and the World Health Organization. If the World Health Organization finds that the drug in question is capable of producing addiction or of conversion into a product capable of producing addiction, it shall decide under what regime the drug shall fall under the 1931 convention. Such decision and finding is required to be communicated promptly by the Secretary General to the several states parties who are thereupon obliged to apply to the drug in question the appropriate control under the 1931 convention.

The 1948 protocol entered into force with respect to the United States of America on September 11, 1950, and there is need for legislation to implement the provisions of the protocol, as represented by section 5 of H.R. 529. A conforming amendment is also necessary to section 4731(g) of the Internal Revenue Code of 1954, to include under the definition of "opiate" a drug which may not itself have addiction liability but may readily be converted into an addicting drug, and to

permit the Secretary or his delegate to withdraw a previous finding that a drug is an "opiate" whenever he determines that such previous finding was erroneous (sec. 4(b) of H.R. 529). The amendment proposed by this section also eliminates the necessity of a proclamation of the finding by the President, reserving to the Secretary or his delegate the duty of making the finding and the proclamation.

The drugs covered by article 10 of the 1925 Geneva Convention and referred to in the 1931 convention and the 1948 protocol are restricted to *narcotic* drugs—that is, drugs having an addiction-sustaining liability similar to morphine or cocaine or convertible into drugs having such addiction-sustaining liability. Therefore, our treaty obligations do not relate to, and the committee's bill does not seek to control, the manufacture of other drugs such as, for example, barbiturates, amphetamines, tranquilizers, and alcohol, which may have some type of addictive or habit-forming qualities, but whose addiction liability is not similar to that of morphine or cocaine.

The bill under discussion, therefore, provides a system of licenses and manufacturing quotas for all manufacturers, with appropriate safeguards, with respect to the manufacture of the basic classes of narcotic drugs, both natural and synthetic, for medical and scientific purposes. This is required to enable the U.S. Government to discharge its treaty obligations and to provide for the general health and welfare.

The bill was amended by the House Committee on Ways and Means to provide a procedure by revision of subsection (a) of section 4702 of the Internal Revenue Code of 1954, to except from application of certain provisions of the code and of export requirements of the Narcotic Drugs Import and Export Act such narcotic preparations as are found to have no addictive liability or minor addictive liability. This exception as far as it relates to a particular narcotic preparation may be withdrawn and revoked if it is subsequently determined, after notice and opportunity for hearing, that the preparation does have an addiction potentiality that results in abusive use of the exception.

III. COMMITTEE AMENDMENTS

At the suggestion of the Treasury Department the Committee on Finance adopted two amendments to the House-passed bill which are explained below.

(1) On page 20, section 8(a), line 6, strike out "1960" and insert "1961". Since the operation of the manufacturing license and quota provisions are designed to become effective on a calendar year basis, it was necessary to change the effective date from January 1, 1960 to January 1, 1961.

(2) On page 14, immediately after line 11, add a new subsection (d) to section 4 of the bill, reading as follows:

> (d) The amendment to subsection (g) of section 4731 of the Internal Revenue Code of 1954, made by subsection (b) of this section, shall not affect any proceeding commenced before such amendment, but such proceeding shall be continued to final disposition as if the amendment had not been made.

Section 4(b) of the bill substantially amends subsection (g) of section 4731 of the Internal Revenue Code of 1954, relating to procedure for

proclaiming new drugs as "opiates" under certain conditions, thus making them subject to control under the Federal narcotic laws. Proceedings under the present subsection (g) of section 4731 of the Internal Revenue Code of 1954 have been initiated, but not yet completed, in the case of two new drugs, and it is possible that such proceedings may be initiated in the case of other new drugs, which proceedings conceivably could not be completely disposed of by the time section 4(b) of this bill may become effective as law. Therefore, the new subsection (d) was added as the necessary saving clause.

IV. TREATY OBLIGATIONS

The following excerpt from House Report No. 1053 is reprinted for the information of the Senate:

> One of the important narcotic conventions to which the United States is a party is the one previously described as the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs. By becoming a party to the 1931 convention, the United States became obligated to carry out certain provisions of the International Opium Convention of 1925 (commonly known as the 1925 Geneva Convention) to which the United States was not a party. Thus, article 13.1(a) of the 1931 convention provides that the parties—
>
> "* * * shall apply to all drugs in group I, the provisions of the Geneva Convention which are thereby applied to substances specified in its fourth Article (or provisions in conformity therewith)."
>
> The provisions of the 1925 Geneva Convention, thus referred to and undertaken, include the obligation to—
>
> "* * * enact effective laws or regulations to limit exclusively to medical and scientific purposes the manufacture, import, sale, distribution and use (of narcotic drugs)" (Geneva Convention, art. 5).
>
> It also includes the obligation to—
>
> "* * * confine the *manufacture* of the substances referred to in Article 4 (b), (c) and (g) to those establishments and premises alone which have been licensed for the purpose (Geneva Convention, art. 6(a))." [Emphasis added.]
>
> The substances referred to in article 4(b), (c), and (g) of the Geneva Convention include—
>
> "(b) Crude cocaine and ecgonine.
>
> "(c) Morphine, diacetylmorphine, cocaine and their respective salts."
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> * * * * *
>
> "(g) Any other narcotic drug to which the present Convention may be applied in accordance with Article 10."
>
> The "catchall" article 10 of the Geneva Convention referred to in article 4(g) above, as amended by the 1946 protocol, provides for the addition to the list of narcotic drugs (to which arts. 5 and 6 of the Geneva Convention shall

be applied) such narcotic drugs as are accepted for inclusion in the list by the contracting parties on the advice of an expert committee of the World Health Organization and recommendation of the Economic and Social Council of the United Nations. Under article 10, as amended by the 1946 protocol, each contracting party had the choice of accepting the recommendations of the U.N. agencies and thereupon applying the provisions of the Geneva Convention to the narcotic drug in question. However, article 10 has since been supplemented by the 1948 protocol, previously described, making it a firm obligation upon all the contracting parties to apply "the appropriate regime laid down by the 1931 convention" to any narcotic drug found by the World Health Organization to be "capable of producing addiction, or conversion into a product capable of producing addiction." In the preamble to the 1948 protocol it is stated that its provisions are directed particularly to synthetic drugs which have resulted from modern pharmacology and chemistry which were not previously covered by the 1931 convention.

By articles 2 and 5 of the 1931 convention, each contracting party is obligated to furnish annual estimates of the quantities of each drug to be required by that country for—

"(a) Medical and scientific needs;

"(b) For conversion, whether for domestic consumption or for export;

"(c) For reserve stocks; and

"(d) For Government stocks."

Article 6 further provides that there shall not be manufactured in any country in any one year a quantity of any drug greater than the total of—

"(a) The quantity estimated to be required for medical and scientific needs;

"(b) The quantity estimated to be required for conversion;

"(c) The quantity required for lawful export;

"(d) The quantity required to maintain reserve stocks at the estimated level; and

"(e) The quantity required for Government stocks at the estimated level."

Article 7 provides that from the total permitted to be manufactured under article 6 there shall be deducted the amount of imports and the amounts seized and used for domestic consumption or for conversion.

Thus the U.S. Government is obligated by treaty to confine the manufacture of all narcotic drugs, including any new synthetic narcotic drugs found by the World Health Organization to be addiction forming or convertible into an addiction-forming drug, to "those establishments and premises alone which have been licensed for the purpose," and to enact laws to limit production and sale to medical and scientific purposes, to furnish an annual estimate of its needs for such purposes, and to restrict the quantity manufactured to the amount of the estimate.

V. DESCRIPTION OF THE BILL

1. *Short title.*—Section 1 provides a short title for the bill so that it could be cited as the "Narcotics Manufacturing Act of 1960."

2. *Necessity for legislation.*—Section 2 states reasons for the need, and constitutional basis, for the proposed legislation.

3. *Definitions.*—Section 3 defines the terms used in the bill. The definitions in subsections (c), (g), (h), and (i) require some explanation.

(c) The administration of the bill, if enacted into law, will be by the Secretary of the Treasury or his delegate, who in practice will presumably be the Commissioner of Narcotics.

(g) This subsection defines the term "basic class of narcotic drug" which is the unit of control employed in the act. The definition is by enumeration. The classes enumerated are adapted from the classification established by the World Health Organization and the Commission on Narcotic Drugs of the United Nations Economic and Social Council and include those classes which are presently commercially produced in the United States. A House committee amendment added a recently discovered drug (phenazocine) and its salts to the basic classes of narcotic drugs. Modification of the list of basic classes of narcotic drugs may be made in accordance with the procedure established by section 6 of the bill, later explained.

(h) This subsection defines the term "net disposal" which is the concept employed in section 11 of the bill as the basis for the automatic manufacturing quotas to which manufacturers of narcotic drugs licensed under the proposed act will be entitled. A detailed explanation of the term will be found in the discussion of section 11.

(i) This subsection defines the term "narcotic precursor," which is a nonnarcotic substance that may conveniently be used to manufacture a narcotic drug. The extent to which narcotic precursors should be subjected to control poses difficult problems. The tentative and temporary solution proposed by this bill is discussed below in connection with section 13.

4. *Amendments to Internal Revenue Code of 1954.*—This section amends the definitions of "narcotic drugs" and "opiates," respectively, as contained in section 4731 of the Internal Revenue Code of 1954, as follows:

(1) It excludes from the definition of "narcotic drugs" decocainized coca leaves or extracts of coca leaves which do not contain narcotic drugs, in order to exempt such substances, which are used primarily in the manufacture of soft drinks, from the controls of the bill.

(2) It adds to the definition of "opiate" (which includes drugs having an addiction-forming or addiction-sustaining liability similar to morphine or cocaine) those drugs or substances found to present a risk of relatively easy and economical conversion into a drug with an addiction liability similar to morphone or cocaine; removes the requirement of a Presidential proclamation of a finding under subsection (g) of section 4731 of the Internal Revenue Code; and authorizes the Secretary or his delegate to withdraw any previous finding that a drug or other substance is an "opiate" whenever he determines that such previous finding was erroneous. A House committee amendment providing for consideration of technical advice of the Secretary of Health, Education, and Welfare, or his delegate, officially recognizes and insures the continuation of the present administrative practice.

The Committee on Finance added an amendment to permit proceedings commenced prior to the amendment to subsection (g) of section 4731 to continue to final disposition as if the amendment had not been made.

5. *Notifications, findings, and decisions under the 1948 protocol.*—This section establishes procedures for notification under the 1948 protocol, and the effect of findings and decisions under that protocol.

(a) Before a notification may be sent on behalf of the United States under the 1948 protocol to the United Nations for the World Health Organization, that a drug is considered addictive or readily convertible into an addicting drug and therefore should be controlled, such drug must first be found to be an "opiate" in accordance with the procedure prescribed by section 4731(g) of the Internal Revenue Code as proposed to be amended by section 4 of this bill. This provision links the U.S. recommendations for international control to the usual route for domestic control, that is the Robertson amendment procedure (as suggested to be revised) of the Harrison Act. This provision affords interested parties opportunity for hearing where desired. At the same time, this provision permits reasonably quick action to establish domestic control of a new synthetic found to be dangerous from the standpoint of addiction liability.

(b) When the United States receives a finding or decision from the World Health Organization or the United Nations Commission on Narcotic Drugs that a drug, which has not already been found to be an "opiate" pursuant to revised Robertson amendment procedure, requires control under the 1931 convention, the Secretary or his delegate will publish the finding in the Federal Register. After publication, the drug is subject to control as an "opiate" as if it had been so determined under the revised Robertson amendment procedure. This provision is considered necessary to effectuate the obligatory provision of the 1948 protocol. A House committee amendment to the first sentence of subsection (b) of section 5 is designed to insure that the finding or decision upon which further action is to be taken shall be pursuant to the standard set by the 1948 protocol.

(c) Any person interested in the U.S. manufacture and distribution of a drug that becomes subject to control by operation of subsection (b), (that is, upon publication of a finding communicated under the 1948 protocol and not pursuant to the revised Robertson amendment procedure) may submit written opposition to the Secretary or his delegate for transmission to the appropriate international group for consideration. If the appropriate international group revokes its former decision, the Secretary or his delegate shall publish the revised finding in the Federal Register within 90 days of receipt. Within this 90-day period, the Secretary or his delegate may initiate an opiate procedure under the revised Robertson amendment. If he does not do so, the drug ceases to be an opiate upon publication in the Federal Register. If he initiates an opiate procedure, the drug continues to be subject to control as an opiate until the opiate proceeding is concluded. This provision is necessary to effectuate the correction procedure of article 3 of the 1948 protocol and at the same time to prevent a gap in control between the time of notification by the United Nations and the conclusion of an opiate proceeding.

(d) If a drug once subject to the 1931 convention is removed from the requirements of international control under the correction pro-

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cedure of article 3 of the 1948 protocol, it does not automatically cease to be an "opiate." If it was determined to be an "opiate" under the Robertson amendment procedure, the Secretary or his delegate may, in his discretion, let it continue to be an "opiate." This provision is necessary to effectuate the purposes of the Robertson amendment in the possible but unlikely event of a relaxation of international standards below those set by the Robertson amendment.

6. *Modification of list of basic narcotic drugs.*—This section gives the Secretary or his delegate (upon his initiative or upon the petition of any interested person) the power by rule made on the record after opportunity for hearing, to alter the classifications set forth in section 3(g), i.e., basic classes of narcotic drugs, by adding to, subtracting from, or further defining such classifications or any one or more of them. However, no basic class may be added unless the drug or drugs falling within it have been determined by the Secretary or his delegate to be narcotic drugs as defined by the Internal Revenue Code, or unless a finding to this effect is published in the Federal Register pursuant to section 5 of the bill. This provision is designed to prevent nonnarcotic substances from being subjected to manufacturing controls under the bill.

7. *Restrictions on the manufacture of narcotic drugs.*—This section makes unlawful the manufacture or permitting the manufacture of narcotic drugs in certain cases, and grants discretion to the Secretary or his delegate, under a specified condition, as to the addition of a new narcotic drug to the classifications set forth in section 3(g) of the bill.

(a) Except as otherwise provided in the bill, it is made unlawful to manufacture any narcotic drug unless the drug is within a basic class and the manufacturer has a currently effective license and quota with respect to such basic class. This makes clear the fundamental basis of the bill, that all narcotic drug manufacture will be carried out under licensing and the establishment of quotas. It is also provided that the Secretary or his delegate is not required to add a narcotic drug to the list of basic classes nor to grant a manufacturing quota for a narcotic drug if he determines that manufacture of the drug is contrary to the public health and safety.

(b) It is made unlawful to manufacture or attempt to manufacture any narcotic drug or knowingly to permit such manufacture by a lessee or tenant, unless the manufacture has been authorized by a license and by the establishment of a quota. It is also unlawful for the holder of a quota to exceed the quota limits.

8. *Licenses to manufacture narcotic drugs.*—This section is the general licensing provision. It also provides for a limited exemption from the license requirement.

(a) Every manufacturer of a basic class of narcotic drugs or intended manufacturer is required to obtain a separate license from the Secretary or his delegate for each basic class which he manufactures or intends to manufacture. A committee amendment requires the license to be obtained, by those currently manufacturing basic classes of narcotic drugs, on or before January 1, 1961. This subsection also sets out the purposes and criteria which are to govern the Secretary or his delegate in determining whether to issue a license to a particular applicant. Considering the importance of exercising close control of the production of these potentially dangerous drugs, it is the intention

that the manufacture thereof be restricted not only to persons having the requisite technical competence, drug-manufacturing experience, and safeguards against diversion, but also to the smallest number of establishments that will produce an adequate and continuous supply of narcotic drugs for medical and scientific purposes.

(b) This subsection ties the regulatory scheme under the bill to the Harrison Act by providing that registration pursuant to the Harrison Act shall be a prerequisite to the issuance of a manufacturing license. Licenses, once issued, will stay in effect subject only to annual registration under the Harrison Act, unless revoked or voluntarily surrendered. This subsection also provides that the issuance of a license does not automatically entitle the holder to perform any act with respect to a narcotic drug which, under this or any other act, requires the consent or approval of the Secretary or his delegate.

(c) This subsection provides that a license to manufacture one basic class of narcotic drugs does not entitle the holder to manufacture any other basic class of narcotic drugs.

(d) This subsection requires the Secretary or his delegate to authorize a person registered as a manufacturer or as a person engaged in research under section 4722 of the Internal Revenue Code of 1954 to produce any narcotic drug (whether or not within an established basic class) except crude opium or coca leaves, solely for research and testing. The person need not hold a license under subsection (a), but he must meet to the satisfaction of the Secretary or his delegate the standards for licensing under subsection (a)(4). The Secretary or his delegate specifies the quantity of the narcotic drug which may be produced pursuant to a research authorization. The producer must report the quantities made and the use and disposal thereof and may dispose of the drug only in accordance with the regulations of the Secretary or his delegate. (Under present regulations, the producer of a drug who is registered as a manufacturer may dispose of the drug under procedures that require compliance with tax stamp, recordkeeping, and reporting obligations. The producer of a drug registered as a person engaged in research may make disposals to other research facilities for testing and clinical evaluation in accordance with special regulations imposing labeling and recordkeeping requirements.) Any research authorization is subject to suspension or revocation.

9. *Revocation or suspension of licenses.*—This section sets forth the criteria and procedure for license revocation or suspension.

(a) This subsection establishes the criteria for license revocation. These criteria are comparatively narrow. They require criminal conviction under Federal or State narcotic laws; or violation of regulations relating to narcotic drugs under circumstances which reflect unfavorably upon the reliability and integrity of the licensee. Revocation may in the discretion of the Secretary or his delegate extent to all licenses held by a licensee.

(b) This subsection establishes the procedure for license revocation and interim suspension. Before any revocation action, an order to show cause with an explanation of its basis is served on the licensee. The license may be suspended pending the revocation proceeding if required by the public interest. The licensee is given a hearing conducted in accordance with section 5 of the Administrative Procedure Act (5 U.S.C.A. 1004). The Secretary or his delegate is "the agency" for the purposes of sections 7 and 8 of the Administrative Procedure

Act, so that his decision is final for administrative purposes. After the hearing, the Secretary or his delegate may issue a revocation order, which must be supported by findings and reasons. This order is subject to judicial review in the manner prescribed in Public Law 901, 81st Congress, approved December 29, 1950. The Secretary or his delegate has the burden of proceeding with evidence and the burden of proof in a revocation hearing. Revocation proceedings do not preclude criminal or other proceedings under this or any other act. The notice and hearing provisions of this section are considered to be constitutionally necessary, since license revocation involves the power to put a manufacturer out of business. The procedure established, while affording due process to the licensee, also protects the public interest by permitting interim suspension.

10. *Authority to seize narcotic drugs, order forms, and tax stamps.*—This section provides for the discretionary impounding by the Secretary or his delegate of all narcotic drugs and all unused order forms or narcotic stamps owned or possessed by a licensee under suspension or a revocation order until the conclusion of all appeals or the running of time for appeal. When the suspension or revocation order becomes final, all such drugs, forms, and stamps are forfeited to the Government.

11. *Manufacturing quotas for basic classes of narcotic drugs.*—This section provides the formulas for determining manufacturing quotas for basic classes of narcotic drugs.

(a) This subsection gives the Secretary or his delegate the responsibility of determining the total quantity of each basic class which should be manufactured in each year for domestic and export requirements and for reserves. This total will be the aggregate from which individual manufacturing quotas will be established.

(b) If it becomes necessary to limit or reduce individual quotas to prevent the aggregate of such individual quotas from exceeding the amount of the determination of the Secretary or his delegate under subsection (a), authority is given by this subsection (b) to limit or reduce the individual quotas on an across-the-board basis. However, if a licensee has already produced in excess of his quota as reduced, the excess amount shall be subtracted from his quota for the following year.

(c) This subsection provides the formula for fixing a manufacturer's calendar year quota, subject to the provisions of subsections (a) and (b). The quota is established by the Secretary or his delegate on or before June 1 of the year, after application therefor by the manufacturer. Subject to possible reduction under susbection (b), the normal minimum quota for an established manufacturer of a particular basic class is his net disposal (as defined in sec. 3(h) to include not only transfers by sale or otherwise, but also use in the production of another basic class, less returns and transfers to another licensee of the same basic class) during the preceding year or average of 3 immediately preceding years if greater, plus one-half his net disposal during the preceding year, minus his inventory on December 31 of the preceding year. Thus, the lower the inventory the greater the quota, thereby providing a built-in growth factor for periods of increasing demand. Conversely, if net disposals decline, so does the quota for the next year.

(d) This subsection provides for a provisional quota for established licensed manufacturers pending the establishment of the annual quota

on or before June 1. This quota is determined by the manufacturer without application to the Secretary or his delegate. This provisional quota is 75 percent of the net disposal during the 12 months preceding September 30 of the past year, or 75 percent of 12 times the average monthly net disposal for the 2¾ years preceding September 30 of the past year, whichever is greater. The provisional quota percentage may be raised or lowered by direction of the Secretary or his delegate for good cause. Any such revision applies to the provisional quotas of all manufacturers of the basic class involved. The provisional quota device is obviously necessary to permit unimpeded production pending the establishment of regular annual quotas.

(e) This subsection provides for the fixing by the Secretary or his delegate, upon application by a licensed manufacturer who has no relevant net disposal experience, of a quota adequate to cover his reasonably anticipated requirements for the year of application. This provision is necessary to meet the case of the licensee who is beginning or resuming the manufacture of a particular basic class.

(f) This subsection authorizes a quota applicant or recipient to apply for an increase to meet an estimated increase in requirements. It is designed for use in the extraordinary case where the increase in demand for a given basic class is so sharp and sudden that the growth factor built into the quota system is inadequate. The Secretary or his delegate may consider such a need and, if the total quantity determined under subsection (a) is greater than the aggregate of all individual quotas established he may consider the equitable distribution of all or a part of such excess among all manufacturers.

12. *Exception from applicability of license and quota provisions.*—This section exempts from the license and quota requirements of the bill the manufacture of such quantities of any basic class as incidentally but necessarily result from the manufacturing process used for the manufacture of a duly licensed basic class. This is designed to take care of the case where the licensee manufactures A, and in its manufacture inevitably produces small quantities of B which he has no desire to deal in commercially, either for purposes of sale or purposes of further processing. This provision must be read in conjunction with section 8(c) which provides in effect that a license for the manufacture of A is not to be construed as a license for the manufacture of B simply because B results from the production of A. If the licensee wants to go into the business of manufacturing B for sale or further processing, he must obtain a separate license for B. In the absence of such a license he is exempt from the license and quota provisions in respect to the amounts of B which he does produce, but he can deal with B only as directed by the Secretary or his delegate. He is not free to sell or use it, unless the Secretary or his delegate determines that it is nonaddicting.

A similar provision is made with respect to the possibility that persons not engaged in the manufacture of narcotic drugs may incidentally produce a basic class of narcotic drug in the course of manufacturing a product which is not a narcotic drug. Again they are exempt from the license and quota requirements, but they must do as the Secretary or his delegate directs them to do with respect to such quantities of the narcotic drug as they may incidentally but necessarily produce.

13. *Regulation with respect to persons who manufacture narcotic precursors.*—Section 13 represents a tentative solution to the problem of "narcotic precursors" previously mentioned in connection with the definition of this term in section 3(i). It would be possible in this proposed statute either to do nothing at all about narcotic precursors or to subject them to the same controls as narcotic drugs themselves. Neither of these extremes appears desirable. The most immediate need is for information about the extent of the narcotic precursor problem. Consequently, regulation of narcotic precursors is limited by this statute to the requirement that persons who deal in narcotic precursors must keep records and make reports with respect to their disposals. On the basis of the information so gathered, the Secretary or his delegate will be able to determine to what extent, if any, the availability of narcotic precursors tends to facilitate the manufacture of narcotic drugs by other than licensees under the act and consequent diversion of narcotic drugs into illegitimate channels. Depending on his judgment as to the character of the problem, the Secretary or his delegate may then see fit to recommend further legislation on the subject of narcotic precursors to the Congress.

14. *Certain procedures for judicial review.*—Every final decision of the Secretary or his delegate relating to (*a*) the determination of a "narcotic precursor," (*b*) modification of the basic classes of narcotic drugs, (*c*) refusal to issue or revocation of a license to manufacture a basic class of narcotic drugs, or (*d*) fixing or denying a regular, special or additional manufacturing quota for a basic class of narcotic drug, is made subject to judicial review in the manner prescribed by Public Law 901, Congress (ch. 19A of title 5, U.S.C.). This is the procedure for the review of the orders of Federal agencies now applicable to orders of the Federal Communications Commission, the Secretary of Agriculture, and so forth.

15. *Amendment to law with respect to exportation of narcotic drugs.*—Section 15 seeks to revise the existing conditions placed upon the granting of an export authorization by requiring that the country of destination of a narcotic shipment from the United States shall have become a party to the particular convention under which the narcotic drug in question is controlled. It also authorizes the special exportation of any narcotic drug to any country which has ratified one of the principal narcotic conventions if the drug is to be applied to a special scientific purpose in the country of destination if the authorities of such country will permit the importation for such purposes.

16. *Authorizing importation of narcotic drugs as to certain persons.*—Under existing law, there is a prohibition against the importation of narcotic drugs into this country except for certain quantities of crude opium and coca leaves. Section 16 relaxes this prohibition to the extent necessary to permit the importation of narcotic drugs for delivery to Government officials or licensed manufacturers for scientific purposes only.

17. *Enforcement and authority to delegate functions.*—Section 17 imposes the duty of enforcement of the act upon the Secretary or his delegate, who is authorized to prescribe enforcement regulations and to delegate any and all of his powers under the act. It is contemplated that the powers conferred on the Secretary by this act will be delegated to the Commissioner of Narcotics.

18. *Penal provisions.*—Section 18 makes it a felony to violate any provision of the act and prescribes penalties therefor. It also makes it a misdemeanor to take part in the preparation or presentation of a false statement in any application under the act, and prescribes penalties for such misdemeanor.

19. Section 19 relieves the Secretary or his delegate of the necessity of negativing possible exemptions in any judicial or administrative proceeding under the act. It also places the burden of proving the existence of an appropriate license or quota on the person who claims such license or quota, and it creates a rebuttable statutory presumption that in the absence of such proof the person does not hold such license or quota.

20. Section 20 is the usual provision as to territorial applicability.

21. Section 21 is the standard separability clause.

22. A House committee amendment adds an effective date provision (sec. 22), which provides that the act shall take effect on January 1 of the year following the date of its enactment, except that section 8(a) shall take effect on the date of enactment of the act. The act should operate on a calendar year basis to conform with the same period for which manufacturing estimates are submitted under the 1931 convention.

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):

INTERNAL REVENUE CODE OF 1954

* * * * * * *

CHAPTER 39—REGULATORY TAXES

Subchapter A—Narcotic Drugs and Marihuana

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SEC. 4701. IMPOSITION OF TAX.

(a) RATE.—There shall be imposed an internal revenue tax upon narcotic drugs, produced in or imported into the United States, and sold, or removed for consumption or sale, at the rate of 1 cent per ounce, and any fraction of an ounce in a package shall be taxed as an ounce. The tax imposed by this subsection shall be in addition to any import duty imposed on narcotic drugs.

(b) BY WHOM PAID.—The tax imposed by subsection (a) shall be paid by the importer, manufacturer, producer, or compounder.

SEC. 4702. EXEMPTIONS.

[(a) PREPARATIONS OF LIMITED NARCOTIC CONTENT.—The provisions of this subpart and sections 4721 to 4726, inclusive, shall not be construed to apply to the manufacture, sale, distribution, giving away, dispensing, or possession of preparations and remedies which do not contain more than 2 grains of opium, or more than one-fourth of a

grain of morphine, or more than one-eighth of a grain of heroin, or more than 1 grain of codeine, or any salt or derivative of any of them, in 1 fluid ounce, or, if a solid or semisolid preparation, in 1 avoirdupois ounce; or to liniments, ointments, or other preparations which are prepared for external use only, except liniments, ointments, and other preparations which contain cocaine or any of its salts or alpha or beta eucaine or any of their salts or any snythetic substitute for them: *Provided*, That such remedies and preparations are manufactured, sold, distributed, given away, dispensed, or possessed as medicines and not for the purpose of evading the intentions and provisions of this subpart and sections 4721 to 4726, inclusive, *Provided further*, That any manufacturer, producer, compounder, or vendor (including dispensing physicians) of the preparations and remedies mentioned in this section, lawfully entitled to manufacture, produce, compound, or vend such preparations and remedies, shall keep a record of all sales, exchanges, or gifts of such preparations and remedies in such manner as the Secretary or his delegate shall direct. Such record shall be preserved for a period of 2 years in such a way as to be readily accessible to inspection by any officer or employee of the Treasury Department duly authorized for that purpose, and the State, Territorial, District, municipal, and insular officers named in section 4773, and every such person so possessing or disposing of such preparations and remedies shall register as required in section 4722 and, if he is not paying a tax under section 4721, he shall pay a special tax of $1 for each year, or fractional part thereof, in which he is engaged in such occupation, to the official in charge of the collection district in which he carries on such occupation as provided in sections 4721 to 4726, inclusive.]

(*a*) *Exceptions From Certain Provisions Authorized for Preparations of No Addictive Quality or of Minor Addictive Quality.*—

(1) If the Secretary or his delegate, either upon his own motion or upon the application of an interested party, after consideration of the report and recommendations of an advisory committee appointed under paragraph (4) of this subsection, and after due notice and opportunity for hearing, finds that a pharmaceutical preparation containing a narcotic drug combined with other active or inactive ingredients—

(A) either possesses no addiction-forming or addiction-sustaining liability, or does not possess an addiction-forming or addiction-sustaining liability sufficient to warrant imposition of all of the requirements of this part, and

(B) does not permit the recovery of a narcotic drug having such an addiction-forming or addiction-sustaining liability, with such relative technical simplicity and degree of yield as to create a risk of improper use;

the Secretary or his delegate may except such pharmaceutical preparation to the extent consistent with the obligations undertaken by the United States pursuant to the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, concluded at Geneva, July 13, 1931, and entered into force with respect to the United States of America, July 9, 1933, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope

of the convention of July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946), signed at Paris, November 19, 1948, and entered into force with respect to the United States of America, September 11, 1950, and with the public health, safety, and welfare, from any or all of the requirements imposed by this part, other than those requirements imposed by sections 4721, 4722, 4724(a), and 4732, and from any or all of the requirements imposed by section 6 of the Act entitled "An Act to prohibit the importation and use of opium for other than medicinal purposes", approved February 9, 1909, as amended by section 15 of the Narcotics Manufacturing Act of 1960.

(2) In excepting any pharmaceutical preparation under paragraph (1), the Secretary or his delegate may, in his discretion, apply any or all of the following requirements:

(A) Such pharmaceutical preparation shall be manufactured, sold, distributed, given away, dispensed, or possessed as a medicine and not for the purpose of evading the intentions and provisions of this subpart and subpart C;

(B) Any manufacturer, producer, compounder, or vendor (including dispensing physicians) of such pharmaceutical preparation, lawfully entitled to manufacture, produce, compound, or vend such pharmaceutical preparation, shall keep such records relating to such pharmaceutical preparation as the Secretary or his delegate shall deem necessary;

(C) Every person so possessing or disposing of such pharmaceutical preparation shall register as required in section 4722 and, if he is not paying a tax under section 4721, shall pay a special tax of $1 for each year, or fractional part thereof, in which he is engaged in such occupation, to the official in charge of the collection district in which he carries on such occupation as provided in subpart C.

(3) If the Secretary or his delegate shall subsequently determine, after due notice and opportunity for hearing, that a pharmaceutical preparation to which such exceptions have been made applicable possesses a degree of addiction liability, or permits recovery of a narcotic drug having a degree of addiction liability, that results in abusive use of such exceptions, he is authorized to withdraw and revoke such exceptions in whole or in part.

(4) Whenever the Secretary or his delegate shall, on his own motion, determine that there may exist reasonable evidence to support a finding in accordance with paragraph (1) of this subection, or whenever an interested party makes an application for such a finding, the Secretary or his delegate shall thereupon appoint an advisory committee of experts. At least one member of such an advisory committee shall be selected by the Secretary or his delegate, one by the interested party making the application, if any, one by the Surgeon General of the (United States) Public Health Service, and one by the Commissioner of the (United States) Food and Drug Administration. The Secretary or his delegate shall submit to such advisory committee the application of the interested party, if any, and any other available data. As soon as practicable thereafter, the advisory committee shall, after independent study of the material submitted to it by the Secretary or his delegate and other data available to it,

certify a report and recommendations to the Secretary or his delegate with respect to the pharmaceutical preparation involved.

(5) After consideration of the report and recommendation of the advisory committee, and after due notice and opportunity for hearing, the Secretary or his delegate shall either make the finding provided for in paragraph (1) of this subsection and grant such exceptions as he deems appropriate, or determine that the evidence does not support such a finding and deny the application, if any.

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SEC. 4731. DEFINITIONS.

[(a) NARCOTIC DRUGS.—The words "narcotic drugs" as used in this part shall mean any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium, isonipecaine, coca leaves, and opiate;

(2) Any compound, manufacture, salt, derivative, or preparation of opium, isonipecaine, coca leaves, or opiate;

(3) Any substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in clauses (1) and (2).]

(a) NARCOTIC DRUGS.—The words "narcotic drugs" as used in this part shall mean any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium, isonipecaine, coca leaves, and opiate;

(2) Any compound, manufacture, salt, derivative, or preparation of opium, insonipecaine, coca leaves, or opiate;

(3) Any substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in clauses (1) and (2);

except that the words "narcotic drugs" as used in this part shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

(b) PERSON.—The word "person", as used in sections 4701 to 4707, inclusive, and sections 4721 to 4726, inclusive, shall be construed to mean and include a partnership, association, company, or corporation, as well as a natural person.

(c) IMPORTER, MANUFACTURER, OR PRODUCER.—Every person who imports, manufactures, compounds, or otherwise produces for sale or distribution narcotic drugs shall be deemed to be an importer, manufacturer, or producer.

(d) WHOLESALE DEALER.—Every person who sells, or offers for sale, any of said drugs in the original stamped packages as provided in section 4704 (a) shall be deemed a wholesale dealer.

(e) RETAIL DEALER.—Every person who sells or dispenses from original stamped packages as provided in section 4704(a) shall be deemed a retail dealer: *Provided*, That the office, or if none, the residence, of any person shall be considered, for the purpose of this part, except sections 4711 to 4715, inclusive, his place of business.

(f) ISONIPECAINE.—The word "isonipecaine", as used in this part shall mean any substance identified chemically as 1-methyl-4-phenyl-piperidine-4-carboxylic acid ethyl ester, or any salt thereof, by whatever trade name designated.

[OPIATE.—The word "opiate", as used in this part shall mean any drug (as defined in the Federal Food, Drug, and Cosmetic Act; 52 Stat. 1041, section 201(g); 21 U.S.C. 321) found by the Secretary or his delegate, after due notice and opportunity for public hearing, to have an addiction-forming or addiction-sustaining liability similar to morphine or cocaine, and proclaimed by the President to have been so found by the Secretary or his delegate. The Secretary or his delegate is authorized to issue necessary rules and regulations for carrying out the provisions of this subsection, and to confer or impose upon any officer or employee of the Treasury Department whom he shall designate or appoint, the duty of conducting any hearing authorized hereunder.]

(g) OPIATE.—

(1) IN GENERAL.—The word "opiate" as used in this part shall mean any drug (as defined in the Federal Food, Drug, and Cosmetic Act (52 Stat. 1041, sec. 201(g): 21 U.S.C. 321)) or other substance found by the Secretary or his delegate and proclaimed by the Secretary or his delegate (after considering the technical advice of the Secretary of Health, Education, and Welfare, or his delegate, on the subject) to have been so found in the Federal Register, after due notice and opportunity for public hearing, to have an addiction-forming or addiction-sustaining liability similar to morphine or cocaine or to be capable of conversion into a drug having such addiction-forming or addiction-sustaining liability, where, in the judgment of the Secretary or his delegate, the relative technical simplicity and degree of yield of such conversion create a risk of improper use of the drug or other substance.

(2) TERMINATION.—The Secretary or his delegate is authorized to withdraw any previous finding that a drug or other substance is an "opiate" whenever (after considering the technical advice of the Secretary of Health, Education, and Welfare, or his delegate, on the subject) he determines that such previous finding was erroneous, and upon publication of such determination in the Federal Register, the particular drug or other substance shall cease to be an opiate. For purposes of the foregoing provision the Secretary or his delegate may consider any action taken pursuant to article 3 of the 1948 protocol (as defined in section 3(b) of the Narcotics Manufacturing Act of 1960).

(3) REGULATIONS, ETC.—The Secretary or his delegate is authorized to issue necessary rules and regulations for carrying out the provisions of this subsection, and to confer or impose upon any officer or employee of the Treasury Department whom he shall designate or appoint, the duty of conducting any hearing authorized hereunder.

(4) CROSS REFERENCE.—

For treatment of certain drugs as being, or ceasing to be, opiates for purposes of this part, see section 5 of the Narcotics Manufacturing Act of 1960.

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AN ACT To prohibit the importation and use of opium for other than medicinal purposes

(Approved February 9, 1909, 21 U.S.C. 182)

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[SEC. 6. (a) That it shall be unlawful for any person subject to the jurisdiction of the United States Government to export or cause to be exported from the United States, or from territory under its control or jurisdiction, or from countries in which the United States exercises extraterritorial jurisdiction, any narcotic drug to any other country: *Provided*, That narcotic drugs (except smoking opium and opium prepared for smoking, the exportation of which is hereby absolutely prohibited) may be exported to a country only which has ratified and become a party to the convention and final protocol between the United States Government and other powers for the suppression of the abuses of opium and other drugs, commonly known as the International Opium Convention of 1912, and then only if (1) such country has instituted and maintains, in conformity with that convention, a system, which the board deems adequate, of permits or licenses for the control of imports of such narcotic drugs; (2) the narcotic drug is consigned to an authorized permittee; and (3) there is furnished to the board proof deemed adequate by it, that the narcotic drug is to be applied exclusively to medical and legitimate uses within the country to which exported, that it will not be reexported from such country, and that there is an actual shortage of and a demand for the narcotic drug for medical and legitimate uses within such country.

[(b) The Secretary of State shall request all foreign Governments to communicate through the diplomatic channels copies of the laws and regulations promulgated in their respective countries which prohibit or regulate the importation and shipment in transit of any narcotic drug and, when received, advise the board thereof.

[(c) The board shall make and publish all proper regulations to carry into effect the authority vested in it by this Act.]

SEC. 6. (a) No person subject to the jurisdiction of the United States Government shall export or cause to be exported from the United States, or from territory under its control or jurisdiction, any narcotic drug to any other country except—

(1) to a country which has ratified and become a party to the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention signed at Geneva on February 19, 1925, any narcotic drugs derived directly or indirectly from crude opium or coca leaves; or

(2) to a country which has ratified and become a party to the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs concluded at Geneva, July 13, 1931, and entered into force with respect to the United States of America, July 9, 1933, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention of July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946) signed at Paris November 19, 1948, and

entered into force with respect to the United States of America, September 11, 1950, any narcotic drugs not derived directly or indirectly from crude opium or coca leaves;

and in the instance of (1) and (2) then only if—

(A) such country has instituted and maintains, in conformity with the respective conventions, a system which the Secretary of the Treasury or his delegate deems adequate, for the control of imports of narcotic drugs;

(B) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import; and

(C) there is furnished to the Secretary or his delegate proof deemed adequate by him that the narcotic drug is to be applied exclusively to medical and scientific uses within the country to which exported, that it will not be reexported from such country, and that there is an actual need for the narcotic drug for medical and scientific uses within such country.

(b) The exceptions contained in subsection (a) shall not apply to smoking opium or opium prepared for smoking, the exportation of which is absolutely prohibited.

(c) Notwithstanding the provisions of subsection (a), the Secretary or his delegate may authorize the exportation of any narcotic drug (including crude opium and coca leaves) to a country which has ratified and become a party either to the 1912 convention, the 1925 convention, or the 1931 convention and supplementing protocols of 1946 and 1948, if the particular drug is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(d) The Secretary of State shall request all foreign governments to communicate through the diplomatic channels copies of the laws and regulations promulgated in their respective countries which prohibit or regulate the importation and shipment in transit of any narcotic drug and, when received, shall advise the Secretary or his delegate thereof.

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