May 9, 1977

77-24 MEMORANDUM OPINION FOR THE ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION

Control of *Papaver bracteatum*—Drug Enforcement Administration

This is in response to your request for our opinion whether the Drug Enforcement Administration (DEA) [1] has the authority to control the production of the plant *Papaver bracteatum,* and, if so, whether its production may be prohibited. In general, we support the Administrator's authority on both these questions because we believe that there exists a reasonable basis for that authority. But we also recognize that reasonable contrary arguments can be advanced, so that it is uncertain whether the Administrator's authority, if challenged, would be sustained in court.

Papaver bracteatum is the great scarlet poppy. *Bracteatum* contains and produces thebaine, which is chemically identical to the thebaine produced by the opium poppy, *Papaver somniferum L.* Thebaine may be converted into other drugs, including codeine. Both thebaine and codeine are currently subject to control pursuant to the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, 21 U.S.C. § 801 *et seq.* (hereafter referred to as the Controlled Substances Act or CSA). *Bracteatum,* itself, however, is not presently a controlled substance because it is not listed in any of the schedules of 21 U.S.C. § 812, or 21 CFR § 1308. Although *bracteatum* contains thebaine, there will be no effect "in the traditional sense of having an abuse potential" upon an individual who chews, smokes, or ingests *bracteatum.*

I. Control

It is our opinion that the Administrator may control the production of *bracteatum,* either (1) pursuant to delegation of the Attorney General's authority to regulate the manufacture of thebaine under the Con-

[1] The Attorney General has delegated the functions vested in him under the Comprehensive Drug Abuse Prevention and Control Act to DEA. 28 CFR 0.100(b).

trolled Substances Act or (2) pursuant to United States obligations under the Single Convention on Narcotic Drugs, 18 U.S.T. 1407, 30 T.I.A.S. No. 6298. But in the case of control pursuant to treaty obligation, such control must be predicated upon certain findings by the appropriate United States officials, and we have some doubt whether the requisite findings can be made.

A. Regulation of the Manufacture of Thebaine

The first ground on which the Administrator may rely to control the production of *bracteatum* derives from authority under the Controlled Substances Act providing for the registration of and control of the manufacture of the drug thebaine.

The term "manufacture" is defined expansively in 21 U.S.C. § 802(14) to mean:

> *the production, preparation, propagation,* compounding or processing *of a drug or other substance,* either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. [Emphasis added.] [2]

A "manufacturer" is defined in the same section as "a person who manufactures a drug or other substance." The term "production," which, as noted above, is included in the definition of the term "manufacture," is defined in 21 U.S.C. § 802(21) to include "the manufacture, planting, cultivation, growing, or harvesting of a controlled substance." Neither of these terms has been the subject of judicial construction.

In our opinion, the growth of *bracteatum*—which contains and produces thebaine—for the purpose of extracting thebaine it produces, constitutes the "manufacture" of thebaine within the meaning of § 802(14). It would be difficult to imagine a definition of manufacture more broadly drawn than § 802(14), especially when taken in conjunction with paragraph (21) defining production. The statute appears to include each step in the development of a controlled substance prior to its distribution and dispensation—thus even packaging and labeling were included.

Applying the statutory definitions to *bracteatum,* it appears that the plant itself would first be "propagated" and then the thebaine "extract-

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[2] This definition is much broader than that found in the Narcotic Manufacturing Act of 1960, 74 Stat. 55, § 3(f):

> The term "manufacture" means the production of a narcotic drug, either directly or indirectly by extraction of substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

ed." Both the "propagation" of a controlled substance [3] and its "extraction" are included within the definitions of "manufacture" and "production."

These definitions fit in with 21 U.S.C. § 822, which requires that every person who "manufactures" a controlled substance or who "proposes to engage in the manufacture" of a controlled substance obtain an annual registration issued by the Attorney General. And 21 U.S.C. § 821 authorizes the Attorney General to promulgate rules and regulations "relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances."

Accordingly, we believe that these provisions permit the Administrator, in the exercise of his delegated authority, to require persons who propose to grow *bracteatum* for the purpose of extracting thebaine to register as manufacturers of thebaine. [4]

B. The Single Convention on Narcotic Drugs

It is also our opinion that the Administrator, acting pursuant to the Attorney General's delegated authority, has the power to control the production of *bracteatum* pursuant to the obligations imposed on the United States by the Single Convention if he can make certain findings. He must determine, first, that *bracteatum* may be "used in the illicit manufacture" of thebaine, and, second, that *bracteatum* is *not* "easily convertible" to thebaine or other controlled drugs, although sufficient support may exist to justify a finding that *bracteatum* may also be found to be readily convertible to thebaine.

The following discussion explains the reasons for our opinion.

The United States ratified the Single Convention on Narcotic Drugs in 1967, three years before the enactment of the Controlled Substances Act, and a number of the provisions of that Act reflect Congress' intent to comply with the obligations imposed by the Single Convention. *See* 21 U.S.C. §§ 801(7), 811(d), 812(b), 953(a)(1), 958(a). Moreover, both the House and Senate reports on the Act mention the need to comply with the international obligations as one reason for Federal legislation on this subject. S. Rep. No. 613, 91st Cong., 1st Sess. at 4 (1969); H. Rep. No. 1444, Pt. 1, 91st Cong., 2d Sess. at 29 (1970).

Accordingly, the Controlled Substances Act authorizes the Attorney General to control drugs where control is required by treaty. Section 811(d) provides:

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[3] It might be argued that the production—including planting, cultivation, and growth—here would be that of *bracteatum* and not of the controlled substance thebaine. The portion of the definition of manufacture by cultivation, etc., could therefore be reserved for cases in which a plant itself is controlled—as is the opium poppy. However, in our opinion, because the plant *bracteatum* contains a controlled substance (thebaine), the propagation of *bracteatum* for the purpose of producing this thebaine is the cultivation or "production" of thebaine.

[4] But we do not believe that the Administrator has the authority to control the growth of *bracteatum* for other purposes.

> If control is required by United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations . . . .

Bracteatum is not scheduled as a drug that must be controlled under the Single Convention,[5] although thebaine and codeine are. But we must also consider in this connection Article II, paragraph 8, of the Single Convention. That paragraph imposes an obligation upon the United States to apply measures of supervision to certain substances not listed in the schedule of the Single Convention. It states:

> The Parties shall use their best endeavors to apply to substances which do not fall under this Convention, but which may be used in the illicit manufacture of drugs, such measures of supervision as may be practicable.

It could be argued that the requirement that each Party use its "best endeavors" to apply "practicable" means of supervision allows such a broad scope of discretion that it cannot be said to create any "obligation" in any meaningful sense of the word. The official commentary on the Convention concludes that "[t]he vagueness of the wording of paragraph 8 leaves it practically to the discretion of each Party to decide to what substances it should apply the control provided in this paragraph, and what measures it would be practicable to take." Commentary on the Single Convention on Narcotic Drugs, 1961 (prepared by the Secretary-General of the United Nations), at 71.

But we conclude, as did the U.S. Court of Appeals for the District of Columbia in *National Organization for the Reform Of Marijuana Laws (NORMAL)* v. *DEA*, No. 75-2025 (April 26, 1977), that DEA may properly rely upon paragraph 8 as creating a treaty "obligation" for purposes of 21 U.S.C. § 811(d). In that case the court upheld DEA's control of *cannabis* seeds capable of germination on the basis of paragraph 8 of the Single Convention and 21 U.S.C. § 811(d). It observed that the official commentary "assigns a specific purpose to the open-endedness of the provision." It concluded that discretion had to be allowed in determining both the substances subject to paragraph 8 because it was impossible to foresee either all the substances that might in the future be used for illicit manufacture, or the controls to be applied, because measures practicable in one country might be impracticable in another where the substance in question is used for legitimate purposes. Slip opinion, at 43-44. Accordingly, the paragraph 8 require-

[5] The Commentary on the Single Convention on Narcotic Drugs, 1961 (prepared by the Secretary General of the United Nations), at 25, expressly notes that *bracteatum* is a species separate from *Papaver somniferum*, which is controlled, and states that the extraction of thebaine from *bracteatum* would be controlled by the provisions of the Convention governing manufacture.

ment is sufficient to create a treaty "obligation" within the meaning of 21 U.S.C. § 811(d).

Therefore, the Single Convention obligates the United States to apply measures of supervision to *bracteatum* if it falls within the scope of paragraph 8. That paragraph calls for control if a substance "may be used in the illicit manufacture of drugs." [6] "Drugs" are defined by Art. I, ¶(j) of the Single Convention as substances on schedule I or II of the Convention; both thebaine and codeine are such scheduled drugs.

But there is a further problem in determining whether *bracteatum* falls within paragraph 8. Both the records of the Convention drafters and the official commentary support the view that paragraph 8 was not intended to apply to substances readily "convertible" into narcotic drugs by traffickers. Commentary at 70, Official Records, United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs, Vol. II at 77–79.[7] Known substances of this nature were included in the Single Convention schedules, and Art. III, ¶3 (iii) provides a procedure whereby additional convertible substances may be added to these schedules and thereby made subject to the specific measures of control required for scheduled substances.

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[6] A narrow interpretation of the term "obligation" would conflict with the legislative intent expressed in the Senate report, which stated that "[*t*]*he Attorney General must* give appropriate consideration to the findings and declarations of certain international bodies and *generally abide by both the letter and the spirit of our treaty agreements* regarding the control of drugs" S Rep No. 613, 91st Cong., 1st Sess. 16 (1969) [Emphasis added.]

[7] The official records of the drafters reflect that the Netherlands representative raised the question whether the substances were covered by the more general obligations of this section, stating that his delegation believed such substances should themselves be scheduled. The Yugoslavian representative stated that the authors of this draft paragraph "had not been thinking of convertible substances . . . . The reference was a general one to raw materials which could be used in manufacturing synthetic drugs . . ." He agreed that convertible substances should be scheduled. The Hungarian representative stated that this paragraph was intended to cover substances not covered elsewhere, and agreed that convertible substances should be scheduled. At this point the Deputy Executive Secretary stated that:

> [d]rugs were placed under international control either because they were addiction-producing or because they were convertible into addiction-producing substances. Drugs of the second type were not grouped separately, but some were included in schedule I and some in schedule II; that was in accordance with existing treaties. The suggestion that there should be a separate schedule for convertible substances would involve a fundamental change in the way the draft Convention and the existing treaties were set out. *It should be made clear that the word "convertible" was used to describe substances that could easily be converted into narcotic drugs by a trafficker; paragraph 3 [now Art. 2 ¶8] was not intended to refer to convertible substances in that sense. If it were felt that the Convention as worded did not make it clear that the substances under control included not only dangerous drugs but also substances which were convertible into dangerous drugs, an explicit statement to that effect could be made either in the definition of the word "drug" or in a paragraph in Article 3 laying down the criteria for deciding that new drugs were to be brought under control.* [Emphasis added.]

The records indicate that after some further discussion it was agreed that a reference to convertibility should be inserted, and consideration of this reference was deferred. As stated in the text, such a provision expressly noting that convertible substances could be added to the various schedules was inserted in Art. III, ¶3 (iii). This appears to comply with the Deputy Executive Secretary's suggestion.

On that basis, it is our view that the Administrator may control *bracteatum* pursuant to paragraph 8 only if he determines that *bracteatum:* (1) may be used in the illicit manufacture of drugs, including thebaine; and (2) is *not* a substance readily "convertible" to thebaine or other controlled drugs by narcotics traffickers.[8] However, if *bracteatum* is a convertible substance, and the Administrator believes that international control is apppropriate, he must follow the procedures in Art. III to have *bracteatum* added to an appropriate schedule of the Single Convention.

C. Other Bases of Control.

In our opinion, neither of the two above theories would authorize the Administrator to control *bracteatum.*

One possible theory is that *bracteatum* might be controlled as an "immediate precursor" of thebaine. Section 811(e) permits the Attorney General to control the "immediate precursor" of a controlled substance, and 21 U.S.C. § 802(22) defines an "immediate precursor" as a substance designated by the Attorney General as "the principal *compound* used, or produced primarily for use, in the manufacture of a controlled substance; . . . *an immediate chemical intermediary* used or likely to be used in the manufacture of such controlled substance. . . ." [Emphasis added.] It is our belief that §§ 802(22) and 811(e) were intended to apply to chemicals, and are not applicable to the plant *bracteatum.*

A second theory is that *bracteatum* might itself fulfill the requirements to be listed independently on one of the schedules detailed in 21 U.S.C. § 812. Inclusion in any of the five schedules set out in this section requires a finding of a degree of potential for abuse of that substance, ranging from a "high potential for abuse" in schedules I and II, to schedule IV, which is characterized by (A) "low potential for abuse relative to the drugs or other substances in schedule III," or (C) "abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III." Because, despite the presence of thebaine, *bracteatum*—whether smoked, chewed, or ingested—has no effect "in the traditional sense of having an abuse potential," it appears that *bracteatum* could not fall within any of the schedules of the CSA.

II. Prohibiting the Production of *Bracteatum*

In view of our conclusion that the production of *bracteatum* may be controlled as the manufacture of thebaine, or possibly pursuant to U.S. treaty obligations under the Single Convention, we reach the question whether all domestic production may be prohibited.

Potentially, there are two grounds upon which production may be prohibited: (1) if production would violate U.S. treaty obligations; or

[8] In this connection it may be useful to compare the concept of a convertible substance with the concept of an "immediate precursor" under the CSA. In our opinion, *bracteatum* is not an "immediate precursor" of thebaine. *See* discussion, p. 10, *infra.*

(2) if production would be inconsistent with the public interest. It is our opinion that a prohibition of all domestic production is not required by the Single Convention. On the other hand, we believe that if the Administrator finds that controlled domestic production would result in a substantial increase in the supply of illicit controlled substances in the United States, then he may determine that any production at all would be inconsistent with the public interest.

A. Treaty Obligations

Section 823 of Title 18 provides that the Attorney General shall not register an applicant to manufacture a substance on schedule I or II of the CSA, unless the registration is consistent with United States obligations under international treaties. It could be argued that domestic production of *bracteatum* as a source of licit narcotic drugs is "in derogation of the spirit of the Single Convention."

The Preamble to the Single Convention states that the Parties recognize that addiction to narcotic drugs is "fraught with social and economic danger to mankind" and that they are "conscious of their duty to prevent and combat this evil" through international coopertion. We do not think that these general statements in and of themselves create a treaty "obligation" not to permit the domestic production of *bracteatum* as a source of thebaine and other drugs, even if this would disturb the international balance of supply and demand for these drugs. The preamble states the general considerations that motivated the Parties to agree to the stringent controls stated in the body of the treaty. The Convention includes controls on the manufacture of scheduled substances, such as thebaine and codeine: Article XXI limits the total that may be manufactured and imported by one country to the sum of the quantity consumed for medical and scientific purposes, the quantity used for the manufacture of other drugs, the quantity exported, the quantity added to stocks to bring them up to standard, and the quantity acquired for special purposes. The Single Convention therefore requires that the United States place an appropriate quota on the production of controlled narcotics derived from *bracteatum,* but does not wholly prohibit the growth of *bracteatum* to produce controlled drugs.[9]

B. Public Interest

The Administrator may refuse to register an applicant to manufacture a schedule I or II drug, such as thebaine, if he determines that registration would not be consistent with the public interest. Section 823(a) of Title 18 provides:

(a) The Attorney General *shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registra-*

[9] In contrast, Art. XXII requires a Party to prohibit the cultivation of the opium poppy (*somniferum*), the coca bush, and the *cannabis* plant in certain circumstances. The official commentary also notes that it would be hypothetically possible that a party would be required to prohibit the cultivation of the *cannabis* plant to satisfy its obligation in Art. XXVIII, ¶3, to prevent illicit traffic.

tion is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. *In determining the public interest, the following factors shall be considered:*

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) *such other factors as may be relevant to and consistent with the public health and safety.* [Emphasis added.]

As your memorandum suggests, because registration of *bracteatum* producers is consistent with U.S. treaty obligations, the only other ground upon which registration could be refused would be § 623(a)(6), namely, the "public health and safety" factor.

This factor should be interpreted, in our judgment, to include consideration of a predictable increase in the domestic supply of illicit controlled substances from foreign sources. The congressional findings in 21 U.S.C. § 801 state that the "illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." There can be no question that the Controlled Substances Act reflects not only Congress' understanding that the availability of illicit drugs has a serious impact on public health, but also that illicit drugs are frequently imported rather than domestically produced. The emphasis throughout the Act on the control of importation and the recognition of U.S. treaty obligations intended to impose international controls bears out this conclusion.

The materials submitted with your memorandum indicate that the Department of State has expressed the view that domestic production of *bracteatum* would weaken the existing constraints on illicit foreign narcotics production, and discourage producing countries from attempting to maintain effective controls. It urges that this will result in the

availability of greater narcotic supplies for traffickers, which supplies will be transported into the United States. This argument is detailed in the Department of State's submission for the hearings held by DEA on this subject.

Accordingly, in our opinion, if the Administrator finds that a substantial increase in the availability of illicit drugs will result from the domestic production of *bracteatum* because of a breakdown in informal international understandings and because of the loss of licit U.S. markets, he could then determine that registration of applicants to grow *bracteatum* would not be consistent with the public interest, and deny registration pursuant to 21 U.S.C. § 823(a)(6).[10] Of course, before making his final determination of the public interest, the Administrator would also have to weigh all other comments received and evidence available in light of the six factors listed in § 823.

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[10] We recognize, however, that the language of § 823(a)(6) is extremely broad or "imprecise," and thus might support many interpretations, some contrary to the one discussed here. We have found nothing in the legislative history to provide specific guidance as to its interpretation in this circumstance.