No. 20-71433

In the United States Court of Appeals for the Ninth Circuit

SUZANNE SISLEY, M.D.; SCOTTSDALE RESEARCH INSTITUTE, LLC; BATTLEFIELD FOUNDATION, DBA FIELD TO HEALED; LORENZO SULLIVAN; KENDRICK SPEAGLE; GARY HESS,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; WILLIAM BARR, ATTORNEY GENERAL; TIMOTHY SHEA, ACTING ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,

Respondents

SUPPLEMENTAL EXCERPTS OF RECORD
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SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''The Use of an Alternate Name for Potassium Chloride in Food Labeling.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of May 20, 2019 (84 FR 22749), we made available a draft guidance for industry entitled ''The Use of an Alternate Name for Potassium Chloride in Food Labeling'' (''draft guidance''), which was intended to explain to food manufacturers our intent to exercise enforcement discretion for the declaration of the name ''potassium chloride salt'' in the ingredient statement on food labels as an alternative to the common or usual name ''potassium chloride.'' The draft guidance considered, in part, a NuTek Food Science citizen petition requesting that we issue guidance recognizing ''potassium salt'' as an additional common or usual name for potassium chloride (see Citizen Petition from NuTek Food Science, LLC, dated June 27, 2016, FDA–2016–P–1826–0001 at page 1). Additionally, we specifically invited comment on how the use of the name ''potassium chloride salt'' in the ingredient statement as an alternative to ''potassium chloride'' would improve consumer understanding of the ingredient and what alternate names to ''potassium chloride salt'' would better promote consumer understanding of potassium chloride (84 FR 22749 at 22750 through 22751). We gave interested parties until July 19, 2019, to submit comments for us to consider before beginning work on the final version of the guidance.

In response to requests for more time to comment on the draft guidance, we issued a notice in the **Federal Register** of July 10, 2019 (84 FR 32848) extending the comment period to September 17, 2019. We received more than 70 comments on the draft guidance. Many comments expressed concerns that declaration of the alternate name ''potassium chloride salt'' would be confusing or would not achieve the public health goal of reduced sodium consumption, as food manufacturers would likely not use the alternate name. Food manufacturers, public health and consumer advocacy groups provided comments and data supporting ''potassium salt'' as an alternate name to ''potassium chloride.''

After careful review and consideration of the comments to the draft guidance, some of which led us to further review of relevant published literature, we have modified the final guidance. Changes to the guidance include:

- Exercising enforcement discretion for declaration of ''potassium salt,'' rather than ''potassium chloride salt,'' in the ingredient statement on food labels as an alternative to declaration of the common or usual name ''potassium chloride;'' and
- Further explaining potassium chloride's technical role as a partial substitute for sodium chloride in food manufacturing through the inclusion of additional examples and references.

As discussed in the final guidance, we have made these changes with the following considerations in mind: Potential public health benefits to the U.S. population from reduced sodium and increased potassium intake, the recognition that potassium chloride can substitute for sodium chloride in a variety of food manufacturing applications across a number of food categories, and the unlikelihood that the alternate name will mislead consumers.

The guidance announced in this notice finalizes the draft guidance dated May 2019.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 11, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27750 Filed 12–17–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1318

[Docket No. DEA–506]

RIN 1117–AB54

Controls To Enhance the Cultivation of Marihuana for Research in the United States

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations to facilitate the cultivation of marihuana for research purposes and other licit purposes to enhance compliance with the Controlled Substances Act, including registering cultivators consistent with treaty obligations. This final rule adopts, with minor modifications, the notice of proposed rulemaking published on March 23, 2020, including regulations that govern applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, and regulations related to the purchase and sale of this marihuana by DEA.

DATES: This final rule is effective January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152–2639; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority and Background

The Controlled Substances Act (CSA) requires all persons who seek to manufacture a controlled substance to obtain a DEA registration.[1] 21 U.S.C. 822(a)(1). The CSA defines ''manufacture'' to include the ''production'' of a controlled substance, which in turn includes, among other things, the planting, cultivation, growing, or harvesting of a controlled substance. 21 U.S.C. 802(15), (22). Thus, any person who seeks to plant, cultivate, grow, or harvest marihuana[2] [3]

[1] All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b).

[2] This document uses both the CSA spelling ''marihuana'' and the modern spelling ''marijuana'' interchangeably.

[3] As defined in Section 802(16).

to supply researchers or for other uses permissible under the CSA (such as product development) must obtain a DEA manufacturing registration. Because marihuana is a schedule I controlled substance, applications by persons seeking to become registered to manufacture marihuana are governed by 21 U.S.C. 823(a). *See generally* 76 FR 51403 (2011); 74 FR 2101 (2009), *pet. for rev. denied, Craker* v. *DEA,* 714 F.3d 17 (1st Cir. 2013). DEA's Administrator has the authority to grant a registration under section 823(a). To do so, the Administrator must determine that two conditions are satisfied: (1) The registration is consistent with the public interest (based on the enumerated factors in section 823(a)), and (2) the registration is consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (''Single Convention'' or ''Treaty''), 18 U.S.T. 1407.[4]

In 2016, DEA issued a policy statement aimed at expanding the number of manufacturers who could produce marihuana for research purposes. *See* Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). Subsequently, the Department of Justice (DOJ) undertook a review of the CSA, including the requirement of section 823(a) that a registration to bulk manufacture a schedule I or II controlled substance must be consistent with United States obligations under international treaties such as the Single Convention, and determined that certain changes to its 2016 policy were needed. As part of this review, in June 2018, the DOJ Office of Legal Counsel (OLC) prepared an opinion (''OLC Opinion''), now publicly available, examining DEA's policies and practices for granting bulk manufacturing registrations to marihuana growers in light of the CSA's requirement that DEA register manufacturers of schedule I and II controlled substances in a manner consistent with the Single Convention.[5]

This rule is being implemented pursuant to the Administrator's authority under the CSA ''to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances,'' 21 U.S.C. 821, and to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under [the CSA],'' 21 U.S.C. 871(b).

Summary of the Notice of Proposed Rulemaking

On March 23, 2020, DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** to (1) facilitate the cultivation of marihuana for research and licit purposes in compliance with the CSA, including a provision requiring consistency with the Single Convention; (2) amend DEA regulations pertaining to applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers; and (3) establish regulations related to the purchase and sale of this marihuana by DEA. 85 FR 16292. This final rule responds to comments received concerning the proposed rule, and DEA is adopting the proposed rule with minor modifications to the regulations to be codified at 21 CFR 1318.04, as described below.

Discussion of Public Comments

DEA received comments from the general public, DEA registrants, applicants for registration to manufacture marijuana, organizations, associations, and a United States Senator. Some commenters expressed general support of the proposed rule because it will increase the number of DEA-registered bulk manufacturers of marihuana for research. Some commenters expressed general concern about the impact of the proposed rule. Other commenters expressed specific concerns about, among other things, the application process and applicant criteria, quality of marihuana produced, DEA's ability and authority to lead the program, controls for the purchase and sale of marihuana, harvest time, quota, and costs. Other commenters submitted comments that are outside of the scope of this rule.

Application Process and Criteria

Commenters expressed concerns about the application process and the criteria for applicants. The following issues raised by the commenters, and DEA's response to each, fall under this category.

Issue 1: Many commenters stated that the approval process for applications takes too long and needs to be streamlined, suggesting that a timeframe for the approval or denial of applications should be determined, specifically within 30 days, 90 days, or six months of receipt of the application.

Response 1: DEA has a process for receiving, reviewing, and acting on applications for a DEA registration or re-registration, as described in 21 CFR part 1301. The process involves applicants submitting applications online or on paper and DEA evaluating all applications and supporting documentation submitted in accordance with the factors specified in 21 U.S.C. 823. The length of this process varies due to the detailed review performed by DEA, and as explained in the NPRM, a review of pending applications to manufacture marihuana has been delayed due to the need to establish the additional policies reflected in this rule. After receiving an application, DEA will send a questionnaire to the applicant to be completed and returned to DEA within 10 business days. DEA uses the information from the questionnaire and the application to determine whether the application should be granted under the factors specified in 21 U.S.C. 823. After the completed questionnaire is processed, DEA publishes a notice of application in the **Federal Register**, and current registrants and applicants for bulk manufacture of the same class of substance have 60 days to comment on, or object to, the application, as required by 21 CFR 1301.33. During the application process, DEA investigators also complete site visits and submit the appropriate reports to aid in the determination of whether to grant a registration. Because the process of evaluating an application to manufacture a schedule I controlled substance includes a 60-day public comment period, DEA cannot act on the application in a shorter timeframe, such as 30 days. Likewise, DEA must balance limited resources to conduct pre-registration vetting of numerous applicants, which impacts the length of time needed to complete the application process. As a result, DEA declines to adopt a specific approval date applicable to all applications for registration to bulk manufacture marihuana.

However, in accordance with 21 U.S.C. 823(i), for applications to manufacture a schedule I or II controlled substance for use only in a clinical trial, DEA will issue a notice of application not later than 90 days after the application is accepted for filing. Additionally, DEA will register the applicant, or serve an order to show cause upon the applicant in accordance with 21 U.S.C. 824(c), not later than 90 days after the date on which the period

[4] Section 823(a) provides that the registrations to manufacture controlled substances in schedule I or II must be ''consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.'' The Single Convention entered into force for the United States on June 24, 1967. *See* Single Convention, 18 U.S.T. 1407.

[5] That opinion is available at *http://www.justice.gov/olc/opinion/licensing-marijuana-cultivation-compliance-single-convention-narcotic-drugs.*

for comment pursuant to such notice ends, unless DEA has granted a hearing on the application under 21 U.S.C. 958(i). An applicant that believes it qualifies for review under these procedures should identify itself as an 823(i) applicant in its initial application for registration submitted to DEA. DEA will then determine whether the applicant qualifies for the review timeline specified under section 823(i).

Issue 2: Some commenters suggested that when there is a denial, DEA should provide notice and allow a hearing.

Response 2: Pursuant to 21 U.S.C. 824(c) and 21 CFR 1301.37, when DEA proposes to deny an application, DEA must serve the applicant with an order to show cause setting forth the factual and legal basis for the proposed denial. The applicant may file a request for a hearing, in accordance with 21 CFR 1301.43. If a hearing is requested, DEA will hold the hearing in accordance with the provisions for formal adjudications set forth in the Administrative Procedure Act and DEA regulation found at 21 CFR 1316 subpart D.

Issue 3: Another commenter stated that DEA used an internal memorandum to delay approval of applications to bulk manufacture marihuana.

Response 3: As mentioned in the NPRM, after the 2016 marihuana grower policy statement issued by DEA,[6] DOJ reviewed DEA's policies and practices for issuing bulk marihuana manufacturing registrations in light of the CSA and determined that DEA needed to amend its policies.[7] DEA has acted as expeditiously as possible to amend its policies to ensure consistency with the Single Convention as required by the CSA, while increasing the number of marihuana growers for research purposes. DOJ and DEA fully support research into the effects of marihuana and the potential medical utility of its chemical constituents, and DEA is working to expand the number of DEA-registered bulk manufacturers of marijuana, including through the finalization of this rule.

Issue 4: One commenter requested that DEA make the revised Form 225 and updated questionnaire available online for applicants.

Response 4: As required by the Paperwork Reduction Act (PRA), DEA must receive approval from the Office of Management and Budget (OMB) when a rule creates a new information collection or modifies an existing collection. This approval must be granted before an agency can use a revised form. In the NPRM, DEA discussed the modification of the existing information collection which would revise Form 225 and add questionnaires to the registration application process. Within the PRA section of the NPRM, DEA explained that an interested party could contact DEA for a copy of the form and questionnaires. The revision of the collection is awaiting approval; and, as such, DEA cannot yet post the proposed revisions to the form online for applicants. However, after the form has been approved, DEA will post the application to its website, and an applicant can complete and submit it online. DEA will then send the applicable questionnaires to the applicant after the application has been received.

Issue 5: Some commenters believe that DEA's consideration of an applicant's compliance with Federal marihuana law would exclude qualified applicants, specifically those who operate in compliance with State laws that are inconsistent with Federal law.

Response 5: Congress has established by statute the factors that DEA must consider when evaluating whether to grant an application for registration. For an applicant to manufacture a schedule I or II controlled substance, DEA must consider, among other factors, the applicant's ''compliance with applicable State and local law;'' ''prior conviction record . . . under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;'' ''past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;'' and ''such other factors as may be relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(a). An applicant that has manufactured marijuana without obtaining a DEA registration has violated Federal law, *see* 21 U.S.C. 841(a), regardless of whether that manufacturer has violated the laws of the State in which the applicant is located. Such activity is relevant to past experience in the manufacture of a schedule I controlled substance, past experience in preventing diversion of a controlled substance from other than DEA-authorized sources, and the promotion and protection of public health and safety. Moreover, prior conduct in violation of the CSA is relevant to determining whether the applicant can be entrusted with the responsibilities associated with being a DEA registrant. Indeed, DEA registration is a fundamental component of the CSA, and it is wholly appropriate to consider an applicant's past noncompliance with the CSA when deciding whether to grant a registration under the Act. DEA will consider all relevant factors for each individual applicant, on a case-by-case basis, when determining whether to grant registration, as provided for in 21 U.S.C. 823(a) and the regulatory text at 21 CFR 1318.05. While the DEA Administrator has discretion to weigh the statutory factors and any one factor need not be dispositive, an applicant's prior compliance with Federal law is a relevant consideration when determining whether to grant an application for registration.

Issue 6: A commenter suggested that a notice of exemption for a new drug application issued by the Food and Drug Administration (FDA) be an alternative to obtaining a DEA registration.

Response 6: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). Using FDA's authorization of a notice of exemption for a new drug application would not be in compliance with the CSA and therefore cannot be considered an alternative for obtaining a DEA registration.

Issue 7: A commenter opined that applicants should only be required to submit proof of State-issued marihuana licenses to DEA, after DEA approves the application.

Response 7: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). In assessing the application, DEA also weighs the applicant's compliance with applicable State law. 21 U.S.C. 823(a)(2). DEA has always required applicants seeking to manufacture a controlled substance to obtain and submit a valid State pharmaceutical manufacturer's license to demonstrate compliance with State law. Likewise, an applicant seeking to manufacture marihuana must submit evidence that it possesses a valid State manufacturer's license as part of its application, or explain why no such license is required by the State to manufacture marihuana for use in research. This evidence must be submitted to DEA as part of the determination of whether to grant a registration.

Issue 8: Some commenters suggested that the registration requirement be waived for marihuana growers (manufacturers) who will be supplying

[6] Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States,'' 81 FR 53846 (Aug. 12, 2016).

[7] The Attorney General determined that adjustments were necessary after receiving the aforementioned advisory OLC Opinion.

marihuana to researchers under 21 U.S.C. 822(d).

Response 8: DEA-registered researchers are not currently allowed to obtain marihuana from entities that are not registered with DEA. DEA is permitted to waive the registration requirement if it finds that doing so is ''consistent with the public health and safety,'' pursuant to 21 U.S.C. 822(d), and acting under authority delegated by the Attorney General. However, DEA has never previously waived the registration requirement to allow controlled substances to be manufactured outside the closed system of distribution, and doing so would be incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. In addition, waiving the requirement of registration for marihuana growers who supply researchers would be inconsistent with U.S. obligations under the Single Convention.[8] It should also be noted that supplying marihuana to researchers does not demonstrate that the material being supplied has been produced in accordance with other Federal laws. As a result, DEA does not consider such a waiver of registration for a bulk manufacturer to be a legally viable option.

The scope of this rule addresses the registration of manufacturers of marihuana, not researchers of marihuana. To the degree that the commenters were seeking to exempt marihuana researchers, rather than manufacturers, from registration, in addition to the foregoing concerns about adherence to treaty obligations, DEA does not at this time conclude that there is a public health need to exempt schedule I researchers from DEA registration. DEA notes that over the last several years, there has been a 149 percent increase in the number of active researchers registered with DEA to perform bona fide research with marihuana, marihuana extracts, and marihuana derivatives (from 237 in November 2014 to 589 in June 2020). At present, more researchers are registered to conduct research in the United States on marihuana, marihuana extracts, and marihuana derivatives than on any other schedule I substance, and more than 72 percent of DEA's total schedule I research registrant population (589 of 808 as of June 2020) is registered to conduct research on these substances. As a result, DEA concludes that there is not currently a public health need to exempt researchers from the registration requirement.

Issue 9: Other commenters suggested that DEA-registered researchers should be exempt from applying for DEA manufacturer registrations if the researchers are growing marihuana for their own studies and not for distribution.

Response 9: As reflected in this rule, any person lawfully growing marihuana must be registered with DEA to allow DEA to fulfill its obligations under the CSA. For the reasons discussed above, DEA has concluded that this requirement cannot be waived for researchers. Thus, under this final rule, when an applicant, including a researcher growing for his or her own use, is approved to grow marihuana, the applicant is registered as a bulk manufacturer. After the applicant is approved as a bulk manufacturer, the registrant must apply for and be issued an individual manufacturing quota (IMQ) for the amount of marihuana it needs to manufacture to meet the legitimate research and scientific needs of its customers. If the manufacturer plans to use the marihuana grown in bulk for its own research, it will also need to apply for a procurement quota. Under this rule, the DEA registrant must sell their harvest to DEA and then purchase from DEA the amount that they are allowed to procure based on the procurement quota issued to them. As such, DEA cannot exempt a researcher from the requirement of a DEA manufacturing registration even if they plan to use the marihuana grown for their own studies.

Issue 10: A few commenters suggested applicants who applied to be registered to grow marihuana soon after DEA published its 2016 marihuana growers policy should receive priority over more recent applicants. On the other hand, some commenters suggested that DEA should not delay consideration of new marihuana grower applications submitted after this rule is promulgated, as 21 CFR 1318.05(c) provides. In particular, some commenters expressed confusion about the ''limited exception'' to this delay noted in the NPRM and suggested that the limited exception should apply to all applicants.

Response 10: As previously stated in the NPRM, applications received after the date the final rule becomes effective will not be considered until all of the applications currently pending have been approved or denied, unless an application requires action under 21 U.S.C. 823(i). Applications already submitted will receive priority, and as a result, DEA will not have to restart its consideration of the pool of pending applications whenever a new application is submitted.

As described in the NPRM, the ''limited exception'' refers to the review of applications claiming the benefit of the statutory timeline of 21 U.S.C. 823(i). Congress has set the timeline for review of such applications by statute. That timeline will apply in lieu of the provision at 21 CFR 1318.05(c) for applicants that clearly identify themselves as 823(i) applicants in their original application, and for which DEA determines that the applicant qualifies for review under 823(i).

Issue 11: Another commenter suggested that the number of applicants selected to bulk manufacture marihuana should be unlimited and that DEA should consider the bulk manufacture of marihuana as a coincident activity to a researcher registration.

Response 11: The CSA mandates that DEA consider the maintenance of effective controls against diversion by limiting the bulk manufacture to a number of establishments which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 U.S.C. 823(a)(1). By statute, DEA is not allowed to register an unlimited amount of manufacturers, and DEA must perform an analysis of each application to determine whether the addition of the applicant is necessary to provide the adequate and uninterrupted supply of marihuana for research needs or whether the legitimate need will be met by the registration of others.

Currently, researchers are only permitted to manufacture as a coincident activity in limited quantities as set forth in a protocol approved by DEA in the researcher's registration application (or re-registration application), and to the extent that manufacture is not for the purposes of dosage form development. 21 CFR 1301.13(e)(1). A researcher's planting, cultivating, growing, or harvesting of marihuana does not constitute such a coincident activity to research. Rather, the planting, cultivating, growing, or harvesting of marihuana requires a manufacturer registration obtained under 21 U.S.C. 823(a), even when the researcher is growing the marihuana for his or her own research use. *See* 21 CFR 1301.33(d). As described in response to Issue 9, and in the section on quota that follows, international treaties require that DEA control manufacturing of marijuana and other schedule I and II controlled substances by means of quota. Although regulatory provisions allow for the approval of certain small-

[8] *See* OLC Op., *supra* note 5, at 7.

scale manufacturing pursuant to a DEA-approved protocol, significant manufacturing, including for research purposes, must be performed pursuant to a quota to maintain effective controls against diversion. As a result, researchers must register with DEA as manufacturers to engage in significant manufacture of controlled substances, even if the manufactured substances will exclusively be used in the grower's own research.

In addition, the Single Convention obligates a single government agency of the United States to purchase and take possession of all marihuana manufactured, and DEA has concluded this includes marihuana manufactured for research even when manufactured for use in research by the grower. By requiring all planting, cultivating, growing, and harvesting of marihuana be performed by DEA registered manufacturers, DEA can ensure that the controls set forth in the Single Convention are properly applied to all registrations to manufacture marihuana for research.

Issue 12: Other commenters suggested that the criteria for applicants should include the applicant's ability to produce high quality marihuana while another commenter suggested that applicants should have prior experience producing quality cannabis or hemp.

Response 12: The CSA provides that two conditions must be satisfied for an applicant to become a registrant: (1) The registration must be consistent with the public interest, and (2) the registration must be consistent with U.S. obligations under the Single Convention on Narcotic Drugs. Congress defined the factors for DEA to evaluate whether granting a registration is consistent with the public interest in 21 U.S.C. 823(a), and the burden lies with the applicant to demonstrate that the application meets those factors. Under those factors, DEA will consider the applicant's ''past experience in the manufacture of controlled substances'' and its ''promotion of technical advances in the art of manufacturing these substances,'' including the applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition. § 1318.05(b)(2). DEA must also consider the applicant's overall past experience with controlled substances in relation to preventing diversion.

Issue 13: Some commenters suggested DEA establish application requirements or committees that ensure diversity and inclusion of minority applicants. Other commenters suggested DEA provide regulatory provisions that afford economic opportunities to communities that have been disproportionately impacted by substance abuse and illicit drug markets and make application selection inclusive to include rural farmers, racial minorities, and disabled persons.

Response 13: DEA gives all applicants equal treatment regardless of the gender, race, socioeconomic status, or disabled status of the applicant. The only criteria used to evaluate the application for registration are those factors defined by Congress at 21 U.S.C. 823(a). *See* 21 CFR 1318.05.

Issue 14: Another commenter inquired whether manufacturers would be permitted to develop contracts, partnerships, or cooperative agreements with international research and development firms.

Response 14: Registrants are permitted to import and export controlled substances, including marihuana, in accordance with the criteria defined at 21 U.S.C. 952(a) (import) and 21 U.S.C. 953(a) (export), and after obtaining registration in accordance with 21 U.S.C. 958. After obtaining a registration to manufacture marihuana, the applicant may form agreements with international firms, but, if the importation or exportation of marihuana or another controlled substance will be involved as part of the agreement, it must ensure that any such importation or exportation complies with 21 U.S.C. 952, 953, and 958, and the relevant implementing regulations. Moreover, in addition to these general regulatory requirements, § 1318.04(b) of this rule specifically requires prior written notice to DEA of each proposed importation or exportation of marihuana, and DEA's express written authorization for the importation or exportation.

Quality of Marihuana

DEA received a number of comments that expressed concerns about the quality of marihuana that will be produced under this rule.

Issue 1: Some commenters stated that the current quality of marihuana produced for Federal research is of poor quality.

Response 1: The purpose of this rule is to increase the number and variety of marihuana growers in order to diversify the supply available to researchers. As proposed in the NPRM and finalized in this rule, one of the selection criteria for marijuana grower applicants is the ''applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition.'' 21 CFR 1318.05(b)(2).

Issue 2: A few commenters suggested that samples of marihuana should be tested to determine the quality prior to sales transactions and that manufacturers should be allowed to send samples of crops before and after harvest to analytical labs for testing, prior to DEA taking possession.

Response 2: DEA has no objection to DEA-registered marihuana growers and buyers exchanging samples or sending such samples to analytical labs for testing so long as this exchange occurs in a manner consistent with the CSA, and is amending the rule to make this clear. DEA understands that it is necessary for registered growers to engage in sampling and testing prior to harvest or DEA taking possession of the crop for growers to demonstrate compliance with contractual specifications to their researcher customers. Prior to the agency taking possession of the marihuana harvest, a registered grower may collect samples and distribute those samples to a DEA-registered analytical laboratory for analysis. It is consistent with the Single Convention to permit growers to conduct sampling and exclude the samples from the total crop that DEA is required to purchase and possess because the Single Convention plainly contemplates that growers will be able to harvest and sell their marijuana crops, and without sampling, sales would be practically impossible because the final intended purchaser could not know whether the marijuana is acceptable for purchase.

DEA is thus modifying the regulations proposed in the NPRM to add a new section at 21 CFR 1318.04(d). This new section explicitly permits DEA-registered manufacturers of marihuana to collect samples and distribute them to DEA-registered analytical laboratories for chemical analysis prior to DEA taking possession of the marihuana grown. However, to limit the risk of diversion and keep the distribution within the legitimate purposes permitted by the CSA, the quantity of samples collected and distributed must be small.

Issue 3: Some commenters stated that the time it takes DEA to take possession of the marihuana could negatively impact the quality of marihuana.

Response 3: To minimize the risk of diversion and delays that may impact the quality of the crop, DEA intends to take physical possession of the crop after harvest and distribute marihuana to the purchaser as soon as practicable.

Issue 4: Many commenters expressed concerns that DEA is excluded from liability for any damage to crops that may occur while in DEA's possession, and that there are no regulations to ensure the quality of marihuana while

in DEA's possession. Other commenters stated that there is no process or remedy for the damage or loss of crops that could occur while in DEA's possession.

Response 4: DEA assesses the risk of marihuana crops being lost or damaged while in DEA's possession to be low. DEA does not anticipate retaining possession of marihuana crops for long periods of time; in most instances, they will be transferred quickly from the seller to the buyer, with DEA's possession being as brief as possible to effectuate its role in transferring the marihuana from buyer to seller. In addition, crops in DEA's possession are largely expected to be maintained at the manufacturer's registered location, in a secure location designated by DEA. Accordingly, crops are highly unlikely to be damaged or lost in DEA's possession. To avoid costly and unnecessary disputes related to any loss or damage of crops, § 1318.07 makes clear that DEA has no liability with regard to the performance of any of the terms agreed to by a grower and buyer of marihuana, including but not limited to the quality of the marihuana. In effect, this rule makes clear that buyers and sellers should structure their marihuana transactions to minimize the risk of damage or disputes over quality, rather than expecting DEA to mediate or bear the costs of such disputes.

DEA recognizes that some growers and buyers may wish the DEA to assume a greater role in assuring the quality of marihuana supplied to researchers. Doing so, however, could significantly increase DEA's costs for operating the marihuana grower program, which would then be transferred to growers and buyers in the form of increased administrative fees. Thus, given the relatively low risk that crops will be lost or damaged in DEA's possession, DEA has concluded that the program will provide marihuana to researchers most efficiently if DEA does not assume any role in quality assurance and accordingly does not assume liability for such risks.

Issue 5: One commenter inquired how DEA will ensure availability of different strains of marihuana for research.

Response 5: DEA does not have the authority to dictate the strains of marihuana to be produced by growers. Rather, DEA believes that market forces will drive the strains of marihuana materials that growers will produce, and the purchasers will be able to choose which DEA-registered grower they believe will best produce the strains or quality of marihuana that will meet their needs. The factors that the Administrator will consider in granting a registration to grow marihuana will be consistent with the public interest factors set forth in section 21 U.S.C. 823(a), including the applicant's ability to consistently produce and supply high quality marihuana and defined chemical composition and other criteria as specified in 21 CFR 1318.05.

Issue 6: Some commenters suggested that DEA-registered researchers be allowed to obtain marihuana and marihuana products from State-authorized sources for the purpose of Federal research.

Response 6: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). State licenses to manufacture marijuana do not satisfy the requirements of Federal law. *See id.;* 21 U.S.C. 841(a)(1). Therefore, possession of a license to manufacture marijuana issued by a State government or agency does not meet the requirements of the CSA and cannot be accepted in lieu of DEA registration to manufacture or distribute. Registrants, including researchers, are only authorized to possess, manufacture, distribute, or dispense controlled substances ''to the extent authorized by their registration and in conformity with the other provisions'' of the CSA. 21 U.S.C. 822(b).

DEA does not view the receipt of a schedule I substance from a non-registrant, distributed in violation of § 841(a), to be ''in conformity with the other provisions'' of CSA as required of registrants by § 822(b). The receipt of controlled substances from outside the CSA's closed system of distribution is incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. In addition, as discussed above, the CSA—including a provision that requires consistency with the Single Convention—requires DEA to, among other things, register marihuana growers and take possession of all marihuana crops. Thus, authorizing researchers to obtain marihuana from unregistered sources is inconsistent with the Single Convention, and with DEA's CSA enforcement duties. Authorizing such research using marihuana from unregistered sources may also be inconsistent with the requirements of other Federal laws, as well as DEA's broader obligation to authorize controlled substances research in a manner consistent with the public safety.

Moreover, such a change is unnecessary. By registering additional marihuana growers pursuant to this rule, DEA will expand researchers' access to marihuana in accordance with the CSA, and in a manner that supports the public health.

Issue 7: Some commenters suggested that growers should be allowed to perform marihuana-related activities that are State-sanctioned but violate Federal law, such as distributing marihuana to recreational users, in the same facilities as DEA-authorized marihuana-related activities to save costs.

Response 7: As previously explained, DEA cannot authorize marihuana growers to violate the CSA or other Federal laws. Endorsing the production of marihuana outside the CSA's closed system of distribution would be incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. Authorizing such activities would also be inconsistent with the Single Convention, and with DEA's CSA enforcement duties, as well as contrary to other Federal laws.

Federal Agency Obligations Pertaining to Cannabis Controls

DEA received several comments regarding the division of authority between agencies in regulating the growing of marijuana for scientific research.

Issue 1: DEA received comments asserting that scientific or public health-based agencies such as the Department of Health and Human Services (HHS), National Institutes of Health (NIH), FDA, or Department of Agriculture should oversee the marihuana grower program. Some of these commenters also suggested that the CSA be amended by Congress to allow a health-related agency to be in charge of this program. Similarly, a commenter suggested that DEA contract with a private third party and authorize that contractor to carry out the functions described in this rule.

Response 1: DEA agrees that HHS and other Federal agencies can offer valuable insights into how the Federal government can best oversee the provision of marihuana for legitimate scientific research. DEA is committed to collaborating with HHS and other Federal agencies to ensure marihuana is available to meet the research and scientific needs of the United States, and that this rule is implemented with minimal disruption of the National Institute on Drug Abuse (NIDA) Drug Supply Program (DSP). That said, as a matter of current law, any registration and coordination of legitimate marihuana growing in the United States will be overseen solely by DEA, not

other Federal agencies. In other words, even if DEA preferred other Federal agencies to carry out these functions, as DOJ has interpreted the CSA, including a provision requiring that registrations be consistent with U.S. obligations under the Single Convention, it would be unlawful for DEA to transfer these functions to another Federal agency. Commenters' suggestions that the law should be changed are beyond the scope of this rulemaking: This rulemaking must follow the law, as enacted by Congress.[9]

As discussed above and in the NPRM, under the CSA, DEA may only grant a person a registration to grow marihuana if: (1) The registration is consistent with the public interest, and (2) the registration is consistent with U.S. obligations under the Single Convention. *See* 21 U.S.C. 823(a). Accordingly, DEA may only grant marihuana grower registrations which are consistent with U.S. obligations under the Single Convention. Article 23(2) of the Single Convention, which is applicable to the cultivation of marihuana through Article 28, describes five functions related to the distribution, supervision, and licensing of marihuana cultivation [10] that the United States is obligated to fulfill as part of a regulatory scheme that authorizes the growing of marihuana.

The Single Convention requires that these five functions ''be discharged by a single government agency if the constitution of the Party concerned permits it.'' Single Convention art. 23(3).[11] Nothing in the U.S. Constitution precludes the United States from discharging all five of those controls through one government agency, so a single U.S. Federal agency must perform all five of the controls. Further, by requiring that the functions be discharged by a government agency, the Single Convention prohibits the United States from assigning them to a private government contractor.

Through the CSA, Congress assigned the first three of the Single Convention functions to DEA by authorizing DEA—and, at least at the Federal level, DEA alone—to register and regulate marihuana growers: Under the CSA, DEA effectively designates the area in which the marihuana cultivation is permitted, limits marihuana growers to those it licenses, and specifies the extent of the land on which marihuana cultivation is permitted as required by the Single Convention. Thus, to fully comply with the CSA provision requiring consistency with the Single Convention, DEA also must perform the remaining two functions of Article 23: Taking possession of marihuana crops after harvest and maintaining the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marihuana and its resin. Congress granted DEA the power to enforce these provisions by directing DEA to grant registrations if the registrations are consistent with U.S. obligations under the Single Convention. 21 U.S.C. 823(a).[12]

Therefore, Congress has assigned DEA the duty and authority to carry out the five functions the Federal government is required to perform under the Single Convention if it authorizes the production of marihuana. DEA has no authority to assign these functions to another agency or a private contractor outside the government. Rather, DEA must perform the functions itself, and this rule will enable DEA to do so more effectively.

Issue 2: Another commenter suggested that NIDA be completely removed from any role in supplying marihuana to researchers.

Response 2: Marihuana research can be enhanced by allowing other growers to supply marihuana to researchers. However, scientific and medical research is likely to benefit from the NIDA DSP's continued involvement in these efforts. As discussed in the NPRM and further discussed below, the NIDA DSP has long played a fundamental role in supplying marihuana to researchers. In doing so, the NIDA DSP has acquired valuable experience and expertise in the production of marihuana. Moreover, because researchers currently obtain their marihuana though the NIDA DSP, the continued operation of the NIDA DSP will allow researchers who wish to continue to receive such NIDA DSP marihuana to do so with minimal disruption. Ultimately, the purpose of this rule is to expand researchers' options for obtaining marihuana, not eliminate them, a result best achieved by allowing the NIDA DSP to continue to operate, while also registering additional marihuana growers.

Issue 3: Some commenters suggested that DEA and DOJ misinterpreted the Single Convention. Some commenters stated that DEA is inappropriately using the Single Convention requirements as a justification to maintain exclusive control over marihuana sales/purchases. Another commenter suggested that DEA's view of the Single Convention is too narrow and not aligned with other parties to the Single Convention with respect to Article 23. This same commenter suggested that the United States withdraw from the Single Convention and rejoin with a formal reservation opting out of the cannabis related provisions of the Single Convention. Some other commenters suggested DEA initiate the process to amend the treaty to accomplish its intent of allowing robust research to be performed.

Response 3: As a matter of law, the CSA requires that registrations to manufacture schedule I and II controlled substances be consistent with U.S. obligations under the Single Convention, which requires a single government agency to regulate the cultivation of and certain trading in marihuana, including taking possession of marihuana after harvest.[13] The CSA assigns this function to the Attorney General, who has delegated this statutory authority to the DEA Administrator. The CSA therefore requires DEA to grant registrations that are consistent with U.S. obligations under the Single Convention, which includes regulating the cultivation of and certain trading in marihuana. DEA acknowledges some may disagree with these legal conclusions, but DEA is bound by the law as DOJ and DEA understand it. Whether the Single Convention's or the CSA's controls of marihuana should be amended and whether the United States should withdraw from the Single Convention

[9] The relevant law is briefly summarized here but is discussed in greater depth in the aforementioned OLC Opinion.

[10] The five functions of Article 23(2) of the Single Convention are as follows: (1) Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis or cannabis resin shall be permitted; (2) ensure that only cultivators licensed by the agency shall be authorized to engage in such cultivation; (3) ensure that each license shall specify the extent of the land on which the cultivation is permitted; (4) require all cultivators of the cannabis plant to deliver their total crops of cannabis and cannabis resin to the agency and ensure that the agency purchases and takes physical possession of such crops as soon as possible, but not later than four months after the end of the harvest; and (5) have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of cannabis and cannabis resin, except that this exclusive right need not extend to medicinal cannabis, cannabis preparations, or the stocks of cannabis and cannabis resin held by manufacturers of such medicinal cannabis and cannabis preparations.

[11] The Commentary to the Single Convention notes that this is in order to facilitate national planning and coordinated management of the various tasks imposed upon a country by Article 23, and that in countries where more than one agency is needed to perform these tasks on constitutional grounds, administrative arrangements should be made to ensure the required coordination.

[12] These issues are discussed further in the OLC Opinion.

[13] As noted, the relevant legal considerations are explored in greater detail in the aforementioned OLC Opinion.

are beyond the scope of this rulemaking and DEA's authority. This rulemaking must be consistent with DEA's obligations under the CSA, including granting registrations which are consistent with the Single Convention as it currently stands.

Issue 4: Some commenters believe that DEA's increased involvement in the provision of marihuana to researchers would have an adverse impact on clinical research, clinical trials, and the creation of cannabis preparations.

Response 4: As explained elsewhere in this rulemaking, DEA anticipates this rule will increase researchers' access to marihuana for medical and scientific research. At present, researchers must obtain marihuana for researchers through the NIDA DSP, and researchers who wish can continue to do so with minimal disruption. However, this rule will also allow researchers to legally obtain marihuana from other DEA-registered growers. DEA's involvement in that process will be limited, as set forth in these regulations, to those activities required by the CSA.

Issue 5: Another commenter suggested that DEA allow researchers to possess marihuana without restriction and that DEA's role in regulating the growing of marihuana be completely eliminated.

Response 5: As explained above, the CSA requires any person seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). More broadly, marihuana remains a schedule I controlled substance, and as such has a high potential for abuse and no currently accepted medical use in treatment in the United States. *See, e.g.,* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 FR 53687 (Aug. 12, 2016). Allowing the cultivation of marihuana for research without a DEA registration or otherwise regulating this activity would be incompatible with the CSA and its requirement of consistency with the Single Convention; it would also fail to protect public health and safety from the danger of that marihuana being diverted and abused.

Issue 6: One commenter suggested that the NPRM is incompatible with the Administrative Procedure Act (APA) on the grounds that DEA did not sufficiently explain the reasoning underlying the proposed rule.

Response 6: The NPRM satisfied the requirements of the APA, as does this final rule. The NRPM and this rule both set out the legal and practical reasons why DEA is promulgating this rule to increase the availability of marihuana for research consistent with the legal requirements of the CSA, as well as with DEA's duty to protect the public interest by preventing its diversion and abuse.

Issue 7: Two commenters requested that DEA extend the comment period given the current coronavirus disease 2019 public health emergency.

Response 7: DEA recognizes the challenges applicants and registrants may be facing during the public health emergency. However, DEA has decided not to extend the comment period beyond the 60 days generally required under Executive Order 12866 to avoid any further delays in registering additional marihuana growers. DEA, therefore, decided that extending the comment period would have unnecessarily delayed the registering of additional marihuana growers without meaningfully enhancing the rulemaking process.

The Meaning of ''Medicinal Cannabis''

Issue 1: Some commenters expressed concern about the definition of medicinal cannabis. Specifically, they argued that ''medicinal cannabis'' should include any cannabis that State law authorized for use as ''medical marijuana.'' One commenter requested DEA amend the definition of medicinal cannabis to include investigational marihuana for an investigational new drug.

Response 1: Under this rule, DEA will have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of marihuana other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations.[14] The term ''medicinal cannabis'' in this rule is limited to ''a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act,'' and DEA continues to believe this is the most appropriate definition for the term.

Through this rule, DEA is asserting an exclusive right of importing, exporting, wholesale trading and maintaining stocks of marihuana so as to ensure compliance with the CSA, including a provision requiring registrations to be consistent with the Single Convention. The exclusion of medicinal cannabis from this function is based on Single Convention Article 23's exclusion of medicinal opium from parties' obligation to maintain an exclusive right over opium trading (as applied to cannabis through Article 28). The Single Convention does not define medicinal cannabis, but its definition of ''medicinal opium'' is limited to opium that ''has undergone the processes necessary to adapt it for medicinal use.'' Single Convention art. 1(o).

Thus, DEA understands ''medicinal cannabis'' to mean drug products derived from cannabis in a form that the United States has approved for medical use, which is most effectively captured in this rule by requiring that the product be able to be legally marketed under the Food Drug and Cosmetic (FD&C Act). The United States, not State governments, is the relevant party to the Single Convention, and thus ''medicinal cannabis'' should only include cannabis-derived products that the United States has approved for medical use, not products States may have approved.

For similar reasons, this definition excludes an investigational new drug containing cannabis; such products may eventually become approved for full medical use in the United States (as opposed to research), but have not yet obtained such approval. The finished dosage form of such a substance may qualify as a ''cannabis preparation,'' which is outside of DEA's exclusive right to engage in the wholesale trade in cannabis, but remains subject to control under the CSA. It should be emphasized, however, that the bulk material from which any cannabis preparation is manufactured must be obtained from DEA.

Security Costs and Requirements Applicable to the Manufacture of Marihuana

Issue 1: Some commenters inquired about the packaging requirements necessary prior to the transport of purchased marihuana and once that marihuana is sent from a grower to a seller. Many commenters suggested DEA use tracking technology, similar to that used by some States, to monitor the movement of marihuana seeds, marihuana plants, and other marihuana products. Some commenters suggested that the use of such tracking technology would eliminate the need for the security measures proposed in the NPRM and required by DEA regulations more generally.

Response 1: DEA registrants are required to maintain effective controls against diversion. DEA registered manufacturers are responsible for providing proper security during the growing process. The crops must either be delivered and stored in a secure storage mechanism at the manufacturer's registered location, if one is designated by DEA, or delivered

[14] The exception that allows DEA registered manufacturers of medicinal cannabis and cannabis preparations to maintain stocks of cannabis materials for the purpose of producing such drugs or preparations only applies where the raw cannabis material was previously delivered to DEA.

to a location designated by DEA. In either case, the registrant must comply with security requirements specified in 21 CFR part 1301. A DEA registrant is also required to adhere to the recordkeeping and reporting requirements set forth in 21 U.S.C. 827 and 21 CFR part 1304, including the requirement to maintain records of all controlled substances which it manufactures, sells, and delivers. Although this regulation does not specify any special measures imposed on a grower for the packaging of a marihuana crop for purchase by DEA, DEA may develop packaging requirements as part of separate agreements between DEA and individual manufacturers; [15] but in all cases, DEA's general security regulations shall apply.

With regard to tracking technology, DEA recognizes that security technology is always evolving, and that in some circumstances tracking technology may present a useful means of protecting against diversion. In addition to security measures specifically required by DEA regulations, registrants should take the appropriate measures to guard against diversion of their crops, which may include the use of new technologies. At this time, however, DEA has concluded that it is not necessary to update its security regulations in this regard, and has not yet seen evidence that tracking technology can adequately replace security measures required by current regulations.

Issue 2: Other commenters suggested that the procedures for inspection of crops and harvests, and physical security requirements are expensive and would discourage applicants.

Response 2: As noted, DEA requires all applicants and registrants to maintain effective controls against the diversion of controlled substances as set forth in 21 CFR part 1301. The proposed rule and this final rule do not impose new or amended regulations for the security requirements set forth in 21 CFR part 1301. Furthermore, DEA registrants are subject to routine scheduled investigations conducted by DEA diversion investigators and other administrative requirements such as those specified in 21 CFR part 1304. DEA understands there will be costs incurred in meeting these administrative requirements; however, these requirements and costs are comparable to those applicable to bulk manufacturers of other controlled substances. Requiring such security controls is a critical part of DEA's efforts to fulfill its duties under the CSA to reduce the diversion and abuse of controlled substances, including marihuana.

Harvest

Issue: One commenter suggested that DEA expand the amount of time to deliver a harvest to DEA. This commenter also suggested DEA change the time period for providing notice of a harvest to five days, instead of 15 days beforehand, and suggested that the amount of harvests per year should be changed from three to five. Other commenters suggested manufacturers provide DEA with notice more than 15 days prior to harvest. Another commenter agreed that DEA should take possession of the crop no later than four months after harvest to maintain chemical composition of the crop.

Response: DEA understands the importance of taking possession of harvested crops in a timely manner to expedite the re-distribution of those crops to researchers and to reduce any potential for changes in the crops' chemical composition. As stated in the NPRM, and to comply with a CSA provision requiring consistency with the Single Convention, DEA must take physical possession of the crops within four months after the end of harvest. The requirement that a grower notify DEA at least 15 days prior to the commencement of a harvest is intended to provide DEA with sufficient time to make the necessary arrangements for traveling to the grower's registered location and to take possession of the crops. DEA has concluded that a five-day notice period will not provide sufficient time to make the arrangements needed to travel to a grower and attend a harvest.

With respect to this commenter's statement that DEA should change the number of harvests per year from three to five, DEA is not regulating the number of growing cycles that a registered grower may conduct. A grower may conduct as many growing cycles as is necessary to meet customer demand, so long as it does not exceed its IMQ for the year. The NPRM used three harvests per year as the estimated average number of harvests only for the purpose of conducting its regulatory analysis.

Quotas

Issue 1: A commenter stated there is a significant lag time from when quota is issued to harvest time. This same commenter inquired as to whether the cultivation of marihuana can begin prior to the issuance of quota. Another commenter suggested that DEA provide a deadline by which DEA must review or approve bona fide supply agreements and make quota determinations based upon them. A commenter also suggested that each manufacturer should be issued IMQ. One commenter suggested that DEA issue a multi-year license for new bulk manufacturers to meet quota needs.

Response 1: Pursuant to 21 U.S.C. 826, DEA is required to ''determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II . . . to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States [and] for lawful export requirements.'' This figure, which is known as the aggregate production quota (APQ), is then allocated to individual registered manufacturers based on each manufacturer's application for an IMQ as set forth in 21 U.S.C. 826(c). Pursuant to section 826(c), DEA is required to issue IMQ ''[o]n or before December 1 of each year'' for the following year.

While there may be significant lead time between the date on which an IMQ is issued and the date of harvest, a grower's lead time is dependent upon the growing techniques it uses. It should also be noted that non-botanical manufacturers of controlled substances frequently deal with significant lead times and have been able to manage them. In any event, Federal law prohibits the manufacturing of a controlled substance by a registrant which ''is not expressly authorized . . . by a quota assigned to him pursuant to'' 21 U.S.C. 826. 21 U.S.C. 842(b).

Thus, a registered manufacturer cannot commence growing marihuana until it has been granted its IMQ. Furthermore, because the CSA expressly requires that both the APQ and an IMQ be determined on a calendar year basis; DEA is not authorized to issue an IMQ other than on a single year basis.

As stated above, the CSA requires that DEA issue IMQ ''[o]n or before December 1 of each year'' for the following year. Thus, the CSA already sets the deadline by which DEA must review a bona fide supply agreement and make a quota determination. Each registered manufacturer of marijuana who produces evidence that it has entered into a bona fide supply agreement with a researcher will be issued an IMQ. In the event a registered manufacturer enters into additional bona fide supply agreements after receiving its IMQ, which would result in an increase in its estimated net disposal for the calendar year, it may apply for an increase in its IMQ for that calendar year. 21 CFR 1303.25.

[15] DEA routinely enters into memoranda of agreement with certain registrants.

Issue 2: A commenter suggested that the price and quantity of extracts is not based on dried flower weight and that different strains of marihuana will yield different extract weights from the same weight of marihuana. Thus, this commenter argued, DEA should set marihuana quotas based on the amount of marihuana extract produced from a harvested marihuana crop, not the weight of the harvested marihuana itself.

Response 2: Under the CSA, IMQ limits the quantity of controlled substances a manufacturer may produce. *See, e.g.,* 21 U.S.C. 826(c). Marihuana itself, not just its extract, is a schedule I controlled substance. Accordingly, when a marihuana grower cultivates a marihuana crop, that grower has produced a schedule I controlled substance. Thus, under the CSA, marihuana growers require an IMQ for the entire marihuana crop, regardless of the value or quantities of other controlled substances produced from that crop. Setting marihuana quota based solely on the amount of extract eventually produced would also inhibit quota enforcement, as DEA may not be able to determine if a marihuana grower was complying with its IMQ until the grower processed the marihuana into an extract. Finally, not all marihuana grown will necessarily be used to produce extracts—some marihuana research makes use of the plant material itself. Thus, not all marihuana production quotas could be tied to the quantity of extract produced from it, because not all marihuana grown for research is converted into an extract.

Costs, Pricing, and Fees of Marihuana for DEA Registrants

Issue 1: A commenter inquired how the purchase price is established when DEA purchases cannabis from a registrant that the registrant intends to use for his/her own research.

Response 1: This scenario was addressed in the NPRM by proposed 21 CFR 1318.06(b)(4), which this rule promulgates without change. Normally, under the rule, the seller and buyer may negotiate their own purchase price, to which DEA will add its administrative fee. When a registrant grows marihuana for its own use, the purchase price is irrelevant, given that the grower is effectively negotiating the price with itself. Thus, the rule will allow the grower to set any ''nominal price'' it chooses, given that the grower will purchase the marihuana back from DEA at the same price at which it is sold to DEA. In this scenario, the only net cost of the transaction is the per-kilogram administrative fee that grower must pay to DEA.

Issue 2: Several commenters suggested the purchase price of cannabis should be the registrant's average purchase price of the last six months or the average U.S. price for high grade commercial cannabis, plus 20 percent due to its research grade. Another commenter suggested a cap on the wholesale value of cannabis.

Response 2: DEA recognizes that supply and demand for the cultivation of marihuana for research and other licit purposes may fluctuate based on the lawful needs of the U.S. market. As such, DEA believes that allowing the buyer and seller to negotiate the purchase price of the marihuana provides more flexibility in determining appropriate prices driven by market forces. Attempting to set a universal price—or schedule of prices—for cannabis, or limiting a registrants' ability to change its prices in response to new circumstances, would unduly restrict the varieties of marihuana grown and may unduly limit growers' ability to produce marihuana to satisfy new research needs. Similarly, setting a price cap may prevent growers from meeting researchers' need for cannabis that is unusually expensive given its strain or the conditions in which it must be grown.

Issue 3: A commenter inquired whether the administrative fees are paid by the purchasing researchers or the selling growers.

Response 3: Under the rule, the administrative fee is considered part of the price of the cannabis DEA sells to the purchasing researcher. That said, the rule requires the ''parties'' to pay the fee to DEA upon entering into a contract for the provision of cannabis, but before the cannabis is actually delivered to the researcher. In other words, DEA is not charging the administrative fee to either party in particular, but to the parties jointly as part of the transaction. The parties are free to apportion the fee among themselves in any way they choose.

Issue 4: Some commenters suggested that the administrative fee be waived for DEA-registered manufacturers who cultivate and research their own marihuana, and do not sell their marihuana. Similarly, some commenters suggested that the administrative fee would discourage research and thus suggested that the administrative fee be waived for researchers in general.

Response 4: As explained in the NPRM, the purpose of the administrative fee is to allow DEA to recover the operational costs of administering the program, as required under 21 U.S.C. 886a(1)(C). Because DEA anticipates the vast majority of marihuana will be sold to researchers, a waiver of the administrative fee in transactions involving researchers would not allow DEA to properly recover its costs of administering the marihuana growers program under 21 U.S.C. 886a(1)(C).

DEA nonetheless continues to encourage lawful cultivation of marihuana for research and other licit purposes through the administration of this program. As discussed in the NPRM and below, DEA does not expect this administrative fee to be a barrier to research. Nothing in this rule prohibits NIH—or any other third-party funder of research grants—from funding marihuana research by covering the cost of marihuana materials used in research, including these administrative fees, via grants to researchers.

DEA also cannot waive the administrative fee for researchers growing marihuana for their own use because that too would prevent DEA from recovering its operational costs. The provisions of this rule—and the CSA and DEA regulations more broadly—apply not only when a grower is selling to a third party, but also when a grower is producing marihuana for its own use. DEA must still register the grower, and purchase and take possession of the marihuana, even if the marihuana is being used for the grower's own research. Thus, DEA does not anticipate its operational costs to be significantly less when it is regulating a grower's cultivation of marihuana for its own research or for another party's use. Accordingly, DEA will charge the same fees in both situations.

Issue 5: One commenter requested that DEA clarify administrative fees.

Response 5: The nature and purpose of the administrative fee, as well as how it is set, are explained both in the rule itself and throughout the NPRM. In sum, an administrative fee for each transaction will be added to the sales price of the marihuana. The administrative fee is a variable fee based on the quantities, in kilogram (not quality, grade, potency, etc.) of bulk marihuana distributed. The parties to the transaction will pay DEA the administrative fee upon entering into a contract for the provision of the marihuana and prior to the delivery of the marihuana. DEA will set the administrative fee rate at least annually at a level adequate to allow DEA to recover the costs of administrating the marihuana growers program under 21 U.S.C. 886a(1)(C).

Issue 6: One commenter suggested that DEA waive the administrative fee

for any crops that are damaged or lost while in DEA's possession.

Response 6: Such a fee waiver is unnecessary and inconsistent with DEA's obligations under the CSA and this rule. As explained elsewhere, DEA generally does not anticipate retaining possession of crops for significant periods of time; in most instances, they should be transferred quickly to the buyer. Accordingly, crops are unlikely to be damaged or lost in DEA's possession. Moreover, as explained above, the administrative fee must be set at a rate that allows DEA to recover the costs of operating the marihuana growers program under 21 U.S.C. 886a(1)(C). Every marihuana transaction under this rule will impose costs on DEA. Thus, if DEA waived fees for some marihuana buyers and sellers, it would have to increase fees on other buyers and sellers to compensate for the amounts lost due to the waiver. DEA has concluded that it is most equitable to base the administrative fee on the weight of marihuana produced, and not other factors.

Out of Scope

Issue: DEA received comments that are outside the scope of this final rule. Some comments raised general concerns regarding the treatment of marihuana under Federal law. Others raised specific issues regarding, among other things, medical illnesses, medical treatments, the scheduled class of marihuana, marihuana-related activities permitted and prohibited in specific States, and the status of previous congressional inquiries.

DEA Response: DEA acknowledges receipt of these comments; however, such comments are outside the scope of the NPRM and the final rule. These comments ultimately have no bearing on the rule under consideration, or on the regulatory decisions DEA is making as part of this rulemaking.

Section-by-Section Summary of the Final Rule

The purposes and functions of this rule were discussed in the NPRM. Aside from a minor amendment to 21 CFR 1318.04, this rule adopts the proposed rule without change. DEA's reasoning was fully explained in the NPRM. However, in addition to describing the amendment—in particular, the added section at § 1318.04(d)—DEA will summarize this rule's various changes to DEA regulations and the reasoning behind these changes for the sake of clarity and convenience.

§ 1301.33: Applying the Marihuana Grower Regulations to All Marihuana Growers

This rule makes two technical changes to 21 CFR 1301.33 to account for the addition of part 1318, which in turn provides regulations specific to the growing of marihuana in accordance with the CSA.

As discussed above, part 1301 of DEA's regulations governs the registration of manufacturers, distributors, and dispensers of controlled substances. It also includes various sections governing how entities are to apply to become registered with DEA. *See, e.g.,* 21 CFR 1301.13–17. These sections include § 1301.33, which contains certain provisions unique to applications to become registered to manufacture schedule I and II substances in bulk. For example, § 1301.33(a) requires that DEA publish a notice of application after receiving a schedule I and II bulk manufacturer application. Previously, § 1301.33(c) provided that the other provisions of § 1301.33 do not apply when the manufacturing at issue is ''as an incident to research or chemical analysis as authorized in § 1301.13(e)(1),'' *i.e.,* when the bulk manufacture is a coincident activity of a DEA-registered researcher or chemical analyst.

This rule amends § 1301.33(c) to modify this exception in the case of marihuana growing. Specifically, under this rule, § 1301.33(c)'s exclusion applies to manufacturing as an incident to research and chemical analysis, except as provided in the newly added § 1301.33(d). And the new § 1301.33(d) provides that an application to manufacture marihuana ''that involves the planting, cultivating, growing, or harvesting of marihuana'' (as opposed to, for example, marihuana manufacturing that merely involves processing marihuana grown by another party into a new marihuana product) shall be subject both to the general requirements of § 1301.33 as well to the newly added requirements of part 1318.

This change serves two purposes. First, by cross-referencing part 1318 in part 1301, this change ensures that marihuana grower applicants reviewing the general registration and application requirements in part 1301 are made aware of the regulations specific to marihuana growers in part 1318. Second, the Single Convention does not distinguish marihuana grown by a researcher or chemical analyst from that grown by other manufacturers; under the Single Convention, a government agency is required to purchase and take possession of that marihuana and then oversee its distribution. Thus, both to ensure that DEA complies with the CSA, including a provision requiring consistency with obligations under international treaties such as the Single Convention, and to ensure that these applications are treated as equitably as possible, DEA is amending its regulations to ensure that all marihuana growers are subject to the requirements of both § 1301.33 and part 1318.

§ 1318.01: The Scope of the New Marihuana Grower Regulations

New 21 CFR part 1318 adds a series of new provisions to ensure that DEA can register additional marihuana growers in a way consistent with its obligations under the CSA, including a provision requiring consistency with the Single Convention. New § 1318.01 clarifies the scope of these new provisions, stating that they govern ''the registration of manufacturers seeking to plant, grow, cultivate, or harvest marihuana.''

Among other things, this serves to make clear that part 1318 only applies to those manufacturers involved in activities related to the cultivation of marihuana, not all forms of marihuana manufacturing. The CSA defines ''manufacturing'' broadly as ''the production, preparation, propagation, compounding, or processing of a drug or other substance,'' including extraction from plant products and certain forms of packaging. 21 U.S.C. 802(15). Thus, under the CSA, entities involved in a variety of marihuana-related activities, not just marihuana growers, are required to register with DEA as marihuana manufacturers.

Section 1318.01 emphasizes that part 1318 does not apply to all marihuana manufactures, but only to those involved in the planting, growing, cultivating, or harvesting of marihuana.[16] Part 1318 limits itself to marihuana growers, rather than all manufacturers, given the unique obligations the Single Convention places on the United States with regard to the growing of marihuana and the unique diversion risks growing presents.

§ 1318.02: Definitions

Part 1318 contains a number of terms that are not used elsewhere in DEA regulations or have a unique meaning when used in the context of part 1318. Thus, to avoid any ambiguity about the meaning of those terms and the regulations in which they are used,

[16] The rule refers to those ''seeking to plant, grow, cultivate, or harvest marihuana'' rather than just to ''grow'' or ''cultivate,'' to ensure that all activities related to growth and cultivation are included.

§ 1318.02 specifically defines those terms for the purposes of part 1318.

Most of the definitions in § 1318.02 are self-explanatory. For example, ''cannabis'' means any plant of the genus Cannabis (unless otherwise excepted, as discussed below), and ''cannabis resin'' (with one exception discussed below) means the separated resin, whether crude or purified, obtained from the cannabis plant. Similarly, the definition of ''Single Convention'' includes a citation to eliminate any possible confusion about the Single Convention at issue, and the definition of ''bona fide purchase agreement'' specifies the broad type of agreements DEA is seeking to encompass by this term.

Several provisions of § 1318.02, however, warrant further discussion. First, as discussed in the NPRM and above, the Single Convention exempts ''medicinal cannabis'' and ''cannabis preparations'' from certain of its requirements. Following suit, part 1318 likewise exempts these substances from certain of its provisions, and, to facilitate this exemption, § 1318.02 defines ''medicinal cannabis'' and ''cannabis preparations.'' Under § 1318.02, ''medicinal cannabis'' means a drug product made from the cannabis plant, or derivatives thereof that can be legally marketed under the FD&C Act. ''Cannabis preparation'' means cannabis that was delivered to DEA and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis or cannabis resin. These definitions track those of the Single Convention, as adapted to account for Federal law.[17]

Finally, § 1301.02(e) clarifies that, when used in part 1318, none of these cannabis-related terms—cannabis, cannabis preparation, cannabis resin, or medicinal cannabis—include substances that fall outside the CSA's definition of marihuana. Among other things, § 1301.02(e) is intended to reflect the CSA amendments made by the Agriculture Improvement Act of 2018 (AIA), Public Law 115–334. The AIA amended the definition of marihuana to exclude ''hemp,'' defined as the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. 7 U.S.C. 1639*o*(1). Thus, under the AIA, anything that meets this definition of hemp is no longer a controlled substance, and the CSA's requirements no longer apply to it. This rule is designed to regulate marihuana growers, not hemp growers; and thus § 1301.02(e) ensures that part 1318 does not apply to the cultivation of substances do not meet the definition of marihuana under the CSA, such as hemp.

§ 1318.03: Implementation of the CSA's Requirements

This section reiterates the requirements of certain other provisions of the CSA and DEA regulations, both to make clear that these requirements apply to marihuana grower applications and as background for other provisions of part 1318. Specifically, § 1318.03(a) reiterates the requirement of 21 U.S.C. 823(a) that the DEA Administrator may only grant an application to cultivate marihuana if he determines that such registration is both consistent with the public interest and with U.S. obligations under the Single Convention. Section 1318.03(b) states that, in accordance with both 21 U.S.C. 823(a) and 21 CFR 1301.44, the applicant has the burden of demonstrating that these requirements are satisfied.

§ 1318.04: Specific Control Measures Applicable to the Cultivation of Marihuana

This section adds a series of control measures designed to ensure that, once DEA registers additional marihuana growers, their marihuana cultivation occurs in accordance with the CSA, including the provision that requires registrations be granted consistent with the Single Convention. In particular, this section adds regulations that will ensure that DEA is able to purchase and take possession of marihuana crops within four months of harvest, and also that DEA has the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marihuana (other than medicinal cannabis or cannabis preparations)—both functions that the Single Convention expressly requires a single agency of the Federal government to perform. This section also contains provisions describing how DEA will perform these functions, provisions that are designed both to guide DEA's performance of these duties (and growers' expectations) as well as to ensure that these functions are performed in a way that protects against diversion of marihuana without placing an undue burden on growers. These provisions—and how they apply to particular scenarios—are discussed in greater depth both above and in the NPRM.

Finally, this section adds a provision that explicitly provides an allowance for registered bulk manufacturers of marihuana to distribute samples to registered analytical laboratories. Because these samples are small, distributed to the laboratory solely for the purpose of analysis, and consumed in the course of the analysis or destroyed upon completion of the testing, DEA has determined that DEA is not required to take possession of these samples to satisfy U.S. obligations under the Single Convention. This allowance permits registered bulk manufacturers to monitor the cannabinoid content of their crop in order to properly time their harvest and demonstrate compliance with contract specifications to their customers.

§ 1318.05: Applying the CSA's Public Interest Factors to Marihuana Grower Applicants

As indicated above, in addition to ensuring registration is consistent with its Single Convention obligations, DEA may grant a registration to manufacture a schedule I or II controlled substance only where the Administrator determines that the registration is consistent with the public interest, based on the factors listed in 21 U.S.C. 823(a).

This section both reiterates these public interest factors and explains how DEA will evaluate whether a particular marihuana grower application is consistent with them. For example, under 21 U.S.C. 823(a)(1), DEA must weigh, as one of the registration factors, the need to maintain effective controls against diversion by limiting the number of registered bulk marihuana growers to that which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. Section 1318.05 states that, for the purpose of assessing this factor, a bona fide supply agreement between a marihuana grower and a duly registered schedule I researcher or manufacturer provides evidence that an applicant's registration is necessary to produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. An applicant proposing to grow marihuana to supply its own research may also be deemed to have satisfied this aspect of public interest factor 823(a)(1) upon the presentation of evidence that it possesses a registration to conduct

[17] Article 1 of the Single Convention defines ''medicinal opium'' and ''opium preparations.'' These definitions apply to cannabis through Article 28, which, with limited exception, subjects the cultivation of cannabis to the system of controls set forth in Article 23 with regard to the cultivation of opium. DEA adapted the Single Convention's definitions to reflect governing Federal law, including the FD&C Act and the CSA.

research with marihuana under 21 CFR 1301.32.

The rule also provides that, when selecting marihuana grower registrants, the DEA Administrator will place particular emphasis on an applicant's ability to consistently produce and supply marihuana of a high quality and defined chemical composition, and whether the applicant has demonstrated prior compliance with the CSA and DEA regulations. These factors are designed to result in registration of those manufacturers of marihuana that can most efficiently supply the lawful needs of the U.S. market in terms of quantity and quality. These factors are further aimed at selecting applicants that can be entrusted with the responsibility of a DEA registration and complying with the corresponding obligations under the CSA and DEA regulations.

Section 1318.05(c) provides that, aside from any applications governed by 21 U.S.C. 823(i), applications DEA accepts for filing after the date this rule becomes effective will not be considered pending until all applications accepted for filing on or before this effective date have been granted or denied by the Administrator. This is because, as explained above, the CSA requires DEA to consider the need to maintain effective controls against diversion by limiting the total number of registered marihuana growers to that necessary to produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. Thus, DEA must consider all pending applicants together when deciding which applications to grant. Given this requirement, DEA is including this provision to avoid a situation in which the agency is in the midst of evaluating these applications and has to begin its evaluation anew each time it accepts a new marihuana grower application for filing.

§ 1318.06: Factors Affecting Marihuana Prices

As discussed in the NPRM and above, to ensure compliance with the CSA, including a provision requiring consistency with the Single Convention (and as specified in § 1301.04 of this rule), DEA will purchase all lawfully grown marihuana crops within four months of harvest and then sell the marihuana to DEA registrants who seek to acquire it for research, product development, or other lawful purposes under the CSA. To do so, DEA will establish purchasing and selling prices: § 1318.06 describes how DEA will do this—and more broadly explains how certain aspects of these transactions will work, as well as how DEA will fund its expenses from carrying out these duties.

As explained elsewhere in the NPRM and this rule, in purchasing such marihuana, DEA will use the Diversion Control Fee Account established in 21 U.S.C. 886a. Thus, DEA must take into account its obligation under 21 U.S.C. 886a(1)(C) to charge fees under its diversion control program ''at a level that ensures the recovery of the full costs of operating the various aspects of that program.'' There are two potential categories of fees that could be used to recover the costs of carrying out the new aspects of the diversion control program relating to marihuana: (1) Fees charged to persons who apply for, and seek to renew, a DEA registration to manufacture marihuana, and (2) fees charged for the sale of marihuana by DEA. Under this rule, DEA intends to recover its basic operating costs primarily through the latter means, by recovering these costs through an administrative fee set based on these costs. Section 1318.06 describes how this will occur.

Under § 1318.06, DEA will allow market forces to direct prices for marihuana grown by the manufacturer and purchased by DEA, allowing the marihuana grower and ultimate purchaser to negotiate a sales price. Where the grower and the buyer are the same entity (or related entities), § 1318.06 allows the entity to set a nominal price.

In addition to that negotiated price, § 1318.06 provides that DEA will add an administrative fee (per kilogram (kg)) to the sales price of the marihuana it sells to end users. As provided in § 1318.06(a), DEA will calculate this administrative fee no less than annually by taking the preceding fiscal year's cost to operate the program and dividing it by the quantity in kg of the total of the IMQs for marihuana issued during the current quota year. Section 1318.06(c) requires DEA to make the updated administrative fee available on DEA's website.

As discussed elsewhere, DEA does not intend for this rule to interfere with HHS's funding of marihuana for use in research. Thus, to avoid any possibility of confusion, § 1318.06(d) notes that this section does not prohibit HHS from funding the purchase cost or associated administrative fees for marihuana purchased for research.

§ 1318.07: DEA's Disclaimer of Liability

As explained above, DEA generally does not anticipate retaining possession of marihuana crops for significant periods of time: In most instances, they should be transferred quickly from the seller to the buyer, with DEA's possession being as brief as possible to effectuate its role in transferring the marihuana from buyer to seller. Accordingly, crops are highly unlikely to be damaged or lost in DEA's possession. That said, if a buyer concludes that a crop is unacceptable, it is conceivable that a grower could claim that the damage is attributable to DEA, leading to costly and unnecessary disputes. To avoid disputes, § 1318.07 makes clear that DEA has no liability with regard to the performance of any of the terms agreed to by a grower and buyer of marihuana, including but not limited to the quality of the marihuana. In effect, this puts buyers and sellers on notice that it is their obligation to structure their marihuana transactions in such a way as to minimize the risk of damage or disputes over quality, rather than looking to DEA to mediate or bear the costs of such disputes.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. Section 3(f) of Executive Order 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of

recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

OMB's Office of Information and Regulatory Affairs (OIRA) has determined that, although this rule is not economically significant, it is a significant regulatory action under section 3(f) of Executive Order 12866, and it therefore has been reviewed by OMB.

I. Need for the Rule

This rule is needed to ensure that DEA complies with the CSA and grants registrations that are consistent with relevant treaty provisions as DEA seeks to increase the number of registered growers of marihuana. Specifically, this rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. These amendments will ensure that DEA carries out all five functions under Article 23 and Article 28 of the Single Convention pertaining to marihuana, thus facilitating the planning and coordinated management of marihuana production necessary as the number of registered marihuana manufacturers increases.

II. Alternative Approaches

This rule amends DEA regulations only to the extent necessary to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana. In areas where DEA has discretion, such as in setting a fee structure to recover the cost of this rule, alternative approaches normally would be discussed. However, because DEA does not have sufficient information at this time to discuss alternatives for either the future registration fees or the fees for the sale of marihuana, the alternative approaches for such provisions are not included in this rule. Consistent with past agency practice, any changes to registration fees will be the subject of a separate rulemaking proceeding, including a discussion of alternative approaches.

III. Analysis of Benefits and Costs

There are two key benefits associated with this rule. First, DEA believes it is possible that the approval of new growers may increase the variety (quality, potency, etc.) of bulk marihuana for research, leading to more effective research and potentially resulting in the development of FDA-approved drug products. Second, this rule ensures that DEA's regulations comply with the requirements of the CSA by granting registrations that are consistent with the Single Convention relating to marihuana. DEA is unable to quantify these benefits at this time.

DEA analyzed the costs of this rule and estimates an annual cost of $651,318.[18] The details of the analysis are below.

This rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. Upon promulgation of this rule, the following key changes are anticipated: More persons will be authorized to grow marihuana, DEA will purchase and take title to the crops of marihuana, and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes mean that authorized purchasers of bulk marihuana to be used for research, product development, and other purposes permitted by the CSA may only purchase from DEA, except that DEA's exclusive rights do not extend to medicinal cannabis or cannabis preparations. The changes described above affect three primary groups of entities: Growers and prospective growers, the authorizing agencies,[19] and purchasers (generally medical and scientific researchers). To examine the impact of the rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the three affected groups.

Current System

To date, DEA has authorized one grower, the National Center for Natural Products Research (National Center), to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana from seeds supplied initially by NIDA for use in research studies.[20] The National Center has designated a secure plot of land or indoor grow facility where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[21] NIDA obligated approximately $1.5 million in Fiscal Year 2015 under this contract.[22] This amount included costs unrelated to growing and cultivating marihuana, such as extracting chemical components and producing marihuana cigarettes and other marihuana-related material. However, based on recent discussion with NIDA,[23] DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 were approximately $2.9 million.[24] The $2.9 million includes compensation for the cultivating and the 2019 manufacturing quota (MQ) of 2,000 kgs for NIDA (National Center) as well as all other duties required in the contract.[25]

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is currently available at no cost to research investigators supported by a NIH grant. Marihuana is also available to research investigators who are funded through non-Federal sources. Although NIDA considered charging for marihuana on a ''cost-reimbursement basis,'' [26] the current policy is to provide the marihuana at no charge.[27]

Changes to Growers

Upon promulgation of this rule, DEA anticipates approving more than one

[18] This is an increase from the estimated cost of $607,644 in the NPRM. The increase is due to change in estimated personnel requirements as described below.

[19] The ''authorizing agency'' refers to federal government agencies, including NIDA and DEA.

[20] Production, Analysis, and Distribution of Cannabis and Related Materials, Federal Business Opportunities (Apr. 12, 2015), *https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N01DA-15-7793/listing.html.*

[21] NIDA's Role in Providing Marijuana for Research, National Institute on Drug Abuse, *https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research.*

[22] Information on Marijuana Farm Contract, National Institute on Drug Abuse, *https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research/information-marijuana-farm-contract.*

[23] Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

[24] Estimated spending for the marihuana DSP for 2019 was $3.3 million to $3.4 million, of which 10%-15% meet the definition of ''hemp'' under the provisions of the AIA. Using the midpoint of these ranges, the estimated spending is $2.9 million for marihuana, excluding hemp. The figures are based on a general discussion, and actual figures may differ.

[25] The 2019 APQ for all marihuana is 2,450 kgs. 2,000 of the 2,450 kgs are for the NIDA (National Center) cultivating and manufacturing quota of bulk marihuana. *See* 83 FR 67348.

[26] Marijuana Plant Material Available from the NIDA Drug Supply Program, National Institute on Drug Abuse, *https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program/marijuana-plant-material-available-nida-drug-supply-program.*

[27] Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

entity to cultivate and harvest bulk marihuana. As explained earlier in this document, the CSA imposes limitations on the number of registrations that DEA may issue to bulk manufacturers of a given schedule I or II controlled substance. In addition, in deciding whether to grant an application for any such registration, the CSA requires DEA to consider the other public interest factors of 21 U.S.C. 823(a), which must be evaluated on an applicant-by-applicant basis. Further, DEA cannot accurately predict in advance which particular applications will be granted, or how many. Accordingly, DEA is unable to accurately estimate the number of registered bulk marihuana growers. As a result, to allow for this analysis, DEA estimated the economic impact of this rule under two different hypothetical scenarios, the first in which the number of growers expands to three growers, and the second in which the number of growers expands to 15 growers. It should be understood that this range of potential registrants is not necessarily reflective of the actual number of applications that DEA will grant.

In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[28] Since the publication of the 2016 policy statement, DEA has received approximately 38 pending applications for registration as bulk manufacturer of marihuana for research. As indicated above, the CSA requires DEA to limit the total number of registered bulk manufacturers of a given schedule I or II controlled substance to that necessary to produce an adequate and uninterrupted supply under adequately competitive conditions. Therefore, DEA believes a range of three to 15 growers is a reasonable estimate for purposes of this economic analysis, with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[29] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and the reimbursement of production cost through sales) is transferred from the single incumbent grower to new growers. This means that there is only a transfer of economic activity rather than any new cost. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[30]

Transitioning from one large grower to multiple growers may introduce inefficiencies, driving up production or facility costs. Some growers may introduce more costly growing techniques to produce certain traits. Alternatively, some growers may introduce more efficient growing methods, driving down costs. Additionally, having more growers may spur more demand in bulk marihuana for research, pushing up the MQ. In particular, one of the goals of this new rule is to enhance marijuana availability for product development, which may have the effect of increasing the MQ. However, DEA does not have a basis to estimate the impact of these possibilities. Therefore, for the purposes of this analysis, DEA estimates that an increase in the number of approved growers does not impact the MQ. In summary, there is no new cost to growers.

Changes to Authorizing Agencies—Cost to DEA

DEA anticipates that there will be a transfer of economic activity from NIDA to DEA as well as several new costs as a result of this rule. This analysis should not be construed as a proposal to modify agency funding or funding sources.

As discussed above, assuming a constant MQ for bulk marihuana of 2,000 kgs, DEA estimates the cost of all the activities the National Center performs under its contract with NIDA and the purchase of the entire aggregate crop, regardless of the number of growers, is $2.9 million. This $2.9 million is not a new cost; it is a transfer. Rather than NIDA paying the current single grower, DEA will pay the multiple new growers. In practice, DEA anticipates crops from multiple growers will be purchased at different times of the year, allowing funds from sales of earlier purchases to pay for subsequent purchases. Therefore, to purchase and distribute $2.9 million in bulk marihuana, a working capital of a lesser amount is likely needed. However, due to many unknowns and to be conservative, for the purposes of this analysis, the estimated transfer and working capital requirement is assumed to be $2.9 million.

DEA anticipates incurring new costs associated with the following activities: Taking title to the crops and employing personnel to administer the program. The growers, purchasers, and DEA will already understand, prior to growing and harvesting, the quantities of marihuana to be distributed and to whom the distribution will be made, because the bona fide supply agreements presented during the registration application process will provide such information. In most instances, DEA is expected to purchase and take title to the crop, then sell and distribute the crop to the purchaser on the same day at the grower's registered location. For the purposes of this analysis, DEA assumes the following process:

1. After marihuana is harvested and prepared for delivery to DEA, the registered manufacturer will contact DEA to inform it that the marihuana is ready for collection.

2. Within a reasonable timeframe, but in no event later than four months after the harvest, DEA will purchase and take title to the marihuana. Two DEA Special Agents from the nearest local DEA field office will drive an estimated 100 miles (200 miles roundtrip) to the registered manufacturer to take title. Any marihuana that is not immediately distributed is stored in a designated secure storage mechanism at the grower's registered location for later distribution. The number of trips by the two DEA Special Agents equals the number of harvests.

3. For marihuana distributed from storage at the grower's registered location, the grower distributes marihuana on DEA's behalf. If DEA deems it necessary to be present at such distribution, the distribution is scheduled to coincide with DEA's visit to take title to the next crop, requiring no additional trips by DEA to the grower.

4. Each grower has three harvests, requiring DEA to collect three times per year per grower.

For each collection, DEA estimates $2,071 of labor cost [31] and $116 of vehicle cost [32] for a total of $2,187 per

[28] Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). This rule supersedes the 2016 policy statement.

[29] 21 CFR 1303.11(a).

[30] The phrase ''multiple growers'' includes the possibility that the current grower is one of ''multiple growers.''

[31] DEA's loaded hourly rate of a Special Agent is $103.54. Assuming 10 hours each (full work-day) for two agents, the total labor cost associated with collection from a registered manufacturer is $2,071. ''Loaded hourly rate'' includes wages, benefits, and ''loading'' of ''non-productive'' hours, *i.e.,* leave, training, travel, etc.

[32] $116 is based on Internal Revenue Service standard mileage rates for 2019 of $0.58 per mile

Continued

collection. DEA understands that some growers, employing certain growing methods, may have more harvests per year. However, DEA does not have a basis to estimate these growers' methods or the number of harvests per year. Therefore, DEA believes three harvests per year is a reasonable estimate. Assuming three collections per year per grower, there would be nine collections with three approved growers and 45 collections with 15 approved growers. Applying the estimated cost of $2,187 per collection, DEA estimates a transport cost of $19,683 and $98,415 for scenarios with three and 15 growers, respectively.

Additionally, DEA anticipates it will need additional personnel resources to operate this program. There are many unknowns and no decisions have been made on hiring. However, for the purposes of this analysis, DEA estimates three full-time-equivalent (FTE) professional staff in the Diversion Control Division will be needed, consisting of two FTE diversion investigator (DI), and one FTE professional/administrative (PA) resources.

Applying the fully loaded annual cost of $211,981 per DI and $168,307 per PA, the estimated total cost of the three FTE employees is $592,269. For the purposes of this analysis, this cost does not vary with the number of growers. Table 1 below summarizes the costs associated with increased staffing.

TABLE 1—COST OF PERSONNEL RESOURCES

Position	Job category	Modular cost/unit cost ($)	Number of FTEs	Cost ($)
Staff Coordinator	DI	211,981	2	423,962
Program Analyst	PA	168,307	1	168,307
Total	N/A	N/A	3	592,269

In summary the estimated cost to DEA is:

- $19,683 or $98,415 per year to purchase and take title to the bulk marihuana for scenarios with 3 or 15 authorized growers, respectively;
- $592,269 per year for three DEA FTE employees;
- The estimated total annual cost is $611,952 with three growers and $690,684 with 15 growers and no offsetting cost savings at NIDA. Using the average of the two values, the estimated cost to DEA is $651,318. Table 2 summarizes the costs.

TABLE 2—DEA COST SUMMARY

	Low ($)	High ($)	Average ($)
Transport Cost	19,683	98,415	N/A
Personnel Cost	592,269	592,269	N/A
Total Cost	611,952	690,684	651,318

Changes Affecting Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that some researchers will acquire the bulk marihuana from DEA, rather than from NIDA. As discussed earlier, the only new cost associated with this regulation is the cost to DEA of $651,318, an average of high and low scenarios, which will be recovered by adding an administrative fee of $326 per kg. The administrative fee was updated from $304 per kg in the NPRM to $326 per kg in this final rule because there is a change in the personnel required to administer the program.[33] As discussed earlier, the administrative fee will be adjusted annually.

While the purchaser will purchase marihuana from DEA, this rule does not in any way affect the purchaser's source of funds to purchase from DEA. If marihuana for research is funded by a third party, the researcher may not experience any cost increase. In particular, NIH has long served as a third-party funder for research through grants, including grants to researchers studying marihuana. Nothing in this rule prohibits NIH from continuing to fund such research by continuing to cover the cost of marihuana materials used in research, via grants to researchers.

Cost Summary

DEA estimates the cost of producing the 2019 MQ for bulk marihuana of 2,000 kgs and operating NIDA's marihuana DSP is $2.9 million per year. Under the rule, DEA anticipates more bulk marihuana producers will be approved. DEA estimates the $2.9 million in economic activity will be transferred across multiple growers, without introducing new costs.

DEA's purchase of bulk marihuana is not a new cost (to the economy); it is a transfer from NIDA to DEA. However, $611,952 to $690,684 in operating costs will be incurred by DEA. DEA will recover the costs of carrying out the new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated

multiplied by the estimated 200 miles driven, roundtrip.

[33] In the NPRM, DEA estimated personnel requirements to administer the program was one DEA Diversion Investigator and two Professional/Administrative personnel. After further review, DEA has estimated in this final rule that two DEA Diversion Investigators and one Professional/Administrative personnel are needed to administer the program. The two Diversion Investigators are needed to provide adequate oversight of reporting and recordkeeping requirements associated with distribution.

sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis.

The net present values (NPV) of the low cost estimate of $611,952 per year over 10 years are $5.2 million and $4.3 million at a three percent discount rate and seven percent discount rate, respectively. The NPVs of the high cost estimate of $690,684 over 10 years are $5.9 million and $4.9 million at a three percent discount rate and seven percent discount rate, respectively. The average of the estimated low and high costs is $651,318. The NPVs of the average of $651,318 over 10 years are $5.6 million and $4.6 million at three percent and seven percent discount rates, respectively. Table 3 summarizes the estimated annual effect and NPVs calculation for each of the transfers and the three scenarios.

TABLE 3—SUMMARY OF ANNUAL EFFECT AND NPVS

	Annual effect ($)	NPVs at 3% ($M)	NPVs at 7% ($M)
Cost (Low)	611,952	5.2	4.3
Cost (Average)	651,318	5.6	4.6
Cost (High)	690,684	5.9	4.9

Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rule is a deregulatory action for the purposes of Executive Order 13771. The rule is an enabling rule which, coincidentally with other provisions, expands the number of authorized bulk marihuana growers.

Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens on regulated parties and the court system.

Executive Order 13132 (Federalism)

This rule does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless the agency can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities and a discussion of its findings is below.

As discussed in the section of this rulemaking relating to Executive Orders 12866, 13565, and 13771, this rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, and adds provisions related to the purchase and sale of this marihuana by DEA. Upon promulgation of this rule, the following key changes are anticipated: More persons will be authorized to grow marihuana; DEA will purchase and take physical possession of crops; and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes, as explained above, mean that authorized purchasers of bulk marihuana may only purchase from DEA, except that DEA's exclusive right will not extend to medicinal cannabis or cannabis preparations as these terms are defined in paragraphs (b) and (c), respectively, of § 1318.02 of this rule.

The changes described above affect three primary groups of entities: Growers and prospective growers, the authorizing agencies (including NIDA and DEA), and purchasers (generally researchers). Because any economic impact on Federal agencies is outside the scope of the RFA, the transfer of economic activity between the agencies is excluded from this discussion. To examine the impact of the rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the two affected non-Federal groups: Growers (bulk manufacturers of marihuana) and researchers.

Current System

To date, DEA has authorized one grower, the National Center, to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana for use in research studies.[34] The National Center designates a secure plot of land where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[35] As explained previously, DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 were approximately $2.9 million.[36] The $2.9 million includes compensation for the cultivating and the 2019 MQ of 2,000 kgs for NIDA as well as all other duties required in the contract.[37]

[34] Production, Analysis, and Distribution of Cannabis and Related Materials, Federal Business Opportunities (Apr. 12, 2015), *https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N01DA-15-7793/listing.html*.

[35] NIDA's Role in Providing Marijuana for Research, National Institute on Drug Abuse, *https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research*.

[36] Estimated spending for the marihuana DSP for 2019 was $3.3 million to $3.4 million, of which 10 percent to 15 percent meet the definition of ''hemp'' under the provisions of the AIA. Using the midpoint of these ranges, the estimated spending is $2.9 million. The figures are based on a general discussion, and actual figures may differ.

[37] The 2019 APQ for all manufacturers of marihuana is 2,450 kgs. 2,000 kgs are for cultivating and manufacturing of bulk marihuana. *See* 83 FR 67348.

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is available at no cost to research investigators who are supported by an NIH grant. Marihuana is also available to research investigators who are funded through non-Federal sources. Although NIDA considered charging for marihuana on a ''cost-reimbursement basis,'' [38] the current policy is to provide the marihuana at no charge.[39]

Impact on Growers

Upon promulgation of this rule, DEA anticipates approving more than one person to cultivate and harvest bulk marihuana. In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[40] Since the publication of the 2016 policy statement, there are approximately 38 pending applications for registration as bulk manufacturer of marihuana for research. Additionally, some applicants may not meet the statutory and regulatory criteria for holding a registration as a bulk manufacture and will be denied. Therefore, for the purposes of this analysis, DEA will estimate the economic impact of this rule at three and 15 growers with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[41] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and reimbursement of their production cost through sales) is transferred from the incumbent grower to new growers. This means that there is no new cost; instead, there is only a transfer of economic activity. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[42]

Transitioning from one large grower to multiple smaller growers may reduce production efficiency, driving up cost. Some growers may introduce more costly growing techniques in order to produce certain traits. Alternatively, some growers may introduce more efficient growing methods, driving down cost. Additionally, having more growers may spur more demand in bulk marihuana for research, pushing up the MQ. However, DEA does not have a basis to estimate the impact of these possibilities.

Impact on Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that the researcher will acquire the bulk marihuana from DEA, rather than from NIDA or the National Center. As discussed earlier, the only new cost associated with this regulation is the cost to DEA of $651,318, which will be recovered by adding an administrative fee of $326 per kg. As discussed earlier, the administrative fee will be adjusted annually. While purchasers will purchase marihuana from DEA, this rule does not in any way affect the purchasers' source of funds to purchase from DEA. If marihuana for research is funded by a third party, the researcher may not experience any cost increase.

Affected Number of Small Entities

This rule affects the current and prospective bulk manufacturers of marihuana for research and researchers. Based on the discussion above, DEA anticipates up to 15 bulk manufacturers are affected by this rule. Additionally, based on a discussion with NIDA,[43] DEA estimates 40 researchers are affected by this rule. The 40 researchers represent the approximate number of researchers that receive marihuana from NIDA's marihuana DSP.

Based on a review of representative North American Industry Classification System (NAICS) codes for bulk manufacturers and researchers, the following number of firms may be affected: [44]

- 421 firms related to 'Medicinal and Botanical Manufacturing' (325411) [45]
- 9,634 firms related to 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712) [46]

The United States Small Business Administration (SBA) sets size standards that determine how large an entity can be and still qualify as a small business for Federal government programs. For the most part, size standards are based on the average annual receipts or the average number of employees of a firm. The SBA size standard for both industries identified by the NAICS codes above is 1,000 employees.[47]

Comparing the SBA size standards to the U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) detailed data on establishment size by NAICS code for each affected industry, DEA estimates the following number of small entities and percent of firms that are small entities by industry:

- 392 (93.1 percent of total) firms in the area of 'Medicinal and Botanical Manufacturing' (325411)
- 9,090 (94.4 percent of total) firms in the area of 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712)

Table 4 details the calculation for the number of small entities by industry.

[38] Marijuana Plant Material Available from the NIDA Drug Supply Program, National Institute on Drug Abuse, *https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program/marijuana-plant-material-available-nida-drug-supply-program.*

[39] *See* note 23.

[40] Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (2016). This rule supersedes the 2016 policy statement.

[41] 21 U.S.C. 826(a).

[42] The phrase ''multiple growers'' includes the possibility that the current grower is one of the ''multiple growers.''

[43] Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

[44] For the purposes of this analysis, the term ''firms'' is synonymous with ''entities.''

[45] 2015 SUSB Annual Datasets by Establishment Industry, U.S. & States, NAICS, Detailed Employment Sizes (U.S., 6-digit and States, NAICS Sectors), United States Census Bureau, *https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html.*

[46] *Ibid.*

[47] Table of Small Business Size Standards Matched to North American Industry Classification System Codes, United States Small Business Association (Oct. 1, 2017). The NAICS code was updated for 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' from 541712 to 541715. The 2015 SUSB data uses 541712 and the 2017 SBA size standard uses 541715 for the same industry.

TABLE 4—NUMBER OF SMALL ENTITIES BY INDUSTRY

NAICS description	Firm size by average employees	Firms	SBA size standard	Small entities	% small entities
325411—Medicinal and Botanical Manufacturing	<500	384	1,000	384	100
	500–749	3		3	100
	750–999	5		5	100
	1,000–1,499	6			0
	1,500–1,999	2			0
	2,000–2,499	1			0
	2,500–4,999	7			0
	5,000+	13			0
	Total	421		392	93.1
541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology).	<500	8,972	1,000	8,972	100
	500–749	68		68	100
	750–999	50		50	100
	1,000–1,499	70			0
	1,500–1,999	40			0
	2,000–2,499	35			0
	2,500–4,999	132			0
	5,000+	267			0
	Total	9,634		9,090	94.4

Applying the calculated respective percentage for small entities to the number of affected bulk manufacturers and researchers, DEA estimates 14 (15 × 93.1 percent) bulk manufacturers and 38 (40 × 94.4 percent) researchers, for a total of 52 small entities, will be affected by this rule. The 14 affected small entity bulk manufacturers represent four percent of the estimated 392 small entities in the 'Medicinal and Botanical Manufacturing' (325412) industry, and the 38 affected small entity researchers represent 0.4 percent of the estimated 9,090 small entities in the 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712) industry. Table 5 summarizes the calculations for the percentage of small entities that are affected by the rule.

TABLE 5—PERCENT OF SMALL ENTITIES AFFECTED BY INDUSTRY

NAICS description	Number of firms	SBA size standard	Estimated number of small entities	Estimated number of affected small entities	Percentage of small entities affected
325411—Medicinal and Botanical Manufacturing	421	1,000	392	14	4
541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)	9,634	1,000	9,090	38	0.4
Total	10,055	N/A	9,482	52	N/A

DEA generally uses a threshold of 30 percent as a ''substantial'' number of affected small entities. Thus, the above analysis reveals that a non-substantial amount of small bulk manufacturer entities (4 percent) and of small researcher entities (0.4 percent) will be affected by this rule.

DEA generally considers impacts that are greater than three percent of annual revenue to be a ''significant economic impact'' on an entity. As discussed earlier, DEA estimates that there will be a new cost to DEA of $611,952 to $690,684 per year, or the average of the high and low estimates of $651,318 per year. DEA will recover the costs of carrying out the new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis. Based on the average of the high and low estimates of $651,318 and MQ of 2,000 kgs, the administrative fee is $326 per kg, adjusted annually.

Furthermore, NIH-funded or other third-party funded researchers are likely to request and receive enough funding for the full price of marihuana, including the administrative fee. There will be no impact to these researchers. However, DEA does not have sufficient information to estimate the number of small entity researchers that will fall under this category. Although DEA is unable to quantify the economic impact for the estimated 14 small entity bulk manufacturers and 38 small entity researchers, the number of affected small entity manufacturers and researchers is not a substantial number of small entities in their respective industries.

Based on the analysis above, and because of these facts, DEA believes this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* DEA has determined that this action will not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' *See* 2 U.S.C. 1532(a). Therefore, neither

a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3521, DEA is revising existing information collection 1117–0012. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *https://www.reginfo.gov/.*

A. Collections of Information Associated With the Rule

Title: Application for Registration (DEA Form 225); Renewal Application for Registration (DEA Form 225A); Affidavit for Chain Renewal (DEA Form 225B).

OMB control number: 1117–0012.

Form numbers: DEA–225, DEA–225A, DEA–225B.

Type of information collection: Revision of a currently approved collection.

Applicable component of the department sponsoring the collection: Department of Justice/Drug Enforcement Administration, Diversion Control Division.

Affected public who will be asked or required to respond: Business or other for-profit.

Abstract: The Controlled Substances Act requires all businesses and individuals who manufacture, distribute, import, export, or conduct research and laboratory analysis with controlled substances to register with DEA. 21 U.S.C. 822; 21 CFR 1301.11, 1301.13. Registration is a necessary control measure that helps to detect and prevent diversion by ensuring that the closed system of distribution of controlled substances can be monitored by DEA, and that the businesses and individuals handling controlled substances are accountable.

This rule amends the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. Persons seeking to become registered with DEA to grow marihuana as bulk manufacturers will still apply for registration using the same DEA Form 225 as other bulk manufacturers, but there will be a new supplemental questionnaire unique to marihuana manufacturers in order to gather additional information about applicants. There will also be new questionnaires used for importer applicants and non-marihuana bulk manufacturer applicants. Forms 225, 225A, and 225B will all receive minor revisions to improve clarity and usability for registrants.

DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 15,919.
- *Frequency of response:* 1 per respondent per year.
- *Number of responses:* 15,919.
- *Burden per response:* 0.1304 hours.
- *Total annual burden in hours:* 2,076.

If you need a copy of the proposed information collection instruments with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152–2639; Telephone: (571) 362–3261.

At this point, any comments related to this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB54/Docket No. DEA–506.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. DEA submitted a copy of the final rule to both Houses of Congress and to the Comptroller General.

National Environmental Policy Act

DEA has analyzed the impacts of this Final Rule on the human environment pursuant to the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* and has determined that it is categorically excluded under 28 CFR part 61, Appendix B. Categorical exclusions are actions identified in an agency's NEPA implementing procedures that normally do not have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant preparation of an EA or EIS. This action is covered by the categorical exclusion for registration of persons authorized to handle controlled substances listed in 28 CFR part 61, Appendix B.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1318

Administrative practice and procedure, Drug traffic control.

For the reasons stated in the preamble, DEA amends 21 CFR chapter II as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

■ 2. In § 1301.33, revise paragraph (c) and add paragraph (d) to read as follows:

§ 1301.33 Application for bulk manufacture of Schedule I and II substances.

* * * * *

(c) Except as provided in paragraph (d) of this section, this section shall not apply to the manufacture of basic classes of controlled substances listed in Schedule I or II as an incident to research or chemical analysis as authorized in § 1301.13(e)(1).

(d) An application for registration to manufacture marihuana that involves the planting, cultivating, growing, or harvesting of marihuana shall be subject to the requirements of this section and the additional requirements set forth in part 1318 of this chapter.

■ 3. Add part 1318 to read as follows:

PART 1318—CONTROLS TO SATISFY THE REQUIREMENTS OF THE ACT APPLICABLE TO THE MANUFACTURING OF MARIHUANA

Sec.

Authority: 21 U.S.C. 801(7), 821, 822(a)(1), (b), 823(a), 871(b), 886a.

§ 1318.01 Scope of this part.

Procedures governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest marihuana are set forth by this part.

§ 1318.02 Definitions.

(a) Except as provided in paragraph (e) of this section, the term *cannabis* means any plant of the genus Cannabis.

(b) Except as provided in paragraph (e) of this section, the term *medicinal cannabis* means a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act.

(c) Except as provided in paragraph (e) of this section, the term *cannabis preparation* means cannabis that was delivered to the Administration and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis, cannabis resin, or extracts of cannabis.

(d) Except as provided in paragraph (e) of this section, the term *cannabis resin* means the separated resin, whether crude or purified, obtained from the cannabis plant.

(e) As used in this part, the terms *cannabis, medicinal cannabis,* and *cannabis preparation* do not include any material, compound, mixture, or preparation that falls outside the definition of marihuana in section 102(16) of the Controlled Substances Act (the Act) (21 U.S.C. 802(16)).

(f) The term *Single Convention* means the Single Convention on Narcotic Drugs, 1961 (18 U.S.T. 1407).

(g) The term *bona fide supply agreement* means a letter of intent, purchase order or contract between an applicant and a researcher or manufacturer registered under the Act.

(h) The term *registered researcher or manufacturer* means a person registered under the Act to perform research or manufacture of marihuana in Schedule I.

§ 1318.03 Implementation of statutory requirements.

(a) As provided in section 303(a) of the Act (21 U.S.C. 823(a)), the Administrator may grant an application for a registration to manufacture marihuana, including the cultivation of cannabis, only if he determines that such registration is consistent with the public interest and with United States obligations under the Single Convention.

(b) In accordance with section 303(a) of the Act and § 1301.44(a) of this chapter, the burden shall be on the applicant to demonstrate that the requirements for such registration have been satisfied.

§ 1318.04 Specific control measures applicable to the bulk manufacture of marihuana.

For a registration to manufacture marihuana that involves the cultivation of cannabis, the following provisions must be satisfied:

(a) All registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis to the Administration, except as provided in paragraph (d). The Administration shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest. The Administration may accept delivery and maintain possession of such crops at the registered location of the registered manufacturer authorized to cultivate cannabis consistent with the maintenance of effective controls against diversion. In such cases, the Administration shall designate a secure storage mechanism at the registered location in which the Administration may maintain possession of the cannabis, and the Administration will control access to the stored cannabis. If the Administration determines that no suitable location exists at the registered location of the registered manufacturer authorized to cultivate cannabis, then the Administration shall designate a location for the authorized grower to deliver the crop as soon as possible, but not later than four months after the end of the harvest. However, in all cases the registrant must comply with the security requirements specified in part 1301 of this chapter.

(b) The Administration shall, with respect to cannabis, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. Such exclusive right shall not extend to medicinal cannabis or cannabis preparations. The Administration may exercise its exclusive right by authorizing the performance of such activities by appropriately registered persons. The Administration shall require prior written notice of each proposed importation, exportation, or distribution of cannabis that specifies the quantity of cannabis to be imported, exported, or distributed and the name, address, and registration number of the registered manufacturer or researcher to receive the cannabis before authorizing the importation, exportation, or distribution. All importation and exportation shall be performed in compliance with part 1312 of this chapter, as applicable. Under no circumstance shall a registered manufacturer authorized to grow cannabis import, export, or distribute cannabis without the express written authorization of the Administration.

(c) A registered manufacturer authorized to grow cannabis shall notify in writing the Administration of its proposed date of harvest at least 15 days before the commencement of the harvest.

(d) A registered manufacturer authorized to grow cannabis may distribute small quantities of cannabis to a registered analytical lab for chemical analysis by such analytical lab prior to the Administration purchasing and taking physical possession of the crop. The cannabis delivered to the analytical lab under such circumstances need not be delivered to the Administration pursuant to paragraph (a), provided such cannabis is destroyed by the analytical lab upon completion of the testing. Any such distribution of cannabis by a registered manufacturer to a registered analytical lab must comply with all applicable requirements of the Act and this subchapter, including but not limited to security and recordkeeping requirements.

§ 1318.05 Application of the public interest factors.

(a) In accordance with section 303(a) of the Act (21 U.S.C. 823(a)), the Administrator shall consider the public interest factors set forth in paragraphs (a)(1) through (6) of this section:

(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.

(b) The Administrator's determination of which applicants to select will be consistent with the public interest factors set forth in section 303(a), with particular emphasis on the following criteria:

(1) Whether the applicant has demonstrated prior compliance with the Act and this chapter;

(2) The applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition; and

(3)(i) In determining under section 303(a)(1) of the Act (21 U.S.C. 823(a)(1)) the number of qualified applicants necessary to produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions, the Administrator shall place particular emphasis on the extent to which any applicant is able to supply cannabis or its derivatives in quantities and varieties that will satisfy the anticipated demand of researchers and other registrants in the United States who wish to obtain cannabis to conduct activities permissible under the Act, as demonstrated through a bona fide supply agreement with a registered researcher or manufacturer as defined in this subpart.

(ii) If an applicant seeks registration to grow cannabis for its own research or product development, the applicant must possess registration as a schedule I researcher with respect to marihuana under § 1301.32 of this chapter. As specified in § 1301.13 of this chapter, chemical analysis and preclinical research (including quality control analysis) are not coincident activities of a manufacturing registration for schedule I substances, including cannabis. In determining under section 303(a)(1) of the Act (21 U.S.C. 823(a)(1)) the number of qualified applicants necessary to produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions, the Administrator shall consider the holding of an approved marihuana research protocol by a registered schedule I researcher seeking to grow cannabis for its own research or product development as evidence of the necessity of the applicant's registration under this factor.

(c) Applications accepted for filing after January 19, 2021 will not be considered pending for purposes of paragraph (a) of this section until all applications accepted for filing on or before January 19, 2021 have been granted or denied by the Administrator. Where an application is subject to section 303(i) of the Act (21 U.S.C. 823(i)), that section shall apply in lieu of this paragraph (c).

(d) In determining the legitimate demand for cannabis and its derivatives in the United States, the Administrator shall consult with the U.S. Department of Health and Human Services, including its components.

§ 1318.06 Factors affecting prices for the purchase and sale by the Administration of cannabis.

(a) In accordance with section 111(b)(3) of Public Law 102–395 (21 U.S.C. 886a(1)(C)), seeking to recover the full costs of operating the aspects of the diversion control program that are related to issuing registrations that comply with the Controlled Substances Act, the Administration shall assess an administrative fee. To set the administrative fee, the Administration shall annually determine the preceding fiscal year's cost of operating the program to cultivate cannabis and shall divide the prior fiscal year's cost by the number of kgs of cannabis authorized to be manufactured in the current year's quota to arrive at the administrative fee per kg. The administrative fee per kg shall be added to the sale price of cannabis purchased from the Administration. The administrative fee shall be paid to the Diversion Control Fee Account.

(b) As set forth in § 1318.04, the Administration shall have the exclusive right of, among other things, wholesale trading in cannabis that it purchases from registered manufacturers. The Administration will, therefore, buy from such manufacturer, sell cannabis to registered researchers and manufacturers, and establish prices for such purchase and sale. The Administration will set such prices in the following manner:

(1) Bulk growers of cannabis shall negotiate directly with registered researchers and manufacturers authorized to handle cannabis to determine a sale price for their cannabis. Upon entering into a contract for the provision of bulk cannabis and prior to the exchange of cannabis, the parties shall pay to the Administration an administrative fee assessed based on the number of kgs to be supplied. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

(2) The Administration shall sell the cannabis to the buyer at the negotiated sale price plus the administrative fee assessed on a per kg basis. Prior to the purchase of the cannabis by the Administration, the buyer shall pay the negotiated purchase price and administrative fee to the Administration. The Administration shall hold funds equal to the purchase price in escrow until the delivery of the cannabis by the grower to the Administration. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

(3) After receiving the purchase price and administrative fee from the buyer, the Administration shall purchase the cannabis from the grower, on behalf of the buyer, at the negotiated sale price. The Administration shall retain the administrative fee. In the event the buyer fails to pay the purchase price and the administrative fee, the Administration shall have no obligation to purchase the crop and may order the grower to destroy the crop if the grower cannot find an alternative buyer within four months of harvest.

(4) In instances where the grower of the cannabis is the same entity as the buyer of the cannabis, or a related or subsidiary entity, the entity may establish a nominal price for the purchase of the cannabis. The Administration shall then purchase the entity's cannabis at that price and sell the cannabis back to the entity, or a related or subsidiary entity, at the same price with the addition of the administrative fee.

(c) Administrative fees set in accordance with this part will be made available, on an updated basis, on the Administration's website, no later than December 15th of the year preceding the year in which the administrative fee will be collected.

(d) Nothing in this section shall prohibit the U.S. Department of Health and Human Services from continuing to fund the acquisition of cannabis for use in research by paying, directly or indirectly, the purchase cost and administrative fee to the Administration.

§ 1318.07 Non-liability of Drug Enforcement Administration.

The Administration shall have no liability with respect to the performance of any contractual terms agreed to by a grower and buyer of bulk cannabis, including but not limited to the quality of any cannabis delivered to a buyer. In

the event that a buyer deems the delivered cannabis to be defective, the buyer's sole remedy for damages shall be against the grower and not the Administration.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–27999 Filed 12–17–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9925]

RIN 1545–BP23

Meals and Entertainment Expenses Under Section 274; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations; correction.

SUMMARY: This document contains corrections to the final regulations (Treasury Decision 9925) that published in the **Federal Register** on October 9, 2020. The final regulations provide guidance under section 274 of the Internal Revenue Code (Code) regarding certain recent amendments made to that section. Specifically, the final regulations address the elimination of the deduction under section 274 for expenditures related to entertainment, amusement, or recreation activities, and provide guidance to determine whether an activity is of a type generally considered to be entertainment.

DATES: These corrections are effective on December 18, 2020 and applicable for taxable years that begin on or after October 9, 2020.

FOR FURTHER INFORMATION CONTACT: Patrick Clinton of the Office of the Associate Chief Counsel (Income Tax and Accounting), (202) 317–7005 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9925) that are the subject of this correction are issued under section 274 of the Internal Revenue Code.

Need for Correction

As published the final regulations (TD 9925) contain errors that need to be corrected.

Correction of Publication

Accordingly, the final regulations (TD 9925), that are the subject of FR Doc. 2020–21990, published on October 9, 2020 (85 FR 64026), are corrected as follows:

1. On page 64031, third column, the second line, the language ''*in Sutherland Lumber*'' is corrected to read ''in *Sutherland Lumber-Southwest*''.

2. On page 64031, third column, the ninth line of the second full paragraph, the language ''§ 1.274–10(a)(2)(ii)(C)(2)'' is corrected to read ''§ 1.274–10(a)(2)(ii)(C)(*2*)''.

3. On page 64032, second column, the second line, the language ''or gross income is zero, whether zero is'' is corrected to read ''or gross income is zero (other than due to a reimbursement by the recipient), whether zero is''.

4. On page 64032, second column, the thirteenth line from the top of the page, the language ''(e)(9) do not apply.'' is corrected to read ''(e)(9) generally do not apply.''.

5. On page 64032, second column, the thirteenth line from the top of the page, the language ''Similarly, the exceptions in section 274(e)(2) and (e)(9) do not apply if'' is corrected to read ''However, the exceptions in section 274(e)(2) and (e)(9) will apply if the recipient reimburses the taxpayer for a portion of the value of the food or beverages even if the value exceeding the reimbursed amount is properly excluded from the recipient's compensation and wages or gross income. In this case, however, the taxpayer must apply the dollar-for-dollar rule as described in § 1.274–12(c)(2)(i)(D). In cases in which''.

6. On page 64032, second column, the second and last sentence from the bottom of the first partial paragraph, remove the language ''. In that case, however,''.

7. On page 64032, third column, the third line of the second full paragraph, the language ''regulations confirm'' is corrected to read ''regulations confirmed''.

8. On page 64032, third column, the twelfth line of the second full paragraph, the language ''demonstrates'' is corrected to read ''demonstrated''.

Crystal Pemberton,

Senior Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2020–26860 Filed 12–17–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2020–0694]

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Madeira Beach FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Welch Causeway (SR 699) Bridge, mile 122.8 at Madeira Beach, Florida. A request was made to place the drawbridge on a daily operating schedule to alleviate vehicle congestion due to on demand bridge openings. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. The Coast Guard is seeking comments from the public regarding these proposed changes.

DATES: This deviation is effective from 12:01 a.m. on January 1, 2021 through 11:59 p.m. on June 25, 2021.

Comments and relate material must reach the Coast Guard on or before February 25, 2021.

ADDRESSES: You may submit comments identified by docket umber USCG–2020–0694 using Federal eRulemaking Portal at *https://www.regulations.gov.*

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this test deviation, call or email LT Clark W. Sanford, U.S. Coast Guard, Sector Saint Petersburg Waterways Management Division; telephone 727–824–7506, email *Clark.W.Sanford@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Background, Purpose and Legal Basis

The Welch Causeway (SR699) Bridge across the Gulf Intracoastal Waterway, mile 122.8, at Madeira Beach, Florida is a double-leaf bascule bridge with a 25 foot vertical clearance at mean high water in the closed position and an 89 foot horizontal clearance between fenders. The normal operating schedule for the bridge is found in 33 CFR 117.287(h). Navigation on the waterway is commercial and recreational.

The City of Madeira Beach Florida has requested the current operating

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1315
Transmittal Sheet
December 8, 2017

ACCESS TO VHA CLINICAL PROGRAMS FOR VETERANS PARTICIPATING IN STATE-APPROVED MARIJUANA PROGRAMS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides policy on access to VHA clinical programs for Veterans participating in a State-approved marijuana program.

2. SUMMARY OF MAJOR CHANGES: Major changes include adding policy to support the Veteran-provider relationship when discussing the use of marijuana and its impact on health including Veteran-specific treatment plans.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: Population Health Services (10P4V) within the Office of Patient Care Services (10P4) is responsible for the content of this directive. Questions may be referred to the Chief Consultant, Population Health Services at (650) 849-0365.

5. RESCISSIONS: VHA Directive 2011-004, Access to Clinical Programs for Veterans Participating in State-Approved Marijuana Programs, dated January 31, 2011, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of December 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

Carolyn M. Clancy, M.D.
Executive in Charge

DISTRIBUTION: Emailed to the VHA Publications Distribution List on December 15, 2017.

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ACCESS TO VETERANS HEALTH ADMINISTRATION CLINICAL PROGRAMS FOR VETERANS PARTICIPATING IN STATE-APPROVED MARIJUANA PROGRAMS

ACCESS TO VETERANS HEALTH ADMINISTRATION CLINICAL PROGRAMS FOR VETERANS PARTICIPATING IN STATE-APPROVED MARIJUANA PROGRAMS

1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy regarding access to VHA clinical programs for Veterans participating in a State-approved marijuana program.

2. DEFINITIONS

a. **Controlled Substance.** A drug or other substance included in Schedule I, II, III, IV, or V established by section 202 of the Controlled Substances Act of 1970 (84 Stat. 1236), as updated and republished under the provisions of that Act (21 United States. Code (U.S.C.) 812). Schedule I includes drugs or other substances with a high potential for abuse, without a currently acceptable medical use in treatment in the United States, and lacking accepted safety for use under medical supervision. Marijuana is classified as a Schedule I.

b. **Marijuana:** All parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

3. POLICY

It is VHA policy that:

a. VHA providers and/or pharmacists discuss with the Veteran marijuana use, due to its clinical relevance to patient care, and discuss marijuana use with any Veterans requesting information about marijuana;

b. To comply with Federal laws such as the Controlled Substances Act (Title 21 United States Code (U.S.C.) 801 et. al.), VHA providers are prohibited from completing forms or registering Veterans for participation in a State-approved marijuana program; and,

c. VHA providers and/or pharmacists should discuss with patients how their use of State-approved medical marijuana to treat medical or psychiatric symptoms or conditions may relate to the Veterans participation in other clinical activities, (e.g., discuss how marijuana may impact other aspects of the overall care of the Veteran such as how marijuana may interact with other medications the Veteran is taking, or how the use of marijuana may impact other aspects of the overall care of the Veteran such as

pain management, Post-Traumatic Stress Disorder (PTSD), or substance use disorder treatment).

4. RESPONSIBILITIES

a. **Under Secretary for Health**. The Under Secretary for Health is responsible for ensuring VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management, or designee, is responsible for ensuring that the Department of Veterans Affairs (VA) medical facility Directors are aware that it is VHA policy for providers to assess Veteran use of marijuana but providers are prohibited from recommending, making referrals to or completing paperwork for Veteran participation in State marijuana programs.

c. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services, or designee, is responsible for assuring that all policies are aligned with the content of this directive.

d. **Assistant Deputy Under Secretary for Health for Policy and Services, Patient Care Services.** The Assistant Deputy under Secretary for Policy and Services, Patient Care Services, or designee, is responsible for assuring that VA providers receive current information regarding known/potential impact of participation in State marijuana program on clinical care and treatment planning.

e. **Chief Consultant, Population Health Services.** The Chief Consultant, Population Health Services is responsible for the content of this directive and development of strategies to educate Veterans and VHA staff regarding this directive.

f. **Veterans Integrated Service Network (VISN) Director.** The VISN Director, or designee, is responsible for assuring that this policy is disseminated and implemented at all facilities in the VISN.

g. **VA Medical Facility Director.** Each VA medical facility Director, or designee, is responsible for ensuring VA facility staff are aware of the following:

(1) Clinical staff may discuss with Veterans relevant clinical information regarding marijuana and when this is discussed it must be documented in the Veteran's medical record. Veterans must not be denied VHA services solely because they are participating in State-approved marijuana programs. Providers need to make decisions to modify treatment plans based on marijuana use on a case-by-case basis, such decisions need to be made in partnership with the Veteran and must be based on concerns regarding Veteran health and safety.

(2) The prohibition on recommending, making referrals to or completing forms and registering Veterans for participation in State-approved marijuana programs.

(3) If a Veteran presents an authorization for marijuana to a VHA provider or pharmacist, VA will not provide marijuana nor will VA pay for marijuana to be provided by a non-VA entity.

(4) Possession of marijuana, even for authorized medical reasons, by Veterans while on VA property is in violation of 38 CFR 1.218(a)(7) and places them at risk for prosecution under the Controlled Substances Act, 21 U.S.C 801 et. al.

(5) Employees of VA, including those who are Veterans receiving care through VHA, are prohibited from using a Schedule 1 drug, including marijuana, by the Mandatory Guidelines for Federal Workplace Drug Testing Programs published by the Department of Health and Human Services and VA Handbook 5383.2, VA Drug-Free Workplace Program.

(6) If a Veteran reports marijuana use and/or participation in a State-approved marijuana program to a member of the clinical staff, that information is entered into the "non-VA/herbal/Over the Counter (OTC) medication section" of the Veteran's electronic medical record following established procedures for recording non-VA medication use (see VHA Directive 2011-012, Medication Reconciliation, or subsequent policy document, VHA Directive 1108.08, VHA Formulary Management Process). If a provider discusses marijuana with a Veteran, relevant information must be documented in progress notes, and considered in the development or modification of the treatment plan.

5. REFERENCES

a. 21 U.S.C. 801 et al, the Controlled Substances Act.

b. 38 CFR 1.218(a)(7).

c. VA Handbook 5383.2, VA Drug-Free Workplace Plan, dated April 11, 1997, or subsequent policy.

d. VHA Directive 1108.08, VHA Formulary Management Process, dated November 2, 2016, or subsequent policy.

e. VHA Directive 2011-012, Medication Reconciliation, dated March 9, 2011, or subsequent policy.

f. Department of Human Health Services, Federal Register 73, Number 228. https://www.gpo.gov/fdsys/pkg/FR-2008-11-25/html/E8-26726.htm.

g. Office of General Counsel (OCG) opinion on State Marijuana Registration Forms—VAOPGCADV 9-2008. SharePoint: https://vaww.ogc.vaco.portal.va.gov/library/Lists/opinions/AllItems.aspx?RootFolder=%2Flibrary%2FLists%2Fopinions%2F2008&FolderCTID=0x012000BE5DF3519EC2CA4BBCDF6A21B2A724C6&View={FEA4080F-164B-4746-855F-F70FE42BE487}. ***NOTE:*** *This is an internal VA Web site that is not available to the public.*

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

November 10, 2020

Carl Olsen
P.O. Box 41381
Des Moines, Iowa 50311-0507

Dear Mr. Olsen:

This letter responds to your petition and your supplement to that petition, received by DEA on February 4, 2019, and August 31, 2020, respectively, asking the Drug Enforcement Administration (DEA) to initiate rule making proceedings pursuant to the Controlled Substances Act (CSA). Specifically you petitioned DEA to exempt the state-authorized use of cannabis for medical use pursuant to 21 CFR 1307.03. DEA accepted your petition for filing despite its failure to comply procedurally with the requirements of 21 CFR 1308.43(b). Specifically, your petition must be submitted in quintuplicate and in the proper format set forth in 21 CFR 1308.43(b).

Your petition is **denied** because the CSA controls marijuana under schedule I, and your requested exemption would result under the circumstances in the lapse of regulatory controls and administrative, civil, and criminal sanctions applicable to substances placed on the various CSA schedules.

Marijuana[1] has been listed in schedule I since the CSA took effect. Under the CSA, a substance is properly placed in schedule I if it (A) "has a high potential for abuse," (B) "has no currently accepted medical use in treatment in the United States," and (C) lacks "accepted safety for use under medical supervision." 21 U.S.C. 812(b)(1). These findings have been made repeatedly with respect to marijuana. *See, e.g.*, *Krumm v. DEA*, 739 F. App'x. 655 (D.C. Cir. 2018) (Mem) (denying petition for review challenging DEA's denial of petition to reschedule marijuana); "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 81 FR 53688 (Aug.12, 2016) ("August 2016 Denial"); "Denial of Petition To Initiate Proceedings To Reschedule Marijuana," 76 FR 40552 (July 8, 2011); *Olsen v. DEA*, 332 F. App'x 359 (8th Cir. 2009) (finding no standing to challenge DEA's denial of marijuana rescheduling petition); Notice of Denial of Petition,"66 FR 20038 (Apr.18, 2001); *Olsen v. DEA*, 99 F.3d 448 (D.C. Cir. 1996) (Table) ("Petitioner's rescheduling request was not supported by grounds sufficient to justify the initiation of rescheduling

1 The CSA defines "marihuana" as "[a]ll parts of the plant Cannabis Sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin." 21 USC 802(16)(A). Marihuana does not include "hemp," as defined in 7 USC 1639o, or "the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." 21 USC 802(16)(B). This definition encompasses the various terms used for marijuana or compound of marijuana you used in your petition. This response uses the CSA spelling "marihuana" and the contemporary spelling "marijuana" interchangeably.

proceedings."); "Marijuana Scheduling Petition; Denial of Petition," 54 FR 53767 (Dec. 29, 1989).

You base your request that DEA exempt the state-authorized use of cannabis for medical use on your assertion that, as a matter of law, "medical cannabidiol or any other form of cannabis, tetrahydrocannabinols and cannabis extracts have 'accepted medical use in treatment'" in states that have exempted "lawful possession or use of medical cannabidiol by qualified patients and caregivers" from the respective state's controlled substance acts.[2]

This assertion is incorrect. DEA uses a five-part test to assess whether marijuana has a "currently accepted medical use": (1) The drug's chemistry must be known and reproducible; (2) There must be adequate safety studies; (3) There must be adequate and well-controlled studies proving efficacy; (4) The drug must be accepted by qualified experts; and (5) The scientific evidence must be widely available." *Americans for Safe Access v. DEA*, 706 F.3d 438, 449 (D.C. Cir. 2013). These criteria have been repeatedly set forth by DEA and upheld by the United States Courts of Appeals. *See*, *e.g., id.* (citing *All. for Cannabis Therapeutics v. Drug Enf't Admin.*, 15 F.3d 1131, 1135 (D.C. 1994)).

The August 2016 denial relied on the assessment of the Department of Health and Human Services (HHS) to conclude that marijuana has no currently accepted medical uses in the United States. Specifically, HHS's assessment concluded that "[m]arijuana does not meet any of the five elements necessary for a drug to have a 'currently accepted medical use.'" 81 FR 53688, 53700, 53707. HHS "identified several methodological challenges in the marijuana studies published in the literature" and recommended that these challenges be "addressed in future clinical studies with marijuana to ensure that valid scientific data are generated in studies evaluating marijuana's safety and efficacy for therapeutic use." *Id.*

Your petition cites no evidence or clinical studies relating to medical uses of marijuana and, therefore, casts no doubt on HHS's findings. Rather, you assert in your petition that the State of Iowa is "the sole authority" to determine whether marijuana has accepted medical use in treatment in Iowa. This assertion is flatly contradicted by binding Supreme Court precedent. In *Gonzales v. Raich*, the Supreme Court held that Congress has the power, and has exercised that power via the CSA, to ban the personal cultivation and medical use of marijuana, even where otherwise authorized by state law. 545 U.S. 1, 29 (2005). The Court based this finding on the long-standing rule "that federal power over commerce is 'superior to that of the States to provide for the welfare or necessities of their inhabitants.'" *Id.* At 29 (quoting *Sanitary Dist. of Chicago v. United States*, 266 U.S. 405, 426 (1925)). Furthermore, in *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Court observed that the CSA explicitly allocates medical judgments in the scheduling context to the Secretary of HHS—and not, as you argue, to the states. *See Oregon*, 546 U.S. at 265.

2 Because your petition does not contest that marijuana has a high potential for abuse and lacks accepted safety for use under medical supervision, this letter addresses only whether your petition demonstrates the existence of accepted medical use in treatment in the United States.

Moreover, the structure of the CSA itself disproves your contention that federal drug law gives states the authority to determine whether a drug law has a currently accepted medical use within the meaning of the CSA. Section 903 of the CSA provides that, where there is a "positive conflict between [a] provision of [the CSA] and [a] State law so that the two cannot consistently stand together," the CSA prevails to the exclusion of the state law. *See* 21 U.S.C. 903; *Raich*, 545 U.S. at 29. Thus, section 903 of the CSA codifies within the CSA what is generally true of federal law under the supremacy clause of the United States Constitution—that where state and federal law directly conflict, state law is preempted by federal law.

The Court's holding in *Raich* likewise contradicts the assertion in your supplement that "DEA has no authority to create a conflict [between state and federal drug laws] if there is a way to resolve it." "The Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail." *Id.* For this reason, your assertion that manufacture, possession, and use of medical marijuana in Iowa is only "*perceived*" to be illegal under federal law is incorrect. Congress's placement of marijuana on schedule I prevails over a state law that ends state penalties for use, possession, or manufacture of marijuana for medical purposes. Manufacture, possession, and use of marijuana in a manner contrary to relevant CSA provisions and DEA regulations *is* illegal under federal law, regardless of state law. *See* 21 U.S.C. 841, 844. Any potential "federal interference," as you style it in your petition, flows naturally from those statutes and regulations.

Your reliance on *Gonzales v. Oregon* to support your assertion that the "Attorney General of the United States . . . is not authorized to make a rule declaring illegitimate a medical standard for care and treatment for patients that is authorized under state law" is misplaced. In *Gonzales*, the Supreme Court was interpreting the requirement set forth in 21 CFR 1306.04 that all prescriptions for controlled substances "must be issued for a legitimate medical purpose." *Gonzales*, 546 U.S. at 254. Specifically, the question was whether a prescription of a controlled substance for use in assisted suicide is a legitimate medical purpose, not whether a particular substance had accepted medical uses. *Id.* And in deciding that question, the Court noted that "Congress' express determination that marijuana had no accepted medical use foreclosed any argument about statutory coverage of drugs available by a doctor's prescription." *Id.* at 269.

Further, the DEA Administrator is obligated under 21 U.S.C. 811(d) to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (Single Convention). Because marijuana is controlled under Schedule I of the Single Convention, the placement of marijuana in either schedule I or schedule II of the CSA is "necessary as well as sufficient to satisfy our international obligations" under the treaty. *NORML v. DEA*, 559 F.2d 735, 751 (D.C. Cir. 1977).

For these reasons, absent evidence showing a currently accepted medical use for marijuana in the United States, it must be placed on CSA schedule I. Marijuana is thus subject to the CSA's schedule

I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research,

and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. Registration with DEA pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.
2. Security requirements, including handling and storage pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, and employee screening requirements of 21 CFR 1301.90–1301.93.
3. Labeling and packaging in compliance with 21 U.S.C. 825 and 958(e) and in accordance with 21 CFR part 1302.
4. Manufacture in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.
5. Inventorying of all stocks of controlled substances on hand on the date the registrant first engages in the handling of controlled substances and every two years thereafter pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.
6. Maintaining records and submitting reports with respect to marijuana pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR parts 1304 and 1312.
7. Compliance with order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.
8. Importation and exportation of marijuana in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

Any activity involving marijuana not authorized by, or in violation of the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Your proposed rule reads as follows: "(t)he listing of marihuana as a controlled substance in schedule I does not apply to the authorized medical use of marihuana authorized by or under any State statute or by any State agency." Notably, your proposed rule does not seek to alter the federal scheduling of marijuana, but rather to exempt the application of the CSA's controls to marijuana. But exempting the foregoing controls over marijuana would be inconsistent with United States obligations under the Single Convention, as noted above. *See also* 81 FR at 53767-68 (noting that U.S. obligations under the Single Convention are carried out by applying the controls specified in schedules I or II of the CSA to marijuana). Moreover, although DEA's Administrator is authorized by 21 CFR 1307.03 to grant an exception to the application of any regulatory provision contained in 21 CFR part 1300 to end, the Administrator does not have the authority to grant exceptions to requirements enacted by Congress in the text of the CSA, including the eight categories of control listed above that are required by statute for all schedule I controlled substances. Because your proposed rule would override the statutory requirements of the CSA enacted by Congress, it is beyond DEA's authority to enact. Additionally, your proposed rule would result in far fewer

controls on marijuana than rescheduling marijuana to schedule II and would lead to the presence of marijuana in the market without the many controls designed to limit the abuse of both schedule I and schedule II drugs.

For these reasons, your proposed rule would be contrary to the purposes of the CSA and to obligations arising from the Single Convention. Your petition is therefore **denied**.

If you have additional information or questions, please contact Terrence L. Boos, Ph.D., Chief, Drug and Chemical Evaluation Section, at (571) 362-3249 or DPE@usdoj.gov.

Sincerely,

Brian Besser
Deputy Assistant Administrator
Diversion Control Division

Federal Register

Wednesday,
September 6, 2006

Part V

Department of Justice

Drug Enforcement Administration

21 CFR Part 1306

Dispensing Controlled Substances for the Treatment of Pain; Notice

Issuance of Multiple Prescriptions for Schedule II Controlled Substances; Proposed Rule

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–286P]

Dispensing Controlled Substances for the Treatment of Pain

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Policy Statement.

SUMMARY: On January 18, 2005, DEA published in the **Federal Register** a solicitation of comments on the subject of dispensing controlled substances for the treatment of pain. Many of the comments that DEA received asked the agency to elaborate on the legal requirements and agency policy relating to this subject. This document provides such information.

DATES: September 6, 2006.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Background

On January 18, 2005, the DEA published in the **Federal Register** a Solicitation of Comments on the subject of dispensing controlled substances for the treatment of pain. 70 FR 2883. Many of the comments sought further information about the legal requirements and agency policy relating to the prescribing of controlled substances for the treatment of pain. DEA stated in the Solicitation of Comments that it would be issuing a document providing such information after reviewing the comments. Accordingly, this policy statement provides practitioners with a recitation of the pertinent principles under the Controlled Substances Act (CSA) and DEA regulations relating to the dispensing of controlled substances for the treatment of pain.

Extent of Abuse in the United States of Controlled Prescription Drugs

The abuse (nonmedical use) of prescription drugs is a serious and growing health problem in this country.[1] As the Administration has announced, recent data indicate that prescription drug abuse, particularly of opioid pain killers, has increased at an alarming rate over the past decade.[2] Statistics published in the National Survey on Drug Use and Health (NSDUH) by the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), demonstrate that prescription drugs account for the second-most commonly abused category of drugs, behind marijuana and ahead of cocaine, heroin, methamphetamine, and other drugs.[3]

One of the areas of concern is the number of persons who have recently begun abusing prescription controlled substances. In its NSDUH Report published in June 2006,[4] SAMHSA states: ''In 2004, among persons aged 12 or older, 2.4 million initiated nonmedical use of prescription pain relievers within the past year. This is more than the estimated number of initiates for marijuana (2.1 million) or cocaine (1.0 million).'' Overall, according to the NSDUH report: ''An estimated 31.8 million Americans have used pain relievers nonmedically in their lifetimes, up from 29.6 million in 2002.''

Another source of data presented by SAMHSA is that collected by the Drug Abuse Warning Network (DAWN), which provides national estimates of drug related visits to hospital emergency departments. According to DAWN, for 2004:

- Nearly 1.3 million emergency department (ED) visits in 2004 were associated with drug misuse/abuse. Nonmedical use of pharmaceuticals was involved in nearly half a million of these ED visits.
- Opiates/opioid analgesics (pain killers), such as hydrocodone, oxycodone, and methadone, and benzodiazepines, such as alprazolam and clonazepam, were present in more than 100,000 ED visits associated with nonmedical use of pharmaceuticals in 2004.[5]

A measure of the problem among young people is the 2005 Monitoring the Future (MTF) survey conducted by the University of Michigan.[6] The MTF survey is funded by the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), and measures drug abuse among 8th, 10th, and 12th graders. NIDA stated: ''While the 2005 survey showed a continuing general decline in drug use, there are continued high rates of non-medical use of prescription medications, especially opioid pain killers. For example, in 2005, 9.5 percent of 12th graders reported using Vicodin in the past year, and 5.5 percent of these students reported using OxyContin in the past year.'' [7] In announcing the latest MTF survey results, NIH Director Dr. Elias Zerhouni said that ''the upward trend in prescription drug abuse is disturbing.'' [8]

Purposes and Structure of This Document

One of the chief purposes of this document is to make clear that the longstanding requirement under the law that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment. DEA also wishes to dispel the mistaken notion among a small number of medical professionals that the agency has embarked on a campaign to ''target'' physicians who prescribe controlled substances for the treatment of pain (or that physicians must curb their legitimate prescribing of pain medications to avoid legal liability).

To achieve these aims, this document begins with a general summary of the relevant legal principles and an explanation of the role of DEA with respect to regulation of controlled substances. The document then addresses specific issues and questions that have been raised on a recurring basis by physicians who seek guidance on the subject of dispensing controlled substances for the treatment of pain.

It should be understood that the legal standard under the Controlled Substances Act (CSA) for prescribing controlled substances to treat pain is the same as that for prescribing controlled substances generally: The prescription must be issued for a legitimate medical purpose by a registered physician acting within the usual course of professional practice. The reason this document focuses on the prescribing of controlled substances for the treatment of pain is that there has been considerable interest among members of the public in having DEA address this specific issue.

[1] National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005). (available at *http://www.drugabuse.gov/PDF/RRPrescription.pdf*).

[2] Office of National Drug Control Policy (ONDCP) press release, March 1, 2004.

[3] 2006 Synthetic Drug Control Strategy (available at *http://www.whitehousedrugpolicy.gov/publications/synthetic_drg_control_strat/synth_strat.pdf*).

[4] The NSDUH report is available at *http://www.oas.samhsa.gov/2k6/pain/pain.pdf*. The report extracted data from the 2004 National Survey on Drug Use and Health.

[5] *http://dawninfo.samhsa.gov/files/TNDR07EDvisitsNonmedicalUseForWeb.pdf.*

[6] *http://monitoringthefuture.org.*

[7] NIDA news release, December 19, 2005 (available at *http://www.nida.nih.gov*).

[8] *Id.*

The Statutory Role of DEA in Regulating the Prescribing of Controlled Substances

DEA is the agency within the Department of Justice responsible for carrying out the functions assigned to the Attorney General under the CSA.[9] These functions include enforcing and administering the CSA provisions governing the prescribing, administering, and dispensing of controlled substances. Thus, the scope of DEA's authority is delineated by the extent to which Congress itself regulated controlled substances through the enactment of the CSA and assigned certain functions under the Act to the Attorney General.

While the CSA is one component of the overall regulation of the practice of medicine in the United States,[10] it bears emphasis that the CSA does *not* regulate the practice of medicine as a whole. Therefore, although DEA is the agency responsible for administering the CSA, DEA does *not* act as the Federal equivalent of a State medical board overseeing the general practice of medicine. *State* laws and *State* licensing bodies (such as medical licensing boards) collectively regulate the practice of medicine.[11] In contrast, the scope of the CSA (and therefore role of DEA) is much narrower. The CSA regulates only the segment of medical practice involving the use of controlled substances, and DEA is correspondingly responsible for ensuring that controlled substances are used in compliance with Federal law.

In particular, DEA's role under the CSA is to ensure that controlled substances are prescribed, administered, and dispensed only for legitimate medical purposes by DEA-registered practitioners acting in the usual course of professional practice and otherwise in accordance with the CSA and DEA regulations. Each State also has its own laws (administered by State agencies) requiring that a prescription for a controlled substance be issued only for a legitimate medical purpose by State-licensed practitioners acting in the usual course of professional practice.

There is nothing new in this arrangement of responsibilities between the Federal and State governments. For more than 90 years (starting with the Harrison Narcotic Act of 1914, which was superseded by the CSA in 1970) Federal law has placed certain restrictions on the medical use of federally controlled substances while, at the same time, the States have regulated the practice of medicine generally. In this respect, there has long been a certain amount of overlap between the Federal and State oversight of controlled substances. Beginning in the 1930s and through to the present, States have adopted uniform controlled substance laws that were designed to promote standards that are consistent from State to State and in harmony with Federal law.[12] One such standard that has always been a fundamental part of these uniform State laws is the requirement that controlled substances be dispensed only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice—a requirement first articulated in the Harrison Narcotic Act. Accordingly, it has been the case for more than 70 years that a practitioner who dispenses controlled substances for other than a legitimate medical purpose, or outside the usual course of professional practice, is subject to legal liability under both State and Federal law.[13]

The Meaning of the ''Legitimate Medical Purpose'' Requirement

As stated above, the core legal standard is that a controlled substance may only be prescribed, administered, or dispensed for a legitimate medical purpose by a physician acting in the usual course of professional practice. This requirement has been construed to mean that the prescription must be ''in accordance with a standard of medical practice generally recognized and accepted in the United States.'' [14] However, Federal courts have long recognized that it is not possible to expand on the phrase ''legitimate medical purpose in the usual course of professional practice,'' in a way that will provide definitive guidelines that address all the varied situations physicians might encounter. As one court explained:

> There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts.[15]

Similarly, another court stated:

> A majority of cases [in which physicians were alleged to have dispensed controlled substances without a legitimate medical purpose] have dealt with facts which were so blatant that a statement of clear-cut criteria in a form useful in other cases would have been superfluous to the decision. We are, however, able to glean from reported cases certain recurring concomitance of condemned behavior.[16]

The foregoing quotation makes a particularly important point: that the types of cases in which physicians have been found to have dispensed controlled substances improperly under Federal law generally involve facts where the physician's conduct is not merely of questionable legality, but instead is a glaring example of illegal activity.

Specific Areas of Interest to the Commenters

The comments DEA received covered a variety of issues related to the dispensing of controlled substances for the treatment of pain. While some of the viewpoints expressed in the comments were in sharp contrast with other viewpoints, taken as a whole, the comments indicate there is significant interest (among those physicians and members of the public who submitted comments) in having DEA address the following topics:

[9] 21 U.S.C. 871(a); 28 CFR 0.100.

[10] As the United States Supreme Court stated in an early decision under the CSA, ''provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits.'' *United States* v. *Moore*, 423 U.S. 122, 141–142 (1975). In *Gonzales* v. *Oregon*, 126 S.Ct. 904, 925 (2006), the Court continued to cite *Moore* with approval and for the proposition that the legitimate medical purpose requirement in the CSA ''ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' The Court further stated: ''As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Id*

[11] Medical specialty boards also play a crucial role in providing information to the public, the government, and the medical profession concerning issues involving specialization and certification in medicine. Specialty boards maintain the quality of medical care in the United States by developing and utilizing professional and educational standards for the evaluation and certification of physician specialists.

[12] The first such uniform act was the Uniform Narcotic Drug Act of 1932, which was eventually adopted by every state. That act was replaced in 1970 by the Uniform Controlled Substances Act, which has been adopted by all but two states (New Hampshire and Vermont).

[13] Congress expressly intended that there would be a dual system of Federal-state regulation of controlled substances by including in the CSA a preemption provision, 21 U.S.C. 903, which reflects that this field of regulation was to be shared by the Federal and state governments. Section 903 states: ''No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State * * *.'' At the same time, this provision reiterates what is inherent in the supremacy clause of the United States Constitution—that no state may enact a law relating to controlled substances that presents a ''positive conflict'' with the CSA.

[14] *Moore*, 423 U.S. at 139 (quoting jury instruction).

[15] *United States* v. *August*, 984 F.2d 705, 713 (6th Cir. 1992).

[16] *United States* v. *Rosen*, 582 F.2d 1032 (5th Cir. 1978).

- The extent and consequences of the undertreatment of pain in the United States.
- The extent and consequences of excessive use of opioids to treat nonsevere pain.
- Providing medical and legal guidance on prescribing opioids for pain.
- Elaborating on DEA's policy regarding the investigation of physicians for improper prescribing of controlled substances for pain.
- Having DEA provide reassurance that it is not targeting physicians who prescribe controlled substances for pain.

Each of these topics is addressed in this document.[17]

Comments Regarding the Use of Opioids

The comments reflect two distinct points of emphasis among physicians who specialize in the treatment of pain. For some, of paramount concern is what they describe as the undertreatment of acute and chronic pain. Illustrative of this viewpoint, one commenter has stated:

> The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in State pain policies. Circumstances that contribute to the prevalence of undertreated pain include: (1) Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes.[18]

One group representing several organizations of physicians who specialize in treating pain commented that it agrees with the following statement made by DEA in the November 16, 2004, Interim Policy Statement published in the **Federal Register** (69 FR 67170): ''[C]hronic pain is a serious problem for many Americans. It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified.'' However, this group expressed the view that the Interim Policy Statement would have ''the exact opposite effect'' by discouraging some practitioners from properly treating pain. The group therefore urged DEA to readdress the subject in a way that will promote proper dispensing of controlled substances for pain. Similar views were expressed in comments submitted by many other organizations whose missions relate to the treatment of pain. For example, an organization representing health care professionals and patient advocates for those with cancer pain stated: ''We respectfully request that the DEA reaffirm its support for areas of the law that support the appropriate use of opioid analgesics for pain control and thereby reduce the fears and uncertainties of health care professionals who treat patients in pain.'' With regard to this point, NIDA has stated in a recent report: ''Many healthcare providers underprescribe opioid pain relievers, such as morphine and codeine, because they overestimate the potential for patients to become addicted.'' [19]

A few other commenters focused primarily on what they believe is the overprescribing of opioids by some physicians to treat pain. For example, one physician who specializes in pain treatment stated that ''the majority of high dose narcotic prescribing is for chronic 'non-malignant' pain,'' that ''the growth of this practice has been exponential,'' and that ''there have been many problems associated with this practice, including the tremendous rise in abuse of prescription drugs in all segments of the population, especially the youth.'' Along similar lines, another physician commented there has been an ''epidemic'' of deaths and addiction resulting from the illicit use of prescription narcotics, which, according to this commenter, is due in large part to the prescribing of narcotics to ''a much wider class of chronic noncancer patients, including those with moderate subjective ailments such as bursitis, neuralgia, arthritis, headaches, and lower back pain.'' Another physician stated the large increase in the use of prescription narcotics and deaths related thereto ''seem to be coincident with growing advocacy for use of opioid pain medications in chronic benign pain syndromes'' and ''also coincide with the marketing of expensive new opioid drug preparations which are aggressively promoted by the drug manufacturers, and with the growth of professional and accrediting organizations that seem determined to promote the use of opioid pain medications.''

The two distinct areas of emphasis reflected in the comments—the commenters' views about the undertreatment of pain and what some perceive as overprescribing of opioids for nonsevere ailments—are not necessarily mutually exclusive. To the contrary, the comments taken collectively suggest that there may be some physicians who ''undertreat'' pain and others who improperly prescribe opioids ostensibly for the treatment of pain. (DEA presumes, however, that most physicians provide appropriate amounts of pain medication.) The comments also reflect that there is a lack of consensus among physicians as to all the circumstances that warrant the use of opioids to treat pain.[20] On this latter point, one physician who specializes in pain treatment commented: ''The treatment of chronic nonmalignant pain syndromes with narcotic medications remains a controversial area with the mainstream medical community.'' This commenter suggested there is a need for randomized, double-blind, controlled clinical trials to fully evaluate this issue. As explained below, it is not DEA's role to issue medical guidelines specifying patient characteristics that warrant the selection of a particular opioid or other medication or regimen for the treatment of pain.

Requests for Guidance on Treating Patients for Pain

Many commenters expressed the view that it would be beneficial if physicians had a single document providing clear guidelines on the use of controlled substances for the treatment of pain. Some believe such a document would remedy their concerns about the undertreatment of pain by giving

[17] Also of chief concern to commenters was the issuance by physicians of multiple schedule II prescriptions. DEA addressed this issue in detail in the August 26, 2005, **Federal Register** document titled ''Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances.'' 70 FR 50403. In addition, DEA is today publishing in the **Federal Register** a notice of proposed rulemaking (Docket No. DEA–287N) that would revise the DEA regulations to allow for the issuance of multiple schedule II prescriptions under certain circumstances.

[18] Federation of State Medical Boards of the United States, Model Policy for the Use of Controlled Substances for the Treatment of Pain (2004).

[19] National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (available at *http://www.drugabuse.gov/PDF/RRPrescription.pdf*).

[20] One indication of the lack of consensus among physicians on this point is the following. The American Medical Association, in a published policy statement (D–120.999) (''Use of opioids in chronic noncancer pain''), states: ''Further controlled trials [should] be conducted on opioid therapy in patients with chronic noncancer pain in an effort to identify best practice with regard to selection of both medication and treatment regimens [to] identify patient characteristics that predict opioid responsiveness [and to] provide support for guidelines on appropriate precautions, contraindications, and the degree of monitoring required in such patients.''

physicians assurance that they can avoid scrutiny by Federal and State regulatory authorities as long as they follow those guidelines when prescribing opioids. More specifically, it has been suggested that these guidelines should take the form of a series of questions and answers to be adopted by DEA. Among the questions that have been proposed for inclusion in these guidelines are:

- What should be the goals of pain management?
- How can a clinician assess a patient's pain?
- When should a primary care physician turn to a pain medicine specialist to manage a patient's pain?
- How are opioids used to manage chronic pain?

It is certainly appropriate for physicians and medical oversight boards to explore these types of questions. However, for the following reasons, it is not appropriate for DEA to address these questions in the form of a guidance document (or to endorse such a guidance document prepared by others).

First, one cannot provide an exhaustive and foolproof list of ''dos and don'ts'' when it comes to prescribing controlled substances for pain or any other medical purpose. As discussed above, the fundamental principle under both Federal and State law is that a controlled substance must be dispensed by a physician for a legitimate medical purpose in the usual course of professional practice. Throughout the 90 years that this requirement has been a part of United States law, the courts have recognized that there are no definitive criteria laying out precisely what is legally permissible, as each patient's medical situation is unique and must be evaluated based on the entirety of the circumstances. DEA cannot modify or expand upon this longstanding legal requirement through the publication or endorsement of guidelines.

Second, as stated earlier in this document, DEA's authority under the CSA is not equivalent to that of a State medical board. DEA does not regulate the general practice of medicine. The responsibility for educating and training physicians so that they make sound medical decisions in treating pain (or any other ailment) lies primarily with medical schools, post-graduate training facilities, State accrediting bodies, and other organizations with medical expertise. Some states also have continuing medical education requirements for licensing. Physicians also keep abreast of the latest findings by reading peer-reviewed articles published in medical and scientific journals. DEA, however, has neither the legal authority nor the expertise to provide medical training to physicians or issue guidelines that constitute advice on the general practice of medicine.[21]

For these reasons, DEA is not proposing any medical guidelines on prescribing controlled substances for the treatment of pain.

Whether To Form an Advisory Committee

Several members of the public have suggested that DEA form an advisory committee, panel, or working group to develop and publish guidelines on the use of controlled substances for the treatment of pain. An agency may not utilize an advisory committee (or panel or working group) to provide advice to the agency or prepare a document for (or in conjunction with) the agency unless all of the procedural requirements of the Federal Advisory Committee Act (FACA) are satisfied.[22] Compliance with FACA ensures, among other things, that persons selected by the agency to serve on the committee constitute a balanced membership that represents a fair cross-section of viewpoints.

If DEA were to conclude that compelling considerations necessitated the formation of an advisory committee subject to FACA, the agency would seek to do so in accordance with the law and Executive Branch directives.[23] At this time, DEA does not believe that such considerations exist warranting the formation of such an advisory committee to address the dispensing of controlled substances for the treatment of pain. However, there are other means available to an agency to obtain valuable public input. Within the bounds permissible by law, DEA remains firmly committed to obtaining the ongoing input of the medical community, law enforcement officials, and other interested members of the public. Toward this end, the agency welcomes written submissions from the public on this document and will continue to explore other legally appropriate means of hearing the views of interested members of the public.

The Number of Physicians Who Prescribe Controlled Substances in Violation of the CSA Is Extremely Small and There Is No DEA ''Crackdown'' on Physicians

DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes. In fact, the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by Federal or State law enforcement officials. Contrary to the impression of some commenters, DEA has not modified its criteria for investigating physicians or increased its emphasis on physicians as part of the agency's overall mission. *In any given year, including 2005, fewer than one out of every 10,000 physicians in the United States (less than 0.01 percent) lose their controlled substance registrations based on a DEA investigation of improper prescribing.*[24] This figure alone should correct any mistaken notions about a supposed DEA ''crackdown'' on physicians. Moreover, as mentioned above, the responsibility for monitoring and preventing controlled substance abuse is shared by State and Federal governments. Even in the rare cases where a physician loses his/her DEA registration for improper prescribing, it is often State officials—not DEA—who initiate the investigations.

DEA always had, and continues to have, a legal obligation to investigate the extremely small fraction of physicians who use their DEA registration to commit criminal acts or otherwise violate the CSA. DEA takes this obligation seriously because even just one physician who uses his/her DEA registration for criminal purposes can cause enormous harm. In the words of one commenter: ''It takes only a few untrained or unscrupulous physicians to create large pockets of addicts.'' But DEA takes just as seriously its obligation to ensure that there is no interference with the dispensing of controlled

[21] As stated above, DEA does have the authority and the expertise to investigate and determine whether a prescription for a controlled substance was issued for a legitimate medical purpose in the usual course of professional practice within the meaning of the CSA and DEA regulations.

[22] As set forth in FACA, a charter must be enacted before an advisory committee can meet. 5 U.S.C. App. 2 § 9(c). For an agency committee, the charter must be filed with the head of the agency, the appropriate Senate and House of Representatives standing committees, the Library of Congress, and the General Services Administration Secretariat, 41 CFR 102–3.70. The charter must contain certain information, including, among other things, the following: the advisory committee's official designation; objectives and the scope of the advisory committee's activity; the time necessary to carry out the advisory committee's purposes; a description of the duties for which the advisory committee is responsible; the estimated annual costs; the estimated frequency of the advisory committee's meetings; and the planned termination date.

[23] *See* Executive Order 12838 (''Termination and Limitation of Federal Advisory Committees'').

[24] The majority of cases in which physicians lose their DEA registrations result from actions by state medical boards to revoke or suspend the physicians' state medical licenses.

substances to the American public in accordance with the sound medical judgment of their physicians. It would be a disservice to many patients if exaggerated statements regarding the likelihood of a DEA investigation resulted in physicians mistakenly concluding that they must scale back their patients' use of controlled substances to levels below that which is medically appropriate.

Furthermore, DEA does not apply a greater level of scrutiny to the prescribing of controlled substances to treat pain as compared to other ailments. Regardless of the ailment, DEA applies evenhandedly the requirement that a controlled substance be prescribed for a legitimate medical purpose in the usual course of professional practice. The idea that prescribing opioids to treat pain will trigger special scrutiny by DEA is false.

Types of Cases in Which Physicians Have Been Found To Have Prescribed or Dispensed Controlled Substances for Other Than a Legitimate Medical Purpose or Outside the Usual Course of Professional Practice

Bearing in mind that there are no criteria that will address every conceivable instance of prescribing, the following examples of cases are provided to explain how Federal courts and DEA have applied the requirement that a controlled substance be dispensed for a legitimate medical purpose in the usual course of professional practice.

Application of the Requirement by Federal Courts

As noted above, the Supreme Court recently stated, in *Gonzales* v. *Oregon*, that the legitimate medical purpose requirement in the CSA ''ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' [25] The Court further stated: ''As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' [26]

Consistent with those views, some years ago, the United States Court of Appeals for the Fifth Circuit summarized the reported cases in which physicians had been found to have violated the requirement that a prescription for a controlled substance be issued only for a legitimate medical purpose in the usual course of professional practice. In this decision, *United States* v. *Rosen*, 582 F.2d 1032 (5th Cir. 1978), the court looked at the case law and found the following recurring patterns indicative of diversion and abuse:

(1) An inordinately large quantity of controlled substances was prescribed.
(2) Large numbers of prescriptions were issued.
(3) No physical examination was given.
(4) The physician warned the patient to fill prescriptions at different drug stores.
(5) The physician issued prescriptions knowing that the patient was delivering the drugs to others.
(6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
(7) The physician involved used street slang rather than medical terminology for the drugs prescribed.
(8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
(9) The physician wrote more than one prescription on occasions in order to spread them out.

The same fact patterns listed by the *Rosen* court remain prevalent today among the cases in which physicians have been found to have improperly prescribed controlled substances. This does not mean that the existence of any of the foregoing factors will automatically lead to the conclusion that the physician acted improperly. Rather, each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient. For example, what constitutes ''an inordinately large quantity of controlled substances'' (factor (1) listed by the *Rosen* court) can vary greatly from patient to patient. A particular quantity of a powerful schedule II opioid might be blatantly excessive for the treatment of a particular patient's mild temporary pain, yet insufficient to treat the severe unremitting pain of a cancer patient.

Again, rather than focusing on any particular factor, it is critical to bear in mind that (i) the entirety of circumstances must be considered, (ii) the cases in which physicians have been found to have prescribed controlled substances improperly typically involve facts that demonstrate blatant criminal conduct, and (iii) the percentage of physicians who prescribe controlled substances improperly (or are investigated for doing so) is extremely small.

Application of the Requirement by DEA

Any final decision by DEA to revoke or deny a DEA registration is published in the **Federal Register**. The following are three examples from 2005 in which DEA revoked physicians' DEA registrations for unlawfully prescribing or dispensing controlled substances. (The complete final orders are published in the **Federal Register** and are available online.)

- *Robert A. Smith, M.D.* (70 FR 33207)—Dr. Smith gave one patient seven to ten prescriptions of OxyContin per visit on a weekly basis. The prescriptions were written in the patient's name as well as the names of the patient's father and her fiancé. Each visit, the patient paid Dr. Smith a $65 fee for the office visit plus an additional $100 for the fraudulent prescriptions. Dr. Smith also asked the patient for sexual favors during office visits. The patient declined, but, as a substitute, paid another woman $100 to perform a sexual act on Dr. Smith. Dr. Smith's office assistant also provided the patient with blank prescriptions, in return for which the office assistant demanded from the patient $40 and OxyContin tablets.

Another patient would give Dr. Smith a list of fictitious names and types of controlled substances he desired, and Dr. Smith would issue three prescriptions under each name, usually for Percocet, OxyContin, and Xanax, at the same time. Dr. Smith issued between nine and fifteen fraudulent prescriptions per visit and received $100 for each set of three prescriptions. The patient then sold the prescriptions to a third party who, in turn, sold the drugs on the street, all with the knowledge of Dr. Smith.

Another individual visited Dr. Smith three times in less than a three-week period, obtaining fraudulent prescriptions each time. The individual paid Dr. Smith $500 for 15 prescriptions for Xanax, OxyContin, and Percocet, which were written under five different fictitious patient names.

- James S. Bischoff, M.D. (70 FR 12734)—Dr. Bischoff took a 16-year-old high school student to an out-of-town physician specialist for emergency medical treatment after the boy's hand was cut in an accident. When the specialist did not recommend treatment with a controlled substance, Dr. Bischoff wrote the boy a prescription for 100 OxyContin, which Dr. Bischoff personally took to a pharmacy to be filled. Dr. Bischoff delivered only 20 tablets to the boy, unlawfully diverting the remaining 80 tablets. Around the same time, Dr. Bischoff wrote another prescription in the boy's name for 120 Adderall tablets. Dr. Bischoff also filled this prescription himself at a pharmacy but never delivered the tablets to the boy. Later, Dr. Bischoff wrote another prescription in the name of the boy for 120 Adderall tablets. The boy's stepmother learned that the boy was taking the medication only after she

[25] 126 S.Ct. at 925.
[26] *Id.*

discovered the bottle a couple of weeks later. She then checked with the pharmacy and discovered that Dr. Bischoff had written and personally filled multiple fraudulent prescriptions for controlled substances in the names of the boy's family members, telling pharmacists that he was a close friend and that the purported patients were too busy to get to the pharmacy. In addition, Dr. Bischoff ordered approximately 46,000 dosage units of schedule III and IV controlled substances from a supplier, and he was unable to account for 32,000 dosage units.

• *John S. Poulter, D.D.S.* (70 FR 24628)—Local law enforcement authorities were called after Dr. Poulter was observed parked in front of a convenience store injecting himself with Demerol. Dr. Poulter failed a field sobriety test, admitted to injecting himself with Demerol, and later pleaded guilty to State felony charges of unlawful possession of a controlled substance. The plea was held in abeyance for three years pending Dr. Poulter's successful completion of a monitoring program for impaired professionals. In addition to the criminal proceedings, his State professional licensing board took action based on the Demerol incident and several instances of improper use of Fentanyl. Dr. Poulter entered into a five-year probationary agreement with the State board, agreeing to abstain from personal use of mood-altering substances. Before completing these probationary periods, Dr. Poulter was involved in an automobile accident in which he drove his car off the road after having injected himself with Fentanyl and Demerol. Responding officers and medical personnel found him ''incoherent and very confused,'' and there were visible needle marks on his arm and hands. A search of the automobile revealed a used syringe and a plastic container holding Demerol and Fentanyl.

These three recent cases provide illustrations of some of the most common behaviors that result in loss of DEA registration: Issuing prescriptions for controlled substances without a bona fide physician-patient relationship; issuing prescriptions in exchange for sex; issuing several prescriptions at once for a highly potent combination of controlled substances; charging fees commensurate with drug dealing rather than providing medical services; issuing prescriptions using fraudulent names; and self-abuse by practitioners.

In another recent case, *United States* v. *Singh,* 390 F.3d 168 (2d Cir. 2004), a physician who claimed to specialize in pain management was convicted following a jury trial of improperly prescribing a controlled substance in violation of the CSA. The court of appeals, which upheld the conviction, described the nature of the physician's prescribing practice as follows (*id.* at 176):

> Singh developed a scheme that enabled nurses to see patients alone, to issue prescriptions for schedule II controlled substances, and to bill for such services. He and the other physicians would pre-sign the triplicate forms and provide them to non-physician personnel to use during patient visits. These employees, although not trained or legally authorized to do so, filled in all the required prescription information—drug type, dosage, and quantity—and provided the prescriptions to the patients.
>
> It appears that the physicians at the practice, including Singh, signed entire books of triplicate prescription forms in blank without even knowing the identities of the patients to whom the prescriptions would be issued or the nature or dosage of the drug to be prescribed. * * *
>
> Data extracted from Singh's office records revealed that the nurses issued prescriptions for at least 76,000 tablets of schedule II controlled substances when Singh was not present in the practice suite.

Thus, *Singh* is another example of a prosecution based on blatant criminal conduct by a physician, and it should cause no concern for any legitimate pain specialist or other physician who properly prescribes controlled substances.

Commencement of Investigations

On the subject of when DEA might commence an investigation of possible improper prescribing of controlled substances, several commenters sought elaboration on DEA's statements in the November 16, 2004 Interim Policy Statement. In that document, DEA stated, among other things:

> [I]t is a longstanding legal principle that the Government ''can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.'' *United States* v. *Morton Salt Co.,* 338 U.S. 632, 642–643 (1950). It would be incorrect to suggest that DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the [CSA].

The foregoing is a correct statement of the law, and DEA is not unique in this regard. All law enforcement agencies—Federal and State—have long been governed by this same principle. The reason DEA mentioned this longstanding maxim in the Interim Policy Statement was to correct an earlier publication attributed to DEA that embodied a contrary view.

While those who commented on the subject of investigations generally acknowledged that DEA had properly stated the law, some asserted that, by doing so, the agency might have caused some physicians to fear the prospect of being investigated and thereby discouraged them from providing proper pain treatment. DEA believes, however, physicians will understand that correctly stating the legal standard which has historically applied to regulatory agencies is no cause for alarm. DEA does not use its investigatory authority in an arbitrary manner. Further, as DEA has repeatedly stated in this document and elsewhere, there is no ''crackdown'' or increased emphasis on investigating physicians, and the statistics bear that out. In 2005, as in prior years, only a tiny fraction of physicians (less than one in ten thousand) lost their registration based on a DEA investigation of improper prescribing of controlled substances.

One commenter suggested DEA should announce it will only commence an investigation when it has evidence that the physician is prescribing in a manner outside of accepted medical standards. To adopt such a standard would conflict with longstanding law, as previously noted. In addition, from a practical perspective, such a standard would be impossible to apply because the agency cannot know—prior to commencing an investigation—whether the activity was proper or improper. Gathering preliminary information is essential to determining whether a full-scale investigation is—or is not—warranted. By stating the governing law, however, DEA is not suggesting that it investigates every instance of prescribing in order to rule out the possibility of illegal activity. To the contrary, the agency recognizes that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose in the usual course of professional practice.

Other Recurring Questions

What is fueling the recent increase in prescription drug abuse?

There are a variety of factors that may be contributing to the increase in prescription drug abuse. The Director of NIDA recently testified before Congress:

> The recent increase in the extent of prescription drug abuse in this country is likely the result of a confluence of factors, such as: Significant increases in the number of prescriptions; significant increases in drug availability; aggressive marketing by the pharmaceutical industry; the proliferation of illegal Internet pharmacies that dispense these medications without proper prescriptions and surveillance; and a greater

social acceptability for medicating a growing number of conditions.[27]

• *Increased availability of prescription drugs and sharing among family and friends*—The United States Government Accountability Office (GAO) published a report in 2003 on the abuse of the most prescribed brand name narcotic medication for treating moderate-to-severe pain.[28] The report states: ''The large amount of [the drug] available in the marketplace may have increased opportunities for abuse and diversion. Both DEA and [the manufacturer of the drug] have stated that an increase in a drug's availability in the marketplace may be a factor that attracts interest by those who abuse and divert drugs.''

The 2006 Synthetic Drug Control Strategy states:

> Preliminary data suggest the most common way in which controlled substance prescriptions are diverted may be through friends and family. For example, a person with a lawful and medical need for some amount of a controlled substance uses only a portion of the prescribed amount. Then a family member complains of pain, and the former patient shares excess medication. Alternatively, for a family member addicted to controlled prescription drugs, the mere availability of unused controlled substance prescriptions in the house may prove to be an irresistible temptation.

• *Ease of access via the Internet*—It is becoming increasingly easy for persons of any age to obtain controlled substances illegally by means of the Internet. Numerous Web sites based in the United States and abroad sell controlled substances to anyone willing and able to provide a credit card number. Some of these Web sites do not require a prescription. Others will provide the buyer with an illegitimate prescription simply by having the buyer fill out an online questionnaire without seeing a physician. As the 2006 Synthetic Drug Control Strategy states, ''the anonymity of the Internet and the proliferation of Web sites that facilitate illicit transactions for controlled substance prescription drugs have given drug abusers the ability to circumvent the law as well as sound medical practice.''

• *Improper prescribing*—As the 2006 Synthetic Drug Control Strategy states: ''The overwhelming majority of prescribing in America is conducted responsibly, but the small number of physicians who overprescribe controlled substances—carelessly at best, knowingly at worst—help supply America's most widespread drug addiction problem. Although the problem exists, the number of physicians responsible for this problem is a very small fraction of those licensed to prescribe controlled substances in the United States.''

• *Drug formulation and marketing*—One of the recommendations in the 2006 Synthetic Drug Control Strategy is to ''[c]ontinue to support the efforts of firms that manufacture frequently diverted pharmaceutical products to reformulate their products so as to reduce diversion and abuse,'' and to ''[e]ncourage manufactures to explore methods to render * * * pain control products, such as OxyContin, less suitable for snorting or injection.'' Whether the marketing of certain opioids has contributed to abuse and diversion has also been an area of discussion.[29]

What are some of the common methods and sources of diversion?

Diversion of prescription drugs containing controlled substances occurs on a variety of levels. Some controlled substances are stolen directly from manufacturers and distributors. Diversion also occurs at the retail level with thefts from, and robberies of, pharmacies. In one survey of over 1,000 pharmacists nationwide, 28.9 percent reported that they had experienced a theft or robbery at their pharmacies within the past five years.[30] A very small percentage of physicians also contribute to the problem of diversion by intentionally, or unintentionally, providing controlled substances to those who are themselves drug abusers or who sell the drugs for profit.

Prescription fraud is another common source of diversion. This occurs whenever prescriptions for controlled substances are obtained under false pretenses, including when prescriptions are forged or altered, or when someone falsely claiming to be a physician calls in the prescription to a pharmacy.

''Doctor shopping'' is another traditional method by which diversion occurs. Some drug abusers visit multiple physicians' offices and falsely present complaints in order to obtain controlled substances.

What are the potential signs to a physician that a patient might be seeking drugs for the purpose of abuse or diversion?

Many physicians have requested a list of the possible indicators that a patient might be seeking controlled substances for the purpose of diversion or abuse. DEA has provided this type of list in various publications over the years. While not an exhaustive list, the following are some of the common behaviors that might be an indication the patient is seeking drugs for the purpose of diversion or abuse:

- Demanding to be seen immediately;
- Stating that s/he is visiting the area and is in need of a prescription to tide her/him over until returning to the local physician;
- Appearing to feign symptoms, such as abdominal or back pain, or pain from kidney stones or a migraine, in an effort to obtain narcotics;
- Indicating that nonnarcotic analgesics do not work for him/her;
- Requesting a particular narcotic drug;
- Complaining that a prescription has been lost or stolen and needs replacing;
- Requesting more refills than originally prescribed;
- Using pressure tactics or threatening behavior to obtain a prescription;
- Showing visible signs of drug abuse, such as track marks.

What are the general legal responsibilities of a physician to prevent diversion and abuse when prescribing controlled substances?

In each instance where a physician issues a prescription for a controlled substance, the physician must properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the physician must be acting in the usual course of professional practice.[31] This is the basic legal requirement discussed

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[27] The NIDA testimony, which was presented July 26, 2006, before the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, appears in full on NIDA's Web site at *http://www.drugabuse.gov/Testimony/7-26-06Testimony.html.*

[28] The GAO report, ''Prescription Drugs OxyContin Abuse and Diversion and Efforts to Address the Problem,'' GAO–04–110 (December 2003), is available at *http://www.gao.gov/new.items/d04110.pdf.*

[29] A detailed discussion of this issue is contained in the above-referenced GAO report, ''Prescription Drugs OxyContin Abuse and Diversion and Efforts to Address the Problem.'' The manufacturer's statement to Congress in response to the GAO report is available at *http://reform.house.gov/UploadedFiles/9-13-2005%20Purdue%20Testimony.pdf.* In 2001, FDA announced that it had worked with the manufacturer of OxyContin to make changes to the drug's labeling, including a ''black box warning,'' which FDA states is ''intended to lessen the chance that OxyContin will be prescribed inappropriately for pain of lesser severity than the approved use or for other disorders or conditions inappropriate for a schedule II narcotic.'' FDA Talk Paper: ''FDA Strengthens Warnings for OxyContin'' (July 25, 2001), available at *http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01091.html.*

[30] The survey was conducted by the National Center on Addiction and Substance Abuse at Columbia University, which published the results in a comprehensive report on prescription drug abuse entitled: ''Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.'' (available at *http://www.casacolumbia.org/absolutenm/articlefiles/380-under_the_counter_-_diversion.pdf).*

[31] 21 CFR 1306.04(a); *United States* v. *Moore, supra.*

above, which has been part of American law for decades. Moreover, as a condition of being a DEA registrant, a physician who prescribes controlled substances has an obligation to take reasonable measures to prevent diversion.[32] The overwhelming majority of physicians in the United States who prescribe controlled substances do, in fact, exercise the appropriate degree of medical supervision—as part of their routine practice during office visits—to minimize the likelihood of diversion or abuse. Again, each patient's situation is unique and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound medical judgment and consistent with established medical standards.

What additional precaution should be taken when a patient has a history of drug abuse?

As a DEA registrant, a physician has a responsibility to exercise a much greater degree of oversight to prevent diversion and abuse in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse. Under no circumstances may a physician dispense controlled substances with the knowledge they will be used for a nonmedical purpose or that they will be resold by the patient. Some physicians who treat patients having a history of drug abuse require each patient to sign a contract agreeing to certain terms designed to prevent diversion and abuse, such as periodic urinalysis. While such measures are not mandated by the CSA or DEA regulations, they can be very useful.

Can a physician be investigated solely on the basis of the number of tablets prescribed for an individual patient?

The Supreme Court has long recognized that an administrative agency responsible for enforcing the law has broad investigative authority,[33] and courts have recognized that prescribing an ''inordinately large quantity of controlled substances'' can be evidence of a violation of the CSA.[34] DEA therefore, as the agency responsible for administering the CSA, has the legal authority to investigate a suspicious prescription of any quantity.

Nonetheless, the amount of dosage units per prescription will never be a basis for investigation for the overwhelming majority of physicians. As with every other profession, however, among the hundreds of thousands of physicians who practice medicine in this country in a manner that warrants no government scrutiny are a handful who engage in criminal behavior. In rare cases, it is possible that an aberrant physician could prescribe such an enormous quantity of controlled substances to a given patient that this alone will be a valid basis for investigation. For example, if a physician were to prescribe 1,600 (sixteen hundred) tablets per day of a schedule II opioid to a single patient, this would certainly warrant investigation as there is no conceivable medical basis for anyone to ingest that quantity of such a powerful narcotic in a single day. Again, however, such cases are extremely rare. The overwhelming majority of physicians who conclude that use of a particular controlled substance is medically appropriate for a given patient should prescribe the amount of that controlled substance which is consistent with their sound medical judgment and accepted medical standards without concern that doing so will subject them to DEA scrutiny.

Can methadone be used for pain control?

Methadone, a schedule II controlled substance, has been approved by the FDA as an analgesic. While a physician must have a separate DEA registration to dispense methadone for maintenance or detoxification, no separate registration is required to prescribe methadone for pain. However, in a document entitled ''Methadone-Associated Mortality: Report of a National Assessment,'' SAMHSA recently recommended that ''physicians need to understand methadone's pharmacology and appropriate use, as well as specific indications and cautions to consider when deciding whether to use this medication in the treatment of pain.'' [35] This recommendation was made in light of mortality rates associated with methadone.

Obtaining Further Input From Physicians and Other Health Care Professionals

In developing policies and rules relating to the use of controlled substances in the treatment of pain, DEA is firmly committed to obtaining input on an ongoing basis from physicians and other health care professionals authorized to prescribe and dispense controlled substances, as well the views of Federal and State agencies, professional societies, and other interested members of the public. DEA welcomes the written comments that any such persons might wish to submit in response to this document. DEA will also continue to evaluate whether it would be beneficial to obtain the additional views of physicians through in-person meetings, to the extent permissible under FACA.

Dated: August 28, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–14517 Filed 9–5–06; 8:45 am]

BILLING CODE 4410–09–P

[32] 21 U.S.C. 823(f).

[33] *Morton Salt,* 338 U.S. at 642–643 (''an administrative agency charged with seeing that the laws are enforced'' may ''investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.'').

[34] *United States* v. *Rosen,* 582 F.2d at 1036.

[35] SAMHSA Publication No. 04–3904. Available at *http://dpt.samhsa.gov/reports/index.htm.*

and then if he wanted to proceed with separate hearings to move it down to III or IV, he can do so. He cannot move it from I to III and IV, and he cannot move it from I out, but he can move it down.

Mr. ROGERS. From I to II?

Mr. SONNENREICH. Yes, sir.

Mr. ROGERS. Can he move it from II to III after that?

Mr. SONNENREICH. Yes, sir, but it requires two separate administrative procedures.

Mr. ROGERS. I understand, two hearings.

Mr. INGERSOLL. Or by the consent of Congress.

Mr. ROGERS. Isn't it a little ridiculous for us to put it in the law, then, that you can't remove a category from category I?

Mr. SONNENREICH. No, because if there is medical use found for anything in category I, it would automatically have to leave category I and go into category II, because then there would be use for it in the United States.

If the doctors say there is a use for heroin as a medically prescribed drug, it has to go down to No. 2.

Mr. ROGERS. So why should we put a prohibition in the law saying you can't remove I to III and IV?

Mr. SONNENREICH. Because these specific drugs in schedule I have certain emotionalism around them. We felt that if Congress saw fit to remove those, that would be one thing, but it should not be in the hands of any administrative official to do it automatically.

Mr. ROGERS. Getting back to those quotas on 35, 36 and 37, as I understand it, you can set individual quotas?

Mr. SONNENREICH. Yes, sir.

Mr. ROGERS. Would he set individual quotas for I and II?

Mr. SONNENREICH. They are set now and set on the basis of the information received from the World Health Organization. I might add with respect to the narcotics drugs required of the Single Convention of 1961, all of these reports have to be filed quarterly with the Bureau. We forward them to the World Health Organization and the World Health Organization has control over all the signatories of the treaty as to how much of these drugs must be shipped back and forth.

This also determines the production quotas of the producing nations in the world, such as Turkey, Iran, et cetera.

Mr. ROGERS. Supposing a new manufacturer wants to come in.

Mr. SONNENREICH. If a new manufacturer wants to come in, he has to petition. Under the Single Convention the requirement is that there be a national or Federal agency established. What we have been going under since 1960 is there are three principal manufacturers of these drugs and they divide up the pie, as it were.

Anybody else who wants to come in, of course, has to conform to the storage facilities and everything else.

Mr. ROGERS. Suppose the quota has already been reached?

Mr. SONNENREICH. The quota can be changed and not only can it be changed in terms of new people, but it can also be changed in terms of any emergency situation and if there is an antitrust problem between these three companies. We are involved in the situation where antitrust effects are felt, and this is a consideration for the Attorney General.

Mr. ROGERS. So that there is no assurance the quota would be changed if a new manufacturer wanted to come in?

42-121—70—pt. 2——17

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

UNITED STATES GOVERNMENT DEPARTMENT OF JUSTICE

Memorandum

to : Mr. Egil Krogh **date:**

Deputy Assistant to the President for Domestic Affairs The White House

from : Donald E. Miller Chief Counsel Bureau of Narcotics & Dangerous Drugs

subject: Petition to Remove Marihuana From Control or Place in Lowest Schedule

On May 18, 1972, BNDD received a petition from the National Organization for the Reform of Marijuana (sic) Laws, petitioning the Director, as the delegate of the Attorney General, to initiate proceedings under 21 U.S.C. 811 (the Controlled Substances Act) to remove marihuana from all controls or in the alternative place it in the lowest schedule.

The alternatives available to us were as follows:

1. We could have argued that we need more time to consider the petition. We have already had the petition for two and one-half months, and the petitioners have dropped hints that they are about to file a mandamus action against the Attorney General and the Director of BNDD. Besides, we have already acted on one or two other matters that were submitted by other petitioners since May 18th.

2. We could have argued that the petitioner has no standing as an "interested party" to submit the petition. It is questionable as to whether the Circuit Court of Appeals would rule in the Government's favor.

Apparently, "Nader's Raiders" have not lost a case on this point. We may still raise the point of no standing, but it is not something we can rely on completely, and we could not deceive the courts by using it as a delay tactic knowing that if we lose, we will be back later with our real reason for rejecting the petition. If we use the point at all, we should do so as a part of the complete pleading.

3. We could rule that the Attorney General does not have the authority to grant the request of the petitioner under section 811(d), title 21, U.S. Code.

4. The final possibility is really not an alternative at all. In order to grant the petitioner's request, we would have to waive the clear intent of the Congress and initiate proceedings under section 811(a) and (b), title 21, U.S. Code. Since section 811(d) provides that all controls relating to our existing treaty obligations shall be decided by the Attorney General without adhering to the classification and hearings procedures in subsections (a) and (b) of section 811, we determined that we could not accept the petition.

There are attached two memorandums that should be read for further elaboration of why we cannot accept the petition.

The first memorandum clearly indicates that the Congress placed absolute decision-making responsibilities on the Attorney General in regard to making the determination of which schedule of the Act appropriately controls a substance controlled under our treaty obligations. Subsection (d) of section 811 specifically states that the Attorney General shall make this determination without referring the matter

to the Secretary of HEW, without findings as to a drug's effects, and without opportunity for a hearing under the Administrative Procedures Act. In other words, Congress decided that since treaties are the law of the land, the Attorney General is in the best position to interpret what controls are necessary to comply with the treaty obligations.

Subsection (d) of section 811 does not specify that the Attorney General has this authority only in the event of a new drug brought under international control by a treaty. The authority extends to any control required by our treaty obligations, and the term "control" is defined in the Act to include rescheduling of substances.

Having established that the responsibility is vested exclusively in the Attorney General to decide what schedule satisfies our treaty obligations in regard to any substance controlled by a treaty, we turn to our obligations under the Single Convention.

The other attached memorandum relates to our treaty obligations. Without going into detail, it is sufficient to say only that marihuana is controlled by the treaty, that we must limit its use for medical and scientific purposes only, that there presently is no currently accepted medical use of marihuana in treatment in the United States, and we would be in violation of our treaty obligations if we were to accept the petitioner's request to decontrol or place marihuana in Schedule V of the Act. It is in light of these obligations and the state of the medical arts that Congress placed marihuana in Schedule I -- for the same reasons, the Attorney General must keep it there until the appropriate

circumstances warrant change.

Therefore, we concluded that the only alternative was to reject the petition. The Attorney General simply has no powers to grant the petitioner's request.

The argument will be made that the authority of the Attorney General under section 811(d) is limited to newly controlled substances under the Single Convention, and that if an interested person seeks to transfer a treaty-controlled drug to a lower schedule, or to decontrol it completely, the regular control mechanism of subsections (a) and (b) of section 811 are applicable.

This could be disastrous. Subsections (a) and (b) do not authorize the Secretary of HEW to consider our treaty obligations -- his recommendations must be restricted to medical and scientific factors. Subsection (b) goes on to say that "if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or substance."

In other words, if subsection (d) is not overriding, the Secretary has the authority to decontrol marihuana completely, and the Attorney General could do nothing about it even though we would be in violation of our treaty obligations. Congress surely could not have intended such a dilemma, and from a policy standpoint we cannot decide on a course that could lead to the embarrassment of the United

States for failure to abide by a drug treaty.

No. 20-71433

In the United States Court of Appeals
for the Ninth Circuit

SUZANNE SISLEY, M.D.; SCOTTSDALE RESEARCH INSTITUTE, LLC; BATTLEFIELD FOUNDATION, DBA FIELD TO HEALED; LORENZO SULLIVAN; KENDRICK SPEAGLE; GARY HESS,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; WILLIAM BARR, ATTORNEY GENERAL; TIMOTHY SHEA, ACTING ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,

Respondents

DECLARATION OF MATTHEW C. ZORN

My name is Matthew C. Zorn. I am over the age of 21, of sound mind, and capable of making this declaration. My address is 811 Main Street, Suite 4100, Houston, Texas 77002. I declare under penalty of perjury that the foregoing is true and correct. I am of sound mind, and capable of making this declaration. I have personal knowledge of the facts stated herein.

1. I am an attorney of Yetter Coleman LLP, in Houston, Harris County, Texas. I am licensed to practice law in the State of Texas. I am one of the attorneys for petitioners in *Suzanne Sisley, M.D. v. U.S. Drug Enforcement Administration*, which is pending in the Ninth Circuit Court of Appeals, Case No. 20-71433. I have personal knowledge of the facts stated in this declaration.

2. Attached is a true and correct copy of Controls to Enhance the Cultivation of Marihuana for Research in the United States, 85 Fed Reg. 82333 (Dec. 18, 2020).

3. Attached is a true and correct copy of the December 8, 2017 Veterans Health Administration directive entitled Access to VHA Clinical Programs for Veterans Participating in State-Approved Marijuana Programs.

4. Attached is a true and correct copy of Dispensing Controlled Substances for the Treatment of Pain; Notice, 71 Fed. Reg. 52716 (Sept. 6, 2006).

5. Attached is a true and correct copy of an excerpt from Drug abuse control amendments—1970. Hearings, 91st Congress, 2d Sess., on H.R. 11701 and H.R. 13743.

6. Attached is a true and correct copy of a PDF printout of an undated memorandum from Egil Krogh, Deputy Assistant to the President for Domestic Affairs at the White House to Donald E. Miller, Chief Counsel of BNDD, that I personally printed out from the full-text database contained on the CD-ROM accompanying the book D. Musto & P. Korsmeyer, The Quest for Drug Control: Politics and Federal Policy in a Period of Increasing Substance Abuse, 1968-1981 (Yale University 2002).

Under 28 U.S.C. § 1746, I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed in Harris County, State of Texas, on the 21st day of December, 2020.

Matthew C. Zorn