

**Statement of  
Patricia Good  
Chief, Liaison & Policy Section, Office of Diversion Control  
Drug Enforcement Administration**

**Before the**

**House Committee on Government Reform  
Subcommittee on Criminal Justice, Drug Policy and Human Resources**

**April 1, 2004**

**“Marijuana and Medicine: The Need for a Science-Based Approach”**

Chairman Souder, Congressman Cummings, and distinguished members of the Subcommittee, I appreciate your invitation to testify today on the process of applying for a registration under the Controlled Substances Act (CSA) to grow marijuana for scientific research. While I cannot discuss specific pending applications or apply the relevant factors to hypotheticals, I am pleased to explain the general process.

**Bulk Manufacturing of Marijuana Registration Application Considerations**

In the United States, those that wish to cultivate marijuana to supply scientific requirements must obtain a bulk manufacturing registration from the Drug Enforcement Administration (DEA). The statutory basis for considering such applicants is contained in Title 21, United States Code, Section 823(a); these considerations are given to all those that wish to manufacture a substance controlled in Schedule I or II of the Controlled Substances Act. Briefly, the Attorney General, who has subsequently re-delegated this function to the Administrator and Deputy Administrator of the DEA, is empowered to register those whose applications are consistent with the public interest and United States' obligations under various international treaties.

The statute sets out six factors that the DEA shall consider to determine whether granting the application is in the public interest. The first factor is DEA's ability to maintain effective controls against diversion of the substance(s) into other than legitimate medical, scientific, research or industrial channels by limiting the number of bulk manufacturers to the number of establishments necessary to produce an adequate and uninterrupted supply of marijuana under adequately competitive conditions for legitimate medical, scientific, and research purposes. The second factor is the applicant's compliance with applicable State and local law. The third factor is the applicant's ability to promote the technical advances in the art of manufacturing controlled substances and the development of new substances. As a fourth factor, the DEA must consider any conviction record of the applicant under both Federal and State laws relating to the manufacture, distribution, and dispensing of controlled substances. The fifth factor is the applicant's past experience in the manufacture of controlled substances and the existence in the establishment of effective controls against diversion. Finally, the sixth factor allows the DEA to consider any other factors which are relevant to and consistent with the public interest.

## **International Treaty Considerations**

In order to determine whether the proposed application would be consistent with United States treaty obligations, as section 823(a) requires, the primary treaty obligations that DEA must take into account are those under the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971. Among the basic principles of these treaties is that the cultivation of marijuana (along with opium poppy and coca leaves) should be limited to the minimum number of producers who can provide an adequate supply to meet the country's legitimate medical, scientific, and research needs. Congress expressly incorporated this principle in subsection 823(a)(1).

## **Bulk Manufacturing of Marijuana Registration Process**

The DEA regulations provide more detailed information on the process required for obtaining a registration to bulk manufacture marijuana, as set forth in Chapter 21, Code of Federal Regulations, Section 1301.33 (21 C.F.R. § 1301.33). Briefly, applicants wishing to cultivate marijuana for scientific studies, or bulk manufacture any basic class in Schedule I for that matter, are required to submit Form DEA-225 "Application for Registration" along with the appropriate registration fee. Upon receipt of a completed application, the DEA publishes a notice of application in the Federal Register. This Notice identifies the applicant as well as the controlled substance for which the applicant has applied to manufacture. Simultaneously, a copy of the Notice is sent to each bulk manufacturer of that same controlled substance as well as the applicants. By regulation, such manufacturers and applicants have 60 days to file written comments on or objections to the proposed registration with the Administrator.

The DEA concurrently conducts an investigation of the applicant in order to obtain the information necessary to make determinations consistent with the six public interest factors previously mentioned (21 U.S.C. § 823(a)).

The DEA takes into consideration any comments or objections filed on behalf of other registered manufacturers of the same controlled substance or applicants therefore as well as the information gained during the investigation in making its decision as to whether the registration of the applicant is consistent with the public interest. In general, if no comments or objections are filed with the DEA and if the results of the investigation conclude that the registration is consistent with the public interest and that U.S. obligations under international treaties have not been contravened, then the application will be approved and a Notice of Registration is published in the Federal Register.

If the DEA seeks to deny an application for registration it must serve the applicant with an order to show cause, which provides the applicant with an opportunity for a hearing in accordance with the Administrative Procedure Act, as set forth in 21 U.S.C. section 824(c). Any applicant whose application is denied is entitled to seek review of the decision in the United States Court of Appeals, as provided in 21 U.S.C. section 877.

## **Conclusion**

The DEA will carefully consider any application for registration as a bulk manufacturer of marijuana consistent with the relevant statutory and regulatory criteria.

Mr. Chairman, thank you for the opportunity to testify here today. I will be happy to answer any questions you may have on this process.