



# OFFICES OF THE GOVERNORS

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WASHINGTON

November 30, 2011

Michele Leonhart, Administrator Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive Springfield, VA 22152

Subject: Rulemaking petition to reclassify cannabis for medical use from a Schedule I controlled substance to a Schedule II

#### Dear Administrator Leonhart:

Pursuant to Section 1308.43 of Title 21 of the Code of Federal Regulations (CFR), we hereby petition to initiate proceedings for the issuance of an amendment of a rule or regulation pursuant to Section 201 of the Controlled Substances Act (CSA). Specifically, we petition for the reclassification of medical cannabis (also known as marijuana) from Schedule I to Schedule II of the CSA.

Attached hereto and constituting a part of this petition are the following as required by the CSA and the CFR:

Exhibit A – The proposed rule. We seek the amendment of an existing rule, so pursuant to 21 C.F.R. §1308.43(6), we have included the existing rule together with a reference to the section in the CFR where it appears, along with our proposed amendment for your consideration.

Exhibit B – A statement of the grounds upon which we rely for the issuance of an amendment of the rule. As required, the grounds we rely on include a reasonably concise statement of the facts, including a summary of relevant medical or scientific evidence in the form of an eight factor analysis that the CSA specifies a petitioner must address (21 U.S.C. §811(c)). The Secretary of the United States Department of Health and Human Services (HHS) through the Food and Drug Administration (FDA) will consider these factors in a report to you for purposes of informing your final decision. The factors include: (1) actual and potential for abuse; (2) pharmacology; (3) other current scientific knowledge; (4) history and current pattern of abuse; (5) scope, duration and significance of abuse; (6) public health risk; (7) psychic or physiological dependence liability; and (8) whether it is an immediate precursor of a controlled substance.

The attached statement of grounds about the scientific and medical record, considering these eight factors, supports recognition of the accepted medical use of cannabis in the United States. Accordingly, we request you to open rulemaking to reschedule cannabis for medical purposes under the CSA from a Schedule I to a Schedule II controlled substance.

## Background:

We are concerned that patients with serious medical conditions who could benefit from medical use of cannabis do not have a safe and consistent source of the drug. As you know, sixteen states and the District of Columbia have decriminalized cannabis for limited medical purposes. Each of these jurisdictions is struggling with managing safe access to medical cannabis for patients with serious medical conditions. Our work with the federal agencies has not resolved the matter. Federal enforcement policies acknowledge the "compassionate use" for seriously ill patients, but the policies do not provide means for safe access of medical cannabis for patients in need.

The divergence in state and federal law creates a situation where there is no regulated and safe system to supply legitimate patients who may need medical cannabis. State and local governments cannot adopt a regulatory framework to ensure a safe supply is available for – and limited to – legitimate medical use without putting their employees at risk of violating federal law. As some states seek to increase regulation, United States Attorneys have warned that the federal government would prosecute "vigorously against individuals and organizations that participate in unlawful manufacturing and distribution activity involving marijuana, even if such activities are permitted under state law." Yet in the absence of state or local regulatory systems, there exists wide spread confusion and proliferation of unregulated activities.

More to the point, it is clear that the long-standing classification of medical use of cannabis in the United States as an illegal Schedule I substance is fundamentally wrong and should be changed. The federal government could quickly solve the issue if it reclassified cannabis for medical use from a Schedule I drug to a Schedule II drug. Most recently the DEA, as noted in your letter dated June 21, 2011 (published July 8, 2011 in the Federal Register), denied a 2002 petition to initiate proceedings to reschedule marijuana based on an outdated 2006 HHS/FDA scientific review. With respect to marijuana, the 2006 HHS/FDA review found: (1) the medical substance has a high potential for abuse; (2) has no currently accepted medical use in treatment in the United States; and (3) lacks accepted safety for use under medical supervision.

Upon review of the enclosed petition, we believe you will find that the mounting evidence refutes the 2006 review and shows that: (1) cannabis for medical purposes has a relatively low potential for abuse, especially in comparison with other Schedule II drugs; (2) the medical community has concluded that cannabis has accepted medical use in treatment in the United States; and (3) cannabis has accepted safety for use under medical supervision and pharmacy based access. It is now the DEA's responsibility to make appropriate decisions and update the scheduling of drugs based on the changing scientific evidence and the opinion of the medical community. We submit that evidence herein.

# The American medical community supports rescheduling, and there are safe pharmacy-based methods to dispense medical cannabis:

The medical community supports rescheduling medical cannabis. In 2009, the American Medical Association (AMA) reversed its earlier position that supported Schedule I classification of cannabis. The AMA now supports investigation and clinical research of cannabis for medicinal use, and urged the federal government to reassess the Schedule I classification. The American College of Physicians recently expressed similar support. A great many other groups also support rescheduling.

The National Academy of Sciences, Institute of Medicine perhaps states it best: "Marijuana is not, to be sure, a completely benign substance. It is a powerful drug that affects the body and mind in a variety of ways. However, except for the damage caused by smoking [which this petition clearly describes non-smoking methods for medical use], its adverse effects resemble those of many approved medications." [Italics added]

Categorizing medical cannabis as a Schedule II drug would also allow pharmacy dispensing. It requires federal changes to allow pharmacy dispensing and regulated manufacturing and distribution, otherwise pharmacies and pharmacists put their DEA license numbers at risk. There are acceptable methods to safely prescribe and dispense medical cannabis. A pharmacy based method is an existing and effective model that could provide safe and reliable access for patients in need, just like it provides for other controlled substances. The well regulated pharmacy system is perfectly suited to providing controlled access to drugs for legitimate medical use.

Recent scientific development like affordable DNA analysis also supports the pharmacy model. With modern DNA analysis, it is easy to obtain an accurate characterization of the plant's beneficial compound. At the pharmacy level, with current technology readily available today, a compounding pharmacist could easily and inexpensively quantify the levels of cannabinoids, and then use the appropriate cannabis blend to create a customized medication for an individual patient. Compounding is now increasingly offered by community pharmacies. Moreover, studies have shown that pharmacists providing compounding reported increased quality of pharmaceuticals and improved collaboration between the patient, physician, and pharmacist. This paradigm would allow safe access to a medicine with proven efficacy and acceptable safety, in a manner that does not endanger the patient and allows for reasonable governmental oversight. It is important to note that medical cannabis can be vaporized, not smoked. Additionally cannabis can be ingested orally, or applied topically in a liniment. These issues are fully addressed in Exhibit B.

### Conclusion:

A public rulemaking process would allow all interested parties to contribute their comments and expertise, and provide a full record for decision. These interested parties include patients and medical professionals and the sixteen states and the District of Columbia, or nearly one-third of the nation's population, that have decriminalized limited possession and use of cannabis for serious medical conditions, and at least ten other states are considering similar measures.

While not required by the law, we urge you to hold public hearings on these issues even before making your decision on whether to initiate formal rulemaking proceedings. You will find that physicians and scientists, mayors and county executives, sheriffs and prosecutors, and the majority of Americans based on reliable national polling, believe rescheduling medical cannabis for serious illnesses is appropriate.

Medical cannabis does have a potential for abuse, but far less so than other Schedule II substances like opiates. There are well researched accepted medical uses; there are ways to safely administer the drug; and, there are effective non-smoking methods like vaporization, oral ingestion or topical application. The exhaustive medical and scientific report attached as Exhibit B, incorporating the necessary eight factors, shows rescheduling cannabis for medical purposes is appropriate.

Current federal rules preclude the adoption of reasonable and workable frameworks for providing access to patients while maintaining the ability of law enforcement agencies to address non-medical/illegal distribution and use of cannabis. The situation has become untenable for our states and others. The solution lies with the federal government. We urge the DEA to initiate rulemaking proceedings to reclassify medical cannabis as a Schedule II drug so qualifying patients who follow state law may obtain the medication they need through the traditional and safe method of physician prescribing and pharmacy dispensing.

Thank you for your consideration.

Sincerely,

Lincoln D. Chafee

Governor of Rhode Island

Christine O. Gregoire

Governor of Washington

**Enclosures:** 

Exhibit A – Proposed Rule

Exhibit B – Statement of Grounds

The Honorable Eric Holder, U.S. Attorney General cc: The Honorable Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services The Honorable Margaret Hamburg, M.D., FDA Commissioner

Please send all notices regarding this petition to:

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