

BOARD OF PHARMACY EXAMINERS

Petition by Carl Olsen and others
for rulemaking
relating to the medical use of marijuana.

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MEMORANDUM
IN SUPPORT OF
PETITION FOR RULE MAKING

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657 IAC § 26.2**

AUTHORITY FOR SCHEDULING AND RULEMAKING

Scheduling of controlled substances in Iowa usually involves two steps. The first step is a recommendation to the Iowa Legislature from the Iowa Board of Pharmacy. The second step is approval of the recommendation from the Iowa Board of Pharmacy by the Iowa Legislature. Iowa Code § 124.201.

Iowa's Uniform Controlled Substances Act (IUCSA hereafter) differs from the Uniform Controlled Substances Act (UCSA hereafter). 9 U.L.A. 42, § 201 (1994). Under the UCSA, a state administrative agency schedules controlled substances by administrative rule. 9 U.L.A. 42, § 201(d) ("adopt and publish a rule"). The same thing is true of the federal Controlled Substances Act (CSA hereafter). 21 U.S.C. § 811(a) ("rulemaking").

The only exception to Iowa's process of scheduling controlled substances by a recommendation from the Iowa Board of Pharmacy to the Iowa Legislature is the specific instance of marijuana and only when the specific scheduling decision is specifically between Schedule I and Schedule II. Iowa Code §§ 124.204(4)(m) and 124.206(7)(a) authorizes the Iowa Board of Pharmacy to transfer marijuana from Schedule I to Schedule II by rulemaking.

The Iowa Legislature has pre-authorized the board to move marijuana from Schedule I to Schedule II whenever the board deems it necessary. Formal rulemaking is how administrative rules are made.

BACKGROUND

The Iowa Board of Pharmacy (hereinafter, "Board") first confronted the issue of marijuana's scheduling in May of 2008 when Carl Olsen (hereinafter, "Olsen") filed a petition to have marijuana removed from Schedule I of the IUCSA on the premise that marijuana now has accepted medical use in several states. See: **Exhibit #1** (the Board's October 7, 2008, denial of Olsen's petition); **Exhibit #2** (the Iowa District Court's April 21, 2009, reversal and remand of the Board's denial of Olsen's petition). On July 21, 2009, the Board issued a supplemental denial of Olsen's petition, but at the same time moved forward on its own initiative and held a series of informal town hall meetings across the state from August to November of 2009 to

determine marijuana's medical value while an appeal was pending from the supplemental denial of Olsen's petition. See: **Exhibit #3** (the Board's July 21, 2009, supplemental denial of Olsen's petition); **Exhibit #4** (the Board's July 21, 2009, announcement of a series of town hall meetings on medical marijuana to be held from August to November of 2009); **Exhibit #5** (the Board's July 29, 2010, announcement of a series of town hall meetings on medical marijuana).

On May 14, 2010, Olsen's appeal was dismissed by the Iowa Supreme Court as being moot after the Board decided on February 17, 2010, to recommend to the Iowa Legislature that marijuana be removed from Schedule I based on the series of informal town hall meetings held during the fall of 2009. See: **Exhibit #6** (the Board's February 16, 2010, meeting minutes); **Exhibit #7** (the Board's February 17, 2010, meeting agenda); **Exhibit #8** (the Board's February 17, 2010, meeting minutes); **Exhibit #9** (the Iowa Supreme Court's May 14, 2010, dismissal of Olsen's appeal).

Unfortunately, the Board overstepped its authority and made a recommendation that the Iowa Legislature convene an interim study committee to consider making marijuana available for medical use in Iowa, a matter which was currently pending before the Iowa Legislature. The Board has absolutely no statutory authority to recommend legislation other than changed in the schedules of controlled substances. This overstepping of the Board's authority clouded the issue and resulted in an observation from House Majority Leader Kevin McCarthy that the Board already has the power to do everything it was asking the Iowa Legislature to do. This seriously poisoned the water and casts doubt on whether the Iowa Legislature actually will accept the recommendation of the Board to reschedule marijuana. If the Iowa Legislature says the Board should reschedule marijuana by rulemaking, then that is what the Board must do. The Iowa Code clearly says the Board can reschedule marijuana by rulemaking, so this is not an unreasonable interpretation of the statute by House Majority Leader Kevin McCarthy. See: **Exhibit #10** (Des Moines Register, June 14, 2010, "McCarthy: No need for interim panel on medical marijuana"); **Exhibit #11** (Des Moines Register, June 16, 2010, "Regulators: Marijuana question needs lawmakers' views"). Lawmakers were already considering the question of medical marijuana before the Board weighed in on the matter.

Two plants which are currently in Schedule II in Iowa are not distributed in their natural plant form for medical use by patients in Iowa, opium poppy and coca leaf. Iowa Code §§ 124.206(2)(c) and 124.206(2)(d). The Board tied the legislative issue of a medical marijuana distribution program in Iowa to its scheduling recommendation without any logical reason for doing so. The two issues are separate and should be dealt with separately. Scheduling is the Board's responsibility. Distribution is the Iowa Legislature's responsibility.

The Iowa Legislature has not yet acted on the board's recommendation to remove marijuana from Schedule I. Olsen complained to the Iowa District Court that the failure of the Board to articulate any reason for moving marijuana from Schedule I to Schedule II would result in the failure of the Iowa Legislature to understand the Board's recommendation. Olsen and George McMahon appeared before Iowa District Court Judge Robert Hansen on June 11, 2010, predicting the Iowa Legislature would not understand the Board's recommendation, and on

June 14, 2010, House Majority Leader McCarthy said the Board already has the power to do everything it was asking the Iowa Legislature to do. Olsen's complaint was dismissed because the Board's informal town hall meetings were not formal rulemaking proceedings and did not give Olsen or McMahan any right to the formal ruling and written explanation the Board had previously promised it would make. See **Exhibit #12** (the Iowa District Court's dismissal of Olsen's complaint on August 23, 2010).

ARGUMENTS SUPPORTING RULEMAKING

The Iowa Legislature has made an exception in Iowa Code §§ 124.204(4)(m) and 124.206(7)(a) to the "recommendation" process for marijuana in Iowa Code §§ 124.201, 124.203, and 124.205, similar to the rulemaking process in the CSA. 21 U.S.C. § 811(a) ("Rules ... under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures ...").

EVIDENCE SUPPORTING RULEMAKING

There is sufficient evidence to support rulemaking.

In 1986, "the principal psychoactive substance in *Cannabis sativa L.*, marijuana" was transferred to Schedule II of the CSA. Volume 51, Federal Register, Number 92, Page 17476, Tuesday, May 13, 1986, Rules and Regulations. See **Exhibit #13**.

At its 1045th meeting, the Commission on Narcotic Drugs, in accordance with article 2, paragraphs 5 and 6, of the Convention on Psychotropic Substances, 1971, decided that delta-9-tetrahydrocannabinol (also referred to as delta-9-THC) and its stereochemical variants should be transferred from Schedule I to Schedule II of that Convention. See **Exhibit #14**.

In 1999, "the major psychoactive component of *Cannibis sativa L.* (marijuana)" was transferred to Schedule III of the CSA. Volume 64, Federal Register, Number 127, Page 35928, Friday, July 2, 1999, Rules and Regulations. See **Exhibit #15**.

In 2003, the U.S. Department of Health and Human Services registered a patent on the extraction of cannabinoids from marijuana. United States Patent No. 6,630,507 B1, October 7, 2003 ("Cannabinoids as Antioxidants and Neuroprotectants"). See **Exhibit #16**.

In 2009, the American Medical Association recommended that marijuana be removed from Schedule I of the CSA:

Conclusions. Results of short term controlled trials indicate that smoked cannabis reduces neuropathic pain, improves appetite and caloric intake especially in patients with reduced muscle mass, and may relieve spasticity and pain in patients with multiple sclerosis. However, the patchwork of state-based systems that have been established for "medical marijuana" is woefully

inadequate in establishing even rudimentary safeguards that normally would be applied to the appropriate clinical use of psychoactive substances. The future of cannabinoid-based medicine lies in the rapidly evolving field of botanical drug substance development, as well as the design of molecules that target various aspects of the endocannabinoid system. To the extent that rescheduling marijuana out of Schedule I will benefit this effort, such a move can be supported.

November 10, 2009. See **Exhibit #17**.

In 2010, the Iowa Board of Pharmacy recommended that marijuana be removed from Schedule I of the IUCSA. February 17, 2010. See **Exhibit #8**.

In 2010, the Iowa Medical Society recommended that marijuana be removed from schedule I of the IUCSA (“**RESOLVED**: That the Iowa Medical Society support the Iowa Board of Pharmacy’s reclassification of marijuana as a Schedule II controlled substance with the goal of facilitating further study into potential medical uses”). April 18, 2010. See **Exhibit #18**.

In 2010, the National Association of Boards of Pharmacy awarded the Iowa Board of Pharmacy for recommending removal of marijuana from Schedule I of the IUCSA.

Fred T. Mahaffey Award: Iowa Board of Pharmacy

In September 2003, the Iowa Board took disciplinary action against a pharmacy for providing prescription drugs outside the usual course of professional practice, and the subsequent investigation of two Internet companies uncovered the loss of over 30 million pills and resulted in multiple convictions. The Iowa Board is also being recognized for its continuous efforts to regulate medical marijuana. After a number of public hearings, many hours spent listening to patients, doctors, pharmacists, and legislators, as well as reviewing hundreds of medical articles and other state laws, the Board moved forward in its decision to recommend that the Iowa state legislature reclassify marijuana as a Schedule II controlled substance, which would allow medical uses of marijuana.

106th Annual Meeting, held May 22-25, 2010, in Anaheim, CA. See **Exhibit #19**.

CONCLUSION

The Iowa Legislature considered the classification of marijuana to be an important decision requiring formal rulemaking. The Iowa Legislature is not bound to accept the informal recommendation of the Board, but has pre-authorized the Board to make a decision by administrative rulemaking. The Board has already recommended that marijuana be removed from Schedule I. The health and welfare of Iowans is unnecessarily placed in greater jeopardy by relying solely on a “recommendation” when the law provides greater protection by formal rulemaking.

Dated this 12th day of October, 2010.

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