May 18, 2010

To the Oregon Board of Pharmacy:

Written Testimony in Support of Placing Cannabis in Schedule III of the Oregon Controlled Substances Act

In 1998 the voters of Oregon passed Ballot Measure 67, removing criminal penalties for marijuana possession for those who met certain qualifying conditions and had a recommendation from a physician. The Oregon Department of Health and Human Services has since created a registry for legally qualified cannabis users and physicians, in order to monitor program growth and to assist state and local police in managing drug enforcement encounters with legally qualified patients. However, cannabis has since remained a Schedule I substance under the Oregon Controlled Substance Act, a classification reserved for drugs that "have no accepted medical use".

To correct this discrepancy and to allow Oregon's classification of cannabis to more accurately reflect its medical acceptance and use under state law, the Oregon General Assembly passed SB 728 in 2009 which mandated that cannabis be removed from Schedule I of the Oregon Uniform Controlled Substances Act and rescheduled in one of schedules II – IV. The Oregon Board of Pharmacy has conducted hearings and received testimony to comply with the terms of this statutory mandate, and the question before it now is which schedule is the more appropriate classification for cannabis between Schedule II and Schedule III.

This written testimony is being submitted to the Oregon Board of Pharmacy in support of classifying cannabis in Schedule III. After a review of the available science and federal policy guiding the movement of drugs across schedules (specifically related to cannabis), cannabis more accurately fits within the criteria outlined for Schedule III substances.

Scheduling Criteria

In addition to Oregon statutes, regulations for controlled substances are also derived from the Federal Controlled Substances Act (1971). The Oregon Uniform Controlled Substances Act provides only limited guidance for the process of rescheduling controlled substances,[1] therefore the rescheduling procedures outlined in sections of the Federal Controlled Substances Act provide useful guidance.

The Food, Drug, and Cosmetic Act (Title 21 U.S.C.) contains two sections which identify criteria that guide the Drug Enforcement Administration (DEA)'s scheduling of controlled substances. Title 21 U.S.C. §811(c) ("Factors Determinative of Control or Removal from Schedules"), and Title 21 U.S.C. § 812(b)(1) – (5) ("Placement on schedules; findings required"). The latter section describes the specific criteria (findings) required to place of a substance in each of schedules I-V.[2]

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[1] ORS 475.035(1)

[2] Title 21 U.S.C §811 & 812.

Title 21 USC §811(c) lists 8 factors for the US Attorney General to consider in determining whether to control or remove a substance from the schedules. These are:

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

A review of whether and to what extent the substance meets each of these criteria informs the decision of the Attorney General to either schedule or not schedule the substance. If it is determined that a controlled substance meets these indicia sufficient to be placed in a schedule for control, the Attorney General is then directed to Title 21 U.S.C. §812(b) for required findings to place a drug in the appropriate schedule. Review of these 8 factors may inform these criteria, as well.

Title 21 U.S.C. §812(b) states "Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance."

The findings required for each of the schedules are as follows:

(II) Schedule II. –
- (A) The drug or other substance has a high potential for abuse.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(III) Schedule III. –
- (A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence." [3]

Application of Scheduling Criteria

Since the Oregon Board of Pharmacy is statutorily required to schedule cannabis in one of schedules II – V, the question of "whether" to schedule cannabis is not relevant. Therefore Title 21 U.S.C. §812(b) provides guidance as the federal standard. Title 21 U.S.C. §812(b) sections II & III each contain 3 standards: one standard pertains to accepted medical use, and is the same for both sections. Two additional standards are related to abuse potential. It is the findings of these two sections (a) & (c) in sections II and III which is the most relevant federal standard to guide placement of cannabis.

Pharmacologically, Delta 9-THC (the active psychoactive compound in cannabis) in the form of the marketed drug Marinol® was rescheduled to Schedule III in 1999 and thus was determined to have a low physical dependence or high rate of psychological dependence. In terms of the pharmacological effect of the psychoactive component of cannabis (Delta-9 THC), it has been determined that there is a comparatively low rate of physical dependence or high rate of psychological dependence.

There has been a longstanding effort, initiated by public advocates, to reschedule cannabis over the course of the last 40 years. This has taken form in numerous petitions, the first of which led to one of the longest running court cases in the history of the United States, lasting from 1970 until 1988 when a final ruling was issued by a DEA Administrative Law Judge in support of rescheduling out of Schedule I (the ruling and recommendations were not acted upon by DEA). During those administrative and legal proceedings, the United States Department of Health, Education, and Welfare (HEW, now the Department of Health and Human Services) conducted a scientific review of the abuse potential of cannabis in order to inform its rescheduling recommendations.

In a 1979 report entitled "Basis for Recommendations for Control of 'Marihuana'", HEW recommended that cannabis remain in Schedule I. However, the Director of HEW received the petition on court order from the United States Court of Appeals for the District of Columbia. According to the report by the HEW Director, which is contained within the Federal Register, "minimum scheduling levels dictated by the United States obligations under international treaty (Single Convention on Narcotic Drugs) were specified by the court."[4] For "cannabis and cannabis resin" HEW was not allowed to recommend scheduling below Schedule II, according to the Court's interpretation of the United States obligations for security requirements for cannabis under international treaty.

Although cannabis had already been placed in Schedule I for 8 years at the time, HEW concluded that "No convincing evidence exists to suggest that abuse of natural marihuana plant materials leads to severe psychological or physical dependence."[5] However, HEW's conclusion that cannabis should remain in Schedule I was based from a "point by point" comparison of the 3 criteria for Schedule I and

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[3] Ibid.
[4] Federal Register / Vol. 44, No. 120 / Wednesday, June 20, 1979 / p. 36125
[5] Ibid.

Schedule II, and did not include consideration of an appropriate fit within any other schedule (III – V), as this was their mandate by the Appeals Court.

This led to some rather counterintuitive conclusions. For example, HEW compared criterion (c) in Schedule I ("there is a lack of accepted safety for use of the drug or other substance under medical supervision") with criterion (c) in Schedule II ("Abuse of the drug or other substance may lead to severe psychological or physical dependence").

> "…due to the substantial unanswered questions about the efficacy and safety of medical use of these substances, it is clear that there is a lack of accepted safety for use of these substances under medical supervision. Thus, the substances do fit within the third criterion for Schedule I. They also, arguably, fall within the third criterion of Schedule II, but the fit is not nearly as good. These substances may "lead to severe psychological or physical dependence," but the evidence that they in fact do so is not strong. **Thus, however anomalous it may seem, the lack of strong evidence of severe psychological or physical dependence militates in favor of placement of Schedule I rather than Schedule II. Indeed, if it should be established that these substances do not lead to severe dependence, then placement in Schedule II would be ruled out altogether. No placement in Schedule III, IV, or V is possible unless the substances have a currently accepted medical use in treatment in the United States."** [emphasis added]

Under HEW's comparison of the criteria, cannabis was recommended to remain Schedule I in part ***because*** there was insufficient evidence of severe psychological or physical dependence. Indeed, the Director wrote that if it were determined that there was found to be no evidence of severe psychological or physical dependence, that warranted a definite placement in the more restrictive, rather than less restrictive schedule. Again, this counterintuitive reasoning was based on the fact that international law precluded any consideration by HEW of Schedules III-V, though they may have been more appropriate by strictly scientific criteria, had HEW been allowed to consider placement in these schedules.

While the question of whether HEW might have recommended a placement of cannabis in Schedule III-V is speculative, its method of reasoning – the point by point comparison of the scheduling criteria – is instructive. Comparing the criteria for Schedules II and III provide some useful insight. Determining whether cannabis "has a high potential for abuse" (Schedule II) or if it "has a potential for abuse less than the drugs or other substances in schedules I and II" (Schedule III) requires a comparison with other drugs in those schedules. Since consideration of schedule I is not an option for the Oregon Board of Pharmacy, comparisons should be limited to Schedule II.

Schedule II overwhelmingly contains drugs that are opiate based, including salts, isomers, compounds, mixtures, etc. of opiate drugs. While Schedule II also contains cocaine, its salts and derivatives, etc.,

every other drug in Schedule II is an opioid or opioid agonist (with one other exception: injectable liquids which contain amounts of methamphetamine).[6] Opioids have a well defined abuse potential, which is significantly higher than cannabis, both physicially and psychologically.

Schedule III contains amphetamines and various other psycho-stimulants, in addition to barbiturates, some of which are fatal and carry severe risk of physical dependence. One particular Schedule III drug of note is phenylcyclohexylpiperidine, commonly known as PCP, or by its street names, "angel dust" or "crystal".

In addition, the Attorney General (DEA), when determining abuse potential liability of a drug for scheduling purposes, considers known prevalence of abuse in society. To determine this, DEA relies upon government data and statistics looking at all forms of marijuana use, such as it did in initial scheduling proceedings conducted by Congress in its Report on the Drug Abuse Prevention and Control Act of 1970 of the Committee on Interstate and Foreign Commerce of the House of Representatives.[7] In that report and others like it, the federal government records all use data as "abuse". In other words, because Oregon law recognizes and sanctions the legitimate medical use of cannabis in the state, it does not consider such use of cannabis "abuse". The federal government makes no such distinction between abuse and medical use of cannabis. In data gathered by the federal government, all cannabis use is classified as "abuse". Legality of use in states without medical cannabis laws notwithstanding, it may be considered reasonable to assume that not all of that use of cannabis in the United States is actually recreational "abuse". Therefore the data that the DEA relies upon to determine the current abuse of cannabis in the US and to make a judgment of that data toward its determination of proper scheduling according to the currently sitting federal rescheduling petitions is likely not accurate.

The Oregon Board of Pharmacy should recognize this discrepancy in data collection over the true current level of abuse of cannabis, and taken in consideration with guidance from previous federal rescheduling methods, procedures, and protocols, should place cannabis in Schedule III of the Oregon Uniform Controlled Substances Act.

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[6] Title 21 U.S.C § 812 (c)
[7] Federal Register / Vol. 44, No. 120 / Wednesday, June 20, 1979 / p. 36125