

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|-----------------------|---|----------------------------|
| RECOMMENDATION TO THE |) | |
| IOWA GENERAL ASSEMBLY |) | RE: CANNABIDIOL AND |
| |) | MARIJUANA |
| |) | |

FACTUAL AND LEGAL BACKGROUND

Marijuana is currently listed in Schedule I under state law. *See* Iowa Code section 124.204(4)"m" (stating "Marijuana, except as otherwise provided by rules of the board for medicinal purposes."). Marijuana is also currently listed in Schedule II under state law. *See* Iowa Code section 124.206(7)"a" (stating "Marijuana when used for medicinal purposes pursuant to rules of the board."). In Iowa, marijuana is defined by Iowa law to include

all parts of the plants of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination.

Iowa Code section 124.101(19). Marijuana is currently listed in Schedule I under federal law. *See* 21 CFR § 1308.11(d)"23".

The Controlled Substances Act places some responsibilities on the Board as it relates to the scheduling of substances. Iowa Code section 124.201 states, in part, "the board shall recommend to the general assembly any deletions from, or revisions in the schedules of substances, enumerated in section 124.204, 124.206, 124.208, 124.210, or 124.212, which it deems necessary or advisable." In addition, Iowa Code section 124.203(2) provides:

1. The board shall recommend to the general assembly that the general assembly place a substance in schedule I if the substance is not already included therein and the board finds that the substance:
 - a. Has high potential for abuse; and

- b. Has no accepted medicinal use in treatment in the United States, or lacks accepted safety for use in treatment under medical supervision.
2. If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or remove the substance from the list of controlled substances, as appropriate.

In 2014, the Iowa General Assembly passed the Medical Cannabidiol Act. *See* Iowa Code chapter 124D. The Act permits the use of cannabidiol by patients suffering from intractable epilepsy. The Iowa General Assembly granted the authority to administer the provisions of the Act to the Iowa Department of Public Health.

RECOMMENDATION

Typically, the Board makes recommendations regarding the scheduling of substances to the Iowa General Assembly when the federal Drug Enforcement Agency (1) adds a new substance to a schedule, (2) moves a scheduled substance to a different schedule, or (3) removes a substance from scheduling. Essentially, the Board notifies the Iowa General Assembly of changes in the federal scheduling of controlled substances and recommends changes in the schedules under state law to be in accordance with federal scheduling.

Despite the passage of laws regarding marijuana in several states, it remains a Schedule I controlled substance under federal law. As a matter of policy, the federal government has allowed states, through non-enforcement of federal law, to serve as laboratories of democracy by experimenting with medical marijuana programs. This, however, is a matter of policy and not of law. The federal government may change its policy at any time, thereby nullifying any laws or programs related to marijuana enacted by any state. The Board is hesitant to recommend a change in the state scheduling of a substance that directly conflicts with federal law.

Regardless of federal law, Iowa Code section 124.203 requires that the Board recommend the removal of a substance from Schedule I if the Board finds that either (1) the substance does

not have a high potential for abuse, or (2) the substance has some accepted medicinal use in treatment in the United States. While the Board believes that marijuana has a high potential for abuse, it also believes that the passage of the Medical Cannabidiol Act is an affirmative recognition by the Iowa General Assembly that there is some medical use for marijuana, as it is defined by Iowa Code section 124.101(19). As a result of the Medical Cannabidiol Act, Schedule I is inappropriate for cannabidiol.

The Board is not inclined to make the broader recommendation that marijuana be removed from Schedule I. Many substances can be derived from marijuana—some may have a medical use, while others may not. Therefore, in the Board's opinion, it would be more accurate to schedule each derivate after an individualized analysis. The Board points out that separately scheduling a substance that is a derivative of marijuana, such as cannabidiol, should be accompanied by an amendment to the definition of marijuana in Iowa Code section 124.101(19), explicitly excluding the derivative from the definition of marijuana, in order to avoid conflict.

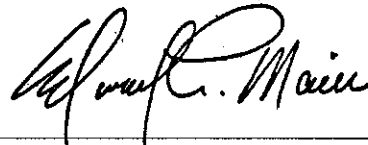
The Board believes it has an obligation under the Controlled Substances Act to recommend the proper schedule for cannabidiol. Iowa Code section 124.205 establishes the criteria for including a substance in Schedule II. The criteria are: (1) the substance has a high potential for abuse, (2) the substance currently has accepted medical use with severe restrictions in the United States, and (3) abuse of the substance may lead to severe psychic or physical dependence. The Board feels that cannabidiol meets the criteria for Schedule II, and thus recommends to the Iowa General Assembly that cannabidiol, as defined by Iowa Code section 124D.2(1), be placed in Schedule II.

The Board believes that, if the Iowa General Assembly chooses to expand the Medical Cannabidiol Act or implement a medical marijuana program, a coalition of stakeholders should

be established to further study the potential medicinal uses of marijuana or its derivatives in Iowa. These stakeholders should include, but not be limited to, the Office of Drug Control Policy, the Iowa Boards of Medicine and Pharmacy, law enforcement agencies, academia, addiction treatment specialists, and patients. It is incumbent that the establishment of a program involving marijuana or its derivatives for medicinal use includes the perspectives of all of these groups. No single entity can determine what conditions marijuana or its derivatives could be used to treat, what safety measures are needed to prevent unlawful use, and the myriad of other concerns raised by a program involving marijuana or its derivatives for medicinal use in Iowa. The Board is particularly concerned about the ability of any program to establish the standardization of dosage and potency necessary to ensure patient safety and effective treatment.

The dual scheduling of marijuana under state law is a holdover from experimental marijuana research programs authorized more than thirty years ago. The dual scheduling has understandably led to confusion as to the Board's authority to promulgate rules authorizing the legal use of medical marijuana. The Board does not believe it was the intention of the Iowa General Assembly for the Board to unilaterally establish and implement a medical marijuana program in Iowa. This is evidenced by the fact that the Department of Public Health was vested with the authority to implement the Medical Cannabidiol Act. To avoid confusion, the Board recommends that the phrase "except as otherwise provided by rules of the board for medicinal purposes" be deleted from Iowa Code section 124.204(4)"m". In addition, the Board recommends that either the entirety of Iowa Code section 124.206(7)"a" be deleted, or, at a minimum, the phrase "pursuant to rules of the board" be deleted from Iowa Code section 124.206(7)"a". References to board rules in Iowa Code sections 124.204(4)"u" and 124.207 should also be deleted to ensure consistency.

Attached are proposed legislative changes reflecting the Board's recommendations described herein.

A handwritten signature in cursive script, reading "Edward C. Maier".

EDWARD MAIER
Chairperson, Iowa Board of Pharmacy

Proposed Legislative Changes relating to Controlled Substances
January 14, 2015

An Act making changes to controlled substances schedules and making penalties applicable.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 124.101, subsection 19, Iowa Code 2015, is amended to read as follows:

19. "*Marijuana*" means all parts of the plants of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination. It does not include cannabidiol, as defined in Iowa Code section 124D.2, subsection 1.

Section 2. Section 124.204, subsection 4, paragraph "m," Iowa Code 2015, is amended to read as follows:

m. ~~Marijuana, except as otherwise provided by rules of the board for medicinal purposes.~~

Section 3. Section 124.204, subsection 4, paragraph "u," Iowa Code 2015, is amended to read as follows:

u. Tetrahydrocannabinols, ~~except as otherwise provided by rules of the board for medicinal purposes,~~ meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (Cannabis plant) as well as synthetic equivalents of the substances contained in the Cannabis plant, or in the resinous extractives of such plant, and synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

- (1) 1 cis or trans tetrahydrocannabinol, and their optical isomers.
- (2) 6 cis or trans tetrahydrocannabinol, and their optical isomers.
- (3) 3,4 cis or trans tetrahydrocannabinol, and their optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

Section 4. Section 124.204, subsection 7, Iowa Code 2015, is deleted in its entirety as follows:

~~7. *Exclusions.* This section does not apply to marijuana, tetrahydrocannabinols or chemical derivatives of tetrahydrocannabinol when utilized for medicinal purposes pursuant to rules of the board.~~

Section 5. Section 124.206, subsection 7, Iowa Code 2015, is amended by adding the following new paragraph:

NEW PARAGRAPH: xx. Cannabidiol, as defined in Iowa Code section 124D.2, subsection 1.

Section 6. Section 124.206, subsection 7, paragraph "a," Iowa Code 2015, is deleted in its entirety as follows:

- a. ~~Marijuana when used for medicinal purposes pursuant to rules of the board.~~