State of Iowa

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July 16, 1996

Carl E. Olsen
Post Office Box 4091
Des Moines, IA 50333

Dear Mr. Olsen:

I am writing in response to your letter dated June 21, 1996. In regard to Senate File 487, this legislative bill was approved on June 1, 1979. The Board of Pharmacy Examiners adopted 620 Iowa Administrative Code chapter 12 "Medicinal Use of Marijuana" on October 1, 1979. A copy of chapter 12 is enclosed per your request.

Subrule 12.3(5) called for the termination of the research program on June 30, 1981. It appears that the program ended on that date. Because of changes in Iowa Code chapter 204 as amended by 1986 Iowa Acts, chapter 1037, chapter 12 was rescinded in its entirety on January 20, 1987. Apparently, the change in the Iowa Code in 1986 eliminated the need for investigational programs on the medical use of marijuana.

In regard to the advisory group of physicians which was required to be formed seventeen years ago in 1979 pursuant to Senate File 487 and 620 I.A.C. chapter 12, these records are either no longer in existence or are nonretrievable. The current office files contain no information about the advisory group or its activities.

Sincerely yours,

Lloyd K. Jessen, R.Ph., J.D.
Executive Secretary/Director

LKJ:jh
Enc.

CHAPTER 12
MEDICINAL USE OF MARIJUANA

620—12.1(204) Purpose. To establish a research program for the investigational medical use of marijuana. Nothing in these rules will preclude the use of any available dosage forms of marijuana or tetrahydrocannabinols.

620—12.2(204) Definitions. For the purpose of these rules, the following terms shall have the meaning in this rule:

12.2(1) *"Board"* means the Iowa Board of Pharmacy Examiners.

12.2(2) *"Drug control program administrator"* or *"administrator"* means the executive secretary of the board or a person appointed by the board.

12.2(3) *"Marijuana"* means that substance as defined in section 204.101(16) Code of Iowa.

12.2(4) *"Tetrahydrocannabinols."* Isolated or synthetic equivalents of substances contained in the plant or resinous fibers of cannabis sp., and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity as defined in 204.204(4)*"q"* Code of Iowa or Part 1308.11(d)(20) Code of Federal Regulations Title 21 revised as of April 1, 1978.

12.2(5) *"Physicians advisory group"* shall mean a committee of at least three physicians organized by the board for the purpose of advising and counseling the board. This advice and counsel shall include the following areas:

a. Designation of diseases or symptomatic conditions to be treated with marijuana or tetrahydrocannabinols.

b. Recruitment and selection of qualified clinical investigators.

c. Assist in the preparation of a plan or protocol for the study which will meet FDA standards and approval.

620—12.3(204) Guidelines.

12.3(1) Physicians who wish to participate as clinical investigators shall submit their names to the administrator for approval by the physicians advisory group. The administrator shall collect such data as is deemed necessary by the advisory group and as required by the Food and Drug Administration, Public Health Service, Department of Health, Education and Welfare.

12.3(2) The administrator, with the approval of the board and the concurrence of the physicians advisory group, shall prepare and file a "Notice of Claimed Investigational Exemption for a New Drug" (FDA Form 1571) with the federal Food and Drug Administration, Department of Health, Education and Welfare.

12.3(3) Concurrent with federal approval of the "Notice of Claimed Investigational Exemption of New Drug" and thereafter, the administrator shall be responsible for insuring adherence to the approved protocol by all parties involved. The administrator shall make quarterly reports on the progress of the program to the board. The administrator shall be responsible for program compliance with all state and federal requirements.

12.3(4) Clinical investigators approved by the board will be registered in accordance with the provisions of section 204.302, Code of Iowa and with Part 1301.32(6) of Title 21 Code of Federal Regulations.

12.3(5) This research program will terminate on June 30, 1981, unless one or more of the following takes place:

a. Legislative action extends the time period.

b. Marijuana or tetrahydrocannabinols are removed from Schedule I of the Federal Controlled Substance Act (Part 1308.11, Title 21, CRF) and placed in a classification which would allow their legal medical use and distribution.

c. Termination of the FDA approval to conduct clinical investigations with marijuana.

These rules are intended to implement Acts of the Sixty-eighth General Assembly, First Session, Senate File 487.