

152.21 THC THERAPEUTIC RESEARCH ACT.

Subdivision 1. **Findings and purpose.** The legislature finds that scientific literature indicates promise for delta-9-tetrahydro-cannabinol (THC), the active component of marijuana, in alleviating certain side effects of cancer chemotherapy under strictly controlled medical circumstances.

The legislature also finds that further research and strictly controlled experimentation regarding the therapeutic use of THC is necessary and desirable. The intent of this section is to establish an extensive research program to investigate and report on the therapeutic effects of THC under strictly controlled circumstances in compliance with all federal laws and regulations promulgated by the federal Food and Drug Administration, the National Institute on Drug Abuse and the Drug Enforcement Administration. The intent of the legislature is to allow this research program the greatest possible access to qualified cancer patients residing in Minnesota who meet protocol requirements. The establishment of this research program is not intended in any manner whatsoever to condone or promote the illicit recreational use of marijuana.

Subd. 2. **Definitions.** For purposes of this section, the following terms shall have the meanings given.

(a) "Commissioner" means the commissioner of health.

(b) "Marijuana" means marijuana as defined in section 152.01, subdivision 9, and delta-9-tetrahydro-cannabinol (THC), tetrahydrocannabinols or a chemical derivative of tetrahydrocannabinols, and all species of the genus *Cannabis*.

(c) "Principal investigator" means the individual responsible for the medical and scientific aspects of the research, development of protocol, and contacting and qualifying the clinical investigators in the state.

(d) "Clinical investigators" means those individuals who conduct the clinical trials.

(e) "Sponsor" means that individual or organization who, acting on behalf of the state, has the total responsibility for the state program.

Subd. 3. **Research grant.** The commissioner of health shall grant funds to the principal investigator selected by the commissioner pursuant to subdivision 4 for the purpose of conducting a research program under a protocol approved by the FDA regarding the therapeutic use of oral THC and other dosage forms, if available, according to the guidelines and requirements of the federal Food and Drug Administration, the Drug Enforcement Administration and the National Institute on Drug Abuse. The commissioner shall ensure that the research principal investigator complies with the requirements of subdivision 5. The commissioner may designate the principal investigator as the sponsor.

Subd. 4. **Principal investigator.** Within three months of April 25, 1980, the commissioner shall, in consultation with a representative chosen by the state Board of Pharmacy and a representative chosen by the state Board of Medical Examiners, select a person or research organization to be the principal investigator of the research program.

Subd. 5. **Duties.** The principal investigator shall:

(1) apply to the Food and Drug Administration for a notice of "Claimed Investigational Exemption for a New Drug (IND)" pursuant to the Federal Food, Drug and Cosmetic Act, United States Code, title 21, section 301, et seq., and shall comply with all applicable laws and regulations of the federal Food and Drug Administration, the Drug Enforcement Administration, and the National Institute on Drug Abuse in establishing the program;

(2) notify every oncologist in the state of the program, explain the purposes and requirements of the program to them, provide on request each of them with a copy of the approved protocol which shall include summaries of current papers in medical journals reporting on research concerning the safety, efficacy and appropriate use of THC in alleviating the nausea and emetic effects of cancer chemotherapy, and provide on request each of them with a bibliography of other articles published in medical journals;

(3) allow each oncologist (clinical investigator) in the state who meets or agrees to meet all applicable federal requirements for investigational new drug research and who so requests to be included in the research program as a clinical investigator to conduct the clinical trials;

(4) provide explanatory information and assistance to each clinical investigator in understanding the nature of therapeutic use of THC within program requirements, including the informed consent document contained in the protocol, informing and counseling patients involved in the program regarding the appropriate use and the effects of therapeutic use of THC;

(5) apply to contract with the National Institute on Drug Abuse for receipt of dosage forms of THC, fully characterized as to contents and delivery to the human system, pursuant to regulations promulgated by the National Institute on Drug Abuse, and the federal Food and Drug Administration. The principal investigator shall ensure delivery of the THC dosages to clinical investigators as needed for participation in the program;

(6) conduct the research program in compliance with federal laws and regulations promulgated by the federal Food and Drug Administration, the Drug Enforcement Administration, the National Institute on Drug Abuse, and the purposes and provisions of this section;

(7) submit periodic reports as determined by the commissioner on the numbers of oncologists and patients involved in the program and the results of the program;

(8) submit reports on intermediate or final research results, as appropriate, to the major scientific journals in the United States; and

(9) otherwise comply with the provisions of this section.

Subd. 6. Exemption from criminal sanctions. For the purposes of this section, the following are not violations under this chapter:

(1) use or possession of THC, or both, by a patient in the research program;

(2) possession, prescribing use of, administering, or dispensing THC, or any combination of these actions, by the principal investigator or by any clinical investigator; and

(3) possession or distribution of THC, or both, by a pharmacy registered to handle Schedule I substances which stores THC on behalf of the principal investigator or a clinical investigator.

THC obtained and distributed pursuant to this section is not subject to forfeiture under sections 609.531 to 609.5316.

For the purposes of this section, THC is removed from Schedule I contained in section 152.02, subdivision 2, and inserted in Schedule II contained in section 152.02, subdivision 3.

Subd. 7. Citation. This section may be cited as the "THC Therapeutic Research Act."

History: 1980 c 614 s 93; 1988 c 665 s 2; 1989 c 290 art 3 s 23; 1997 c 7 art 2 s 22