

## POSITION STATEMENT ON "MEDICAL" MARIJUANA IN THE STATE OF FLORIDA

There is growing pressure being placed on the members of the Florida legislature to pass legislation to legalize cannabis for "medical" purposes. Some believe that if the legislature does not take such action, the state will be faced with another ballot initiative in 2016 that will seek to legalize "Medical Marijuana" and there is a high probability that it would pass thus embedding the issue in the state constitution. Others believe that no matter what the legislature does or does not do, the legalization advocates will not be happy and, therefore, an initiative will be placed on the ballot anyhow.

It is the belief of many that a new "Medical Marijuana" law is not needed in the state of Florida because patients already have the following options that should be adequate:

- the low THC bill commonly referred to as the Charlotte's Web Bill, also known as Senate Bill 1030;
- the FDA-approved synthetic THC medication known as Marinol;
- the CBD-extract medication known as Epidiolex that is undergoing the FDA process and is currently available in Florida through clinical trials; and
- Florida Statutes 893.13 and 893.05 which allow for patients to be exempt from prosecution for the possession of marijuana if they can establish legitimate medical necessity for using it.

Should any attempts be made in the Florida legislature to advance a "Medical Marijuana" bill it is imperative that, at a minimum, any bill should take into consideration and close loopholes that have been found in other states with "Medical Marijuana" laws and also should follow the guidelines that were issued by the Institute of Medicine for allowing marijuana to be used as a medicine. Any such bills would, therefore, need to adhere to the guidelines that were issued in 1999 by the Institute of Medicine ([http://books.nap.edu/openbook.php?record\\_id=9586&page=174](http://books.nap.edu/openbook.php?record_id=9586&page=174)), as well as lessons learned from other states, that include at a minimum the following:

### **PATIENT REQUIREMENTS**

- Only allow for the use of a cannabis extract; not smoked marijuana, including prohibition of the use in electric cigarettes.
- Only allow for the use of a cannabis extract that is obtained from a state-licensed nonprofit co-op.
- Qualifying patient must be defined as a Florida resident who is 21 years of age or older. (We already have the low-THC legislation for minors.)
- Require that a panel of doctors review each case individually and concur that it is appropriate for that individual to use to treat his/her specific condition and provide documentation of this review to a governing body (Department of Health, herein identified as the Department) and issue a recommendation.
- Require all patients to apply for and obtain a photo ID card to be issued by the Department which authorizes the use of "Medical Marijuana."

- Require that ID cards issued to patients who have not been diagnosed with a terminal illness only be valid for 6 months. Any such renewal requests would require the cardholder to repeat the entire application process and apply for a new card.
- Restrict possession of cannabis extract to no more than 1 ounce of usable product.
- Restrict use of the cannabis extract to the privacy of one's home; no public use, no use in "private clubs."

#### **RECOMMENDING PHYSICIANS REQUIREMENTS**

- Require any physician who recommends marijuana to be certified by the Department. The certification requirements include:
  - physicians must have training or certification in addiction medicine;
  - physicians must demonstrate knowledge of the physiological effects of marijuana, its side effects, and its interaction with other drugs before recommendation; and
  - physicians must have a DEA issued license that is required for dispensing controlled substances.
- Require the Department to establish a Standard of Care for physicians recommending marijuana to a patient. Standard of Care guidelines should require:
  - documentation demonstrating that the patient has had failure of all other conventional medication to treat his or her condition;
  - that the patient sign an informed consent document regarding the medical risks of the use of marijuana (this document should at minimum include risk of infection, pulmonary complications, suppression of immunity, impairment of driving skills and habituation.);
  - compilation of documentation on a patient's history as to past marijuana use or other psychoactive and addictive drugs;
  - physician requirement to consult the Prescription Drug Monitoring Program prior to making or issuing a recommendation to use marijuana as a medicine;
  - monthly drug testing of all patients who have been recommended to use marijuana and exclude all patients who are found to be using other illicit drugs;
  - monthly follow up examinations of patients who use marijuana as a medical treatment to include pulmonary function testing, evaluation of the immune system, and the presence of any superadded infection;
  - the exercise of due care by the recommending physician in assuring the standardization of the THC potency content of the marijuana extract to be considered for the medicinal use and whether it is free of microbial contaminants;
  - careful review of exactly which patients should be allowed to use this drug medicinally and for how long;
  - requirement by recommending physician to comply with reporting recommendation to the Department for a statewide tracking system; and
  - no physician shall issue a recommendation to him or herself;

- Require that recommendations for “Medical Marijuana” be written and signed by the physician and contain a specific dosage amount, THC level, and instructions on how often to administer the substance.
- Require the Department to establish an investigational review board that will:
  - monitor physicians who recommend the medical use of marijuana to ensure they are following the guidelines put forth in the Standard of Care;
  - require that all patients using marijuana as a medicine take part in a study or clinical trial to further research the potential therapeutic values of marijuana; and
  - require physicians to provide valid research indicating marijuana is an effective treatment for the disease or condition the patient is treating.

### **CAREGIVER REQUIREMENTS**

- Allow for Caregivers to assist patients. A Caregiver must:
  - be 21 years or older;
  - not be a felon;
  - have medical training as determined by the Department or be the legally designated health care surrogate for the qualifying patients; and
  - assist no more than one patient.
- Restrict each patient to having only one designated “Caregiver.”
- Restrict possession of the usable marijuana product to no more than one (1) ounce.

### **CULTIVATION AND DISTRIBUTION REQUIREMENTS**

- Ban the commercialization of “Medical Marijuana” by prohibiting for-profit dispensaries and the sale of marijuana-infused products.
- Allow for the establishment of no more than five (5) not-for-profit co-ops statewide that would grow and harvest cannabis plants, perform the extraction of the THC and/or CBD from the cannabis plant, and provide the extract to the patient.
- Require the Department to license and regulate not-for-profit co-ops with minimum requirements that include:
  - a fee associated with registration that would go to the Department to fund inspectors that would ensure regulations;
  - rules on cultivation that would include at a minimum:
    - an enclosed locked and secured facility to cultivate plants;
    - safety and security procedures and other regulations for cultivation and harvesting of the plant; and
    - safety procedures and other regulations for the performance of the extraction of the THC and/or CBD from the cannabis plant.
  - rules on dispensing that would include at a minimum:
    - dispensing no more than one (1) ounce of usable marijuana extract at a time to qualifying patients or Caregivers;

- verification that patients and Caregivers possess a valid and current state-issued ID that permits them to obtain “Medical Marijuana”;
- requiring that all dispensed products be packaged in a manner consistent with child-proof prescription bottles;
- requiring that all dispensed products have labeling that includes THC potency, disclosure that the product has not been evaluated by the FDA and is not intended to diagnose, treat, cure, or prevent any disease and warnings about potential side effects and drug interaction. (These disclosures are required on “health food” products that are not FDA approved.)
- rules on extracting the THC and CBD that would include at a minimum:
  - safety and quality control procedures.

### **OTHER FUNDING, REPORTING AND REGULATIONS REQUIREMENTS**

- The legislature shall adequately fund the inspection and enforcement of the cultivation, manufacturing and distribution of “medical marijuana.”
- The legislature shall seek a federal waiver to allow a Florida research institution to grow, study and publish academic research on the medicinal value of marijuana.
- The Department shall establish and maintain a database of patients and Caregivers that is accessible by recommending physicians and law enforcement.
- The Department shall establish a system for testing the potency of the cannabis products that are cultivated and distributed by the licensed co-ops.
- The Department shall establish penalties for violations by the non-profit co-ops; three (3) or more violations shall result in suspension or permanent revocation of license to operate in the state of Florida.
- The Department shall establish penalties for violations of any established rules by patients and Caregivers; three (3) or more violations shall result in suspension or permanent revocation of state-issued ID cards.
- The Department shall establish an independent committee to monitor the program’s impact to public health and public safety. The committee would report its findings yearly to the legislature who would be empowered to take any and all corrective action needed, including repeal of the law. Monitoring would include at minimum:
  - marijuana-related traffic fatalities and injuries;
  - marijuana-related workplace incidences;
  - adolescents youth use rates and perception of harm statistics;
  - ER admission rates; and
  - school drop-out and expulsion rates.