



**Testimony pertaining to the use of “medical” marijuana as pertaining to
SB 1064
Submitted on March 12, 2015
To the Connecticut Senate**

Dear Members of the Connecticut Senate:

We respectfully request that this testimony, on behalf of Save Our Society From Drugs, a national drug policy organization with members in the state of Connecticut be included in any discussions that pertain to *Raised Bill No. 1064: An Act Concerning the Palliative Use of Marijuana*:

The additions to this bill that we are particularly concerned about are:

- Provide for licensure of medical marijuana laboratories
- Provide for the establishment and approval of medical marijuana research programs
- Allow licensed producers and dispensary facilities to sell and transport medical marijuana to licensed laboratories and health care facilities
- Expand the definition of "qualifying patient"
- Ease restrictions on the membership of the Board of Physicians.

Save Our Society From Drugs (S.O.S.) is opposing the following additions and will provide a detailed testimony in opposition to the additions in SB 1064. S.O.S. is eminently qualified to provide this testimony. S.O.S. has more than ten years of experience in monitoring and making policy recommendations on drug policy issues including those pertaining to “medical” marijuana. S.O.S. understands the need for a comprehensive approach to promote sound drug policy that includes education, prevention, abstinence-based treatment, scientific research, and community awareness. Our members include doctors, researchers, law enforcement officials, business leaders, lawyers, and parents.

Provide for licensure of medical marijuana laboratories and the establishment and approval of medical marijuana research programs

What you need to know about marijuana and research

Marijuana has not been accepted as medicine because it hasn't met key criteria, which includes:

- Its chemical composition is variable; safe and effective dose ranges (and plant strain) for each medical condition is uncertain and unresolved.
- Efficacy criteria have not been fulfilled by rigorous research.
- Safety studies are inadequate; a growing body of scientific evidence shows that marijuana use is unsafe and associated with unhealthy outcomes.
- There is no consensus by qualified experts that marijuana is a medicine.

- Raw data is not available.

Why Raised Bill No. 1064 is bad for Connecticut and ultimately the United States

- It is dangerous to allow a political movement set forth by state legislation, circumvent the federal Food and Drug Administration's rigorous and carefully crafted process – especially when this legislation is in direct conflict with federal laws.
- Raised Bill # 1064 proposes to create a research program on marijuana as a medicine. The federal Food and Drug Administration (FDA) already performs the function of research on medicines and has done so for 100 years. They are currently working on approving marijuana based medicines. There is no need to replicate this on the state level. The state will not be able to match the resources of the FDA and it is a waste of Connecticut's public funds too.

Connecticut legislators have a responsibility to protect their citizens by implementing safe legislation – This is not safe!

Any research that is done on marijuana as medicine, or that is considered as evidence of the effectiveness of marijuana as medicine, should take into account the below recommendations from the Institute of Medicine for research on non-smoked marijuana. The use of smoked marijuana is inherently dangerous. Smoking is a very poor way to deliver a drug because we cannot calculate the dose of smoked marijuana because we can't determine how much is actually inhaled. In addition, the harmful chemicals and carcinogens that are byproducts of smoked marijuana create new health problems. The smoking of marijuana has significant risks. For a drug to be acceptable, its beneficial results must outweigh the adverse effects, especially when the advocates argue for its repeated use for symptomatic relief. *Reference: "Smoked Marijuana as Medicine: Not Much Future," Clinical Pharmacology & Therapeutics (2008), H Kalant, Department of Pharmacology, University of Toronto, Toronto, Ontario, Canada*

Recommendation 1: Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body. Because different cannabinoids appear to have different effects, cannabinoid research should include, but not be restricted to, effects attributable to THC alone.

Recommendation 2: Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems.

Recommendation 3: Psychological effects of cannabinoids such as anxiety reduction and sedation, which can influence perceived medical benefits, should be evaluated in clinical trials.

Recommendation 4: Studies to define the individual health risks of smoking marijuana should be conducted, particularly among populations in which marijuana use is prevalent.

Recommendation 5: Clinical trials of marijuana use for medical purposes should be conducted under the following limited circumstances: trials should involve only short-term marijuana use (less than six months); be conducted in patients with conditions for which there is reasonable expectation of efficacy; be approved by institutional review boards; and collect data about efficacy. *Source: Marijuana and Medicine: Assessing the Science Base. Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors. Division of Neuroscience and Behavioral Health. Institute of Medicine, National Academy of Sciences. National Academy Press, Washington D.C., 1999.*

In addition, all such studies should be FDA quality and should include:

1. Independent verification - the study is not financed by the industry that has a financial gain to be had on the study's outcome.
2. Double-blind controls.
3. Study done on a significant patient population.
4. Peer reviewed and published in a respectable journal dedicated to medicine or the particular illness.
5. Controlled comparison to existing medications for the particular illness.

Ease restrictions on the membership of the Board of Physicians.

This legislation seeks to eliminate an expert Board of Physicians, virtually “dumbing” it down. The question is why? One might consider this to be effort to locate any physician who will agree with so-called medical marijuana. Perhaps it is difficult to find the specified experts outlined in the original bill to serve on such a board, why? If you look at the major medical organizations who oppose crude marijuana you may find the answer. The Connecticut legislature should be consulting with these respected medical organizations such as the American Medical Association, the American Psychiatric Association, the American Academy of Pediatrics, the National Multiple Sclerosis Society and the American Cancer Society (all of which oppose crude marijuana as medicine.)

Expand the definition of "qualifying patient"

This may be the most alarming addition to this bill, which would allow access of marijuana to those under 18. We know marijuana use poses significant health concerns.

The following concerns associated with long term marijuana use, are increasingly supported by research:

- Brain changes in structure, circuitry, biochemistry, function
- Association with psychosis, correlated with marijuana strength, use levels
- Earlier age of onset of schizophrenia
- Reduced IQ, with early initiation and continued abuse
- Compromised cognitive ability, executive function after acute effects wane
- Marijuana addiction in a significant number of frequent users, with increased risk for addiction to other drugs
- Amotivational syndrome

- Increased traffic accidents and mortality
- Increased school drop-outs, compromised academic and work achievement
- Compromised lung and heart function

A brain is not fully developed until after age 24. Research has shown marijuana is detrimental to the developing brain. Here are concerns regarding youth use:

- Young people using marijuana frequently experience an increased risk of schizophrenia and greater levels of depression including being three times more likely to have suicidal thoughts.
- Marijuana-using teens are more likely to have multiple sexual partners and engage in unsafe sex.
- Marijuana use has been shown to permanently impair brain development in youth.
- Learning skills such as problem solving, concentration, motivation and memory are negatively affected.
- The number of teenage and adult users would increase if marijuana was legalized.
- The number would double and most likely triple. There are 16.7 million regular marijuana users.
- The increase would mean an additional 17 to 34 million users in the United States.
- Teens' perceptions of the harmfulness of marijuana are down, which could lead to increased use of the drug. According to the Monitoring the Future Survey, only 41% of eighth graders see occasional use of marijuana as harmful; 66.9% see regular use as harmful. Both rates are at the lowest since the survey began tracking risk perception for this age group in 1991. Only 20.6% of 12th graders see occasional use as harmful (lowest since 1983), and 44.1 % see regular use as harmful, the lowest since 1979.
- Studies shows that persistent use of cannabis from childhood to adulthood was associated with neuropsychological decline presenting as an average 8-point IQ decline.

There is also a growing body of research that indicates marijuana use induces psychosis and exacerbates mental illness. The most recent study published in the *Lancet*, looked at those who frequently use a certain high potency cannabis, known as "skunk," in south London (UK) and the association between this use and psychotic disorders.

A team of twenty-three scientists showed that those who use "skunk" cannabis with approximately 16% THC (the marijuana compound that causes intoxication) and no CBD (a non-euphoric marijuana compound) were up to 5 times more likely to have a psychotic disorder as compared to non-users. Further, high potency cannabis use alone was responsible for 24% of adults seeking psychiatric assistance for their first episode of psychosis in that community.

Further, Marijuana is not harmless or resistant to abuse. Research increasingly shows that intensive marijuana use often meets the technical requirements for addiction or dependence. According to the 2012 National Survey on Drug Use and Health, marijuana was the illicit drug with the highest rate of past year dependence or abuse. In 2012, 5.4 million persons aged 12 or older used marijuana on a daily or almost daily basis in the past 12 months, which was an increase from the 3.1 million daily or almost daily marijuana users in 2006. The number of daily or almost daily users of marijuana in 2012 represented 17.0 percent of past year users.

What about a low-THC strain of marijuana for use in producing crude CBD oil for children with severe forms of epilepsy?

THC has been shown to have undesirable effects on young brains and grand mal seizures have been recorded after marijuana use. Science has shown that marijuana can cause permanent brain damage and other health problems and there may be other dangers that are not yet known. Crude CBD oil has never been clinically tested, a process that would identify side effects or problems that may be encountered through the interaction with other drugs.

CBD found in marijuana has, however, demonstrated some promise in controlling epileptic seizures and this finding has resulted in several treatment programs using an expanded access Investigational New Drug Application (IND) filed and approved by the Food and Drug Administration. As of January 2015, GW Pharmaceutical reported in a press release, "FDA has granted 20 expanded access IND's and 7 individual emergency IND's to independent investigators in the U.S. to treat approximately 410 children and young adults with intractable epilepsy with Epidiolex in the U.S. at 15 clinical sites."

Expanding access to Epidiolex clinical trials would allow physicians and patients access to the Drug Master File (DMF) with data from pre-clinical animal studies to rule out birth defects, detailed drug composition (each dose will be same as previous or future doses), how the drug is manufactured in order to be used in humans, stability of the drug, a metabolism profile and other data. The compilation of a DMF costs millions; dismissing an opportunity to utilize this data and instead push forward an unregulated, unapproved crude oil as medicine takes us back to the days of snake-oil opportunists.

Below are possible solutions that we believe would be in the best interests to patients by providing real medicine for those who truly need it and the best interest of the state by eliminating the diversion for recreational use seen in other state medical marijuana programs.

1. The Connecticut Legislature could authorize a Demonstrational Project at an accredited research university and file an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration (FDA) to obtain Epidiolex from GW Pharmaceutical which is manufactured under Good Manufacturing Procedures (cGMP) and use the Drug Master File already on file for Epidiolex. The site would also register with the DEA for clinical trials to move forward principal investigators' authority. This could be funded by the legislature as a Demonstrational Project or a State Sponsored IND and the clinical trials would be state-owned.
2. Similar to the above option, the legislature could fund a clinical trial site at one of Connecticut's research universities, but instead of an IND the site would operate under a GW Pharmaceutical IND. GW would provide the drug and combine clinical data from this site with their other sites for national research. This would be GW owned and would be the most expeditious option.
3. The state could file an IND with the university and petition the National Institute on Drug Abuse (NIDA) for pure CBD that NIDA currently has in stock for human experiments

manufactured under (cGMP). In this option, the site would use NIDA's Master Drug File and do trials on pure CBD (not use Epidiolex as in the above options).

Citizens of Connecticut deserve medical treatment that is based on both compassion and scientific research. I hope you will consider these findings and possible alternatives.

Allow licensed producers and dispensary facilities to sell and transport medical marijuana to licensed laboratories and health care facilities

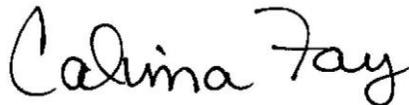
This bill will make it easier to transport marijuana between states. We already have a big problem with the trafficking of marijuana on the national level. Why make this worse? State-to-state transport of marijuana will open the floodgates for drug traffickers to expand their businesses. Allowing inter-state distribution of marijuana could open the state of Connecticut up to lawsuits by neighboring states who have not legalized marijuana. For instance Nebraska and Oklahoma are suing Colorado because Colorado's marijuana is being trafficked in these states and draining their law enforcement resources along with taxpayer dollars.

If state legislators want to tread down the dangerous and irresponsible path of circumventing the FDA process, they should follow the same guidelines that have protected the public for decades in this country. Research that should be conducted in order to reschedule marijuana must include:

- the drug's actual or relative potential for abuse,
- scientific evidence of the drug's pharmacological effects,
- the state of current scientific knowledge regarding the substance,
- its history and current pattern of abuse,
- the scope, duration, and significance of abuse,
- what, if any, risk there is to the public health,
- the drug's psychic or physiological dependence liability, and
- whether the substance is an immediate precursor of a substance already controlled.

Thank you for allowing us to submit testimony on these important issues. I hope that you will carefully consider our findings and reject Raised Bill No. 1064.

Respectfully Submitted,



Calvina Fay
Executive Director