

Good Morning, my name is Karolin Regan, I am a Licensed Clinical Social Worker and Program Director at Guilford Youth & Family Services in Guilford, Ct. I am here today to speak on the DCP regulations concerning the Palliative use of Marijuana.

Guilford Youth & Family Services surveyed Guilford youth in grades 7-12 in 2010 and 2012. It appears the decriminalization of marijuana contributed to Guilford kids' belief that marijuana is not a problem. In 2010, 22% of Guilford kids in grades 7-12 believed there was no risk or slight risk from using marijuana regularly. After decriminalization that percentage increased to 35%. There was no similar increase for alcohol, prescription drugs, cocaine, heroin or other illegal substances. I am here today to protect the youth in Guilford and in the State of Connecticut by having a voice in this matter to prevent unintended access and appeal to youth and to urge scientific studies on the risks and benefits of palliative use of marijuana.

The U.S. Food and Drug Administration (FDA), which provides a scientific and medical evaluation of drugs, maintains that marijuana is a Schedule I drug. Schedule I substances are those that have the following findings: (A) The drug or other substance has a high potential for abuse; (B) The drug or other substance has no currently accepted medical use in treatment in the United States; and (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

If marijuana is a Schedule 1 drug, how can it be regulated as a medicine?

Marijuana has a significant potential for abuse:

-Children and teens are six times likelier to be in treatment for marijuana addiction than for all other illegal drugs combined¹.

-More than two-thirds of treatment admissions involving those under the age of 18 cite marijuana as their primary substance of abuse, more than three times the rate for alcohol and more than twice for all other drugs combined².

-Overall, Marijuana is the most commonly abused illicit drug in the United States³.

Clinical trials that identify the risks and benefits of the palliative use of marijuana need to be conducted. If it is deemed a medicine, proper dosing needs to be identified.

In Section 21a-408-1 (29) of the draft regulations – “Dispensing error” means an act or omission relating to the dispensing of marijuana that results in, or may reasonably be expected to result in, injury to or death of a qualifying patient or results in any detrimental change to the medical treatment for the patient.

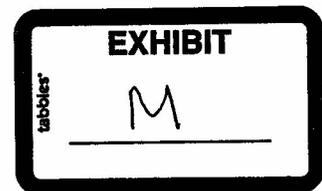
With its great potential for abuse, how will dosing be identified?

How will adverse effects be identified?

What about contraindications with other medications?

If marijuana is deemed a medicine, further research, scientific studies and clinical trials are necessary before moving forward with these regulations.

-Cannabis impairs cognitive and psychomotor performance. The effects are similar to those of alcohol and benzodiazepines and include slowing of reaction time, motor incoordination, specific defects in short-term memory, difficulty in concentration and particular impairment in complex tasks which require divided attention. The effects are dose-related but can be demonstrated after relatively small doses (5±10 mg THC in a joint), even in experienced cannabis users, and have been shown in many studies across a wide range of neurocognitive and psychomotor tests. These effects are additive with those of other central nervous system depressants⁴. In addition, there are long-term effects of chronic use. There is considerable evidence (reviewed by Hall et al 1994) that



performance in heavy, chronic cannabis users remain impaired even when they are not actually intoxicated. These impairments, especially of attention, memory and ability to process complex information, can last for many weeks, months or even years after cessation of cannabis use⁴.

With this evidence of impairment, it is critical that clinical trials are completed to identify risks and benefits of the palliative use of marijuana.

Here are some statements from medical organizations regarding prescribing marijuana as medicine. Links to the full articles are included.

-American Glaucoma Society (AGS) states that marijuana's mood altering side effects and short duration of action, coupled with a lack of evidence that its use alters the course of glaucoma, preclude recommending this drug in any form for the treatment of glaucoma at the present time. The organization's full position statement can be found here:

http://www.americanglaucomasociety.net/patients/position_statements/marijuana_glaucoma

-The American Academy of Ophthalmology (AAO) states that no scientific evidence has been found that demonstrates increased benefits and/or diminished risks of marijuana use to treat glaucoma compared with the wide variety of pharmaceutical agents now available. The organization's full position statement can be found here:

http://one.aao.org/CE/PracticeGuidelines/Therapy_Content.aspx?cid=9871fa42-cf40-4c1f-b05c-c816d5f93126

-National Comprehensive Cancer Network (NCCN) has stated that the use of marijuana is not recommended for management of chemotherapy-induced nausea and vomiting, and is not part of the NCCN Clinical Practice Guidelines of Oncology in Antiemesis. The organization's journal article on this issue can be found here:

<http://www.jnccn.org/content/10/4/487.abstract>

-The American Academy of Child and Adolescent Psychiatry (AACAP) has stated its concern about the negative impact of "medical" marijuana on youth. Adolescents are especially vulnerable to the many adverse developmental, cognitive, medical, psychiatric, and addictive effects of marijuana. Of particular concern to our field, adolescent marijuana users are more likely than adult users to develop marijuana dependence, and their heavy use is associated with increased incidence and worsened course of psychotic, mood, and anxiety disorders. Furthermore, marijuana's deleterious effects on cognition and brain development during adolescence may have lasting implications. The organization's journal article on this issue can be found here:

http://www.aacap.org/cs/root/policy_statements/aacap_medical_marijuana_policy_statement

-National Multiple Sclerosis Society (NMSS) states that there are serious uncertainties about the benefits of marijuana relative to its side effects and that studies completed thus far have not provided convincing evidence that marijuana or its derivatives provide substantiated benefits for symptoms of MS. The organization's journal article on this issue can be found here:

<http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/complementary--alternative-medicine/marijuana/index.aspx>

Section 21a-408-2 (6&8) – Physician's requirements for issuing written certification to the department states..the physician-

Be reasonably available to provide follow-up care and treatment to the qualifying patient including, but not limited to, physical examinations, to determine the efficacy of marijuana for treating the qualifying patient's debilitating medical condition or the symptom of the debilitating medical condition for which the written certification was issued.

Explain the potential risks and benefits of the palliative use of marijuana to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent, guardian or person having legal custody of the qualifying patient, prior to submitting the written certification.

How will physicians determine the efficacy of marijuana for treating the patient's debilitating medical condition?

What are the potential risks and benefits of palliative use of marijuana for each debilitating condition defined in the regulations?

Have they been identified and what scientific research was used?

Section 21a-408-1 (28) "Dispense" or "dispensing" means those acts of processing marijuana for delivery or for administration for a qualifying patient pursuant to a written certification consisting of (A) comparing the directions on the label with the instructions on the written certification, if any, to determine accuracy; (B) the selection of the appropriate marijuana product from stock; (C) the affixing of a label to the container; and (D) the provision of any instructions regarding the use of the marijuana.

How will the directions on the label be determined?

Who will define what the "appropriate" marijuana from stock will be?

Will that information be based on scientific studies?

Who will define instructions regarding the use of marijuana?

How will dosages be determined?

Section 21a-408-1 (43) – "One-month supply" means the amount of marijuana reasonably necessary to ensure an uninterrupted availability of supply for a period of one month for qualifying patients, which amounts, including amounts for topical treatments, shall be determined by the commissioner on the basis of practical administration of the Act, available research and recommendations from the Board of Physicians.

What is practical administration of the Act?

What is the current available research that you are using to determine the "one-month supply"?

Thank you for your time. I respectfully request that further clinical trials on the palliative use of marijuana be implemented to determine risks and benefits associated with marijuana use. I also recommend that if marijuana is to be used as a medicine that further clinical studies are done to identify appropriate dosing.

CITATIONS

1. The National Center on Addiction and Substance Abuse (CASA) at Columbia University. CASA white paper, *Non-Medical Marijuana II: Rite Of Passage Or Russian Roulette?* 2008.
2. Substance Abuse and Mental Health Services Administration. 2009. Office of Applied Studies. Treatment Episode Data Set (TEDS): 2009 Discharges from Substance Abuse Treatment Services, DASIS.
3. National Institute on Drug Abuse. 2010. InfoFacts, Marijuana. Available: <http://www.drugabuse.gov/publications/drugfacts/marijuana>
4. Ashton, H.C. 2001. "Pharmacology and effects of cannabis: A brief review." *British Journal of Psychiatry*, 178:101-106.

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