



Concerns Regarding HB 63

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We have significant concerns regarding HB 63, a bill that seeks to amend low-THC marijuana legislation previously passed in the 2014 session.

In 2013, after the CNN Sanjay Gupta documentary made them famous, the Stanley brothers began touring the US to visit with legislators to lobby for laws that allowed the sale of their “low-THC” marijuana that they market as “Charlotte’s Web.” This seemed to be an obvious compromise for lawmakers in states where the pro-marijuana lobby has been a constant presence. With the media practically declaring low-THC marijuana and CBD products a miracle cure-all, many people assume that the use of marijuana as a medicine is carefully regulated, dosed and researched. **THIS IS NOT THE CASE.**

➤ **No Randomized Controlled Clinical Trials**

The legislature must understand that no randomized, controlled clinical trials have been conducted to show that cannabidiol (CBD) preparations, low-THC, and other forms of marijuana that states have legalized are safe or effective for the treatment of any disease. None has been approved by FDA. The medical community refers to legalized CBD products as “artisanal CBD.” All of the evidence we have about artisanal CBD is anecdotal.

Who cannot feel compassion for our children that suffer from epilepsy and other diseases of the brain? While no one would deny their families any medicine that might help their children, without scientific evidence gained from randomized controlled trials we cannot know if low-THC or artisanal CBD is doing more harm than good. Dr. Amy Brooks-Kayal, a pediatric neurologist at the University of Colorado and president of the American Epilepsy Society, writes:

The families and children coming to Colorado are receiving unregulated, highly variable artisanal preparations of cannabis oil prescribed, in most cases, by physicians with no training in pediatrics, neurology, or epilepsy. As a result, the epilepsy specialists in Colorado have been at the bedside of children having severe dystonic reactions and other movement disorders, developmental regression, intractable vomiting, and worsening seizures that can be so severe they have to put the child into a coma to get the seizures to stop. Because these products are unregulated, it is impossible to know if these dangerous adverse reactions are due to the CBD or because of contaminants found in these artisanal preparations. The Colorado team has also seen families who have gone into significant debt, paying hundreds of dollars a month for oils that do not appear to work for the vast majority. For all these reasons not a single pediatric neurologist in Colorado recommends the use of artisanal cannabis preparations. Possibly of most concern is that some families are now opting out of proven treatments, such as surgery

or the ketogenic diet, or newer anti-seizure medications because they have put all their hope in CBD oils.ⁱ

➤ **Most Medical Marijuana States Do Not Test for Potency or Contaminants**

Few of the states that have legalized marijuana for medical use require that any marijuana products be tested for contaminants or potency. In 2015, a Denver lab tested 600 marijuana samples from across the state. It found that Colorado marijuana is twice as potent—in some cases three times more potent (from 18.7 percent THC to 30 percent THC on average)—than marijuana in other parts of the country. What the lab didn't find was surprising. Most CBD samples contained little to no CBD (average: less than 0.1 percent). Many samples contained large amounts of contaminants, including fungi and solvents such as butane. (Other reports from medical marijuana states in similar random tests are finding mildew, mold, pesticides, solvents, E coli, or salmonella in marijuana). The president of the Denver lab which conducted the tests said, "It's disturbing to me because there are people out there who think they're giving their kids Charlotte's Web. And you could be giving them no CBD — or even worse, you could be giving them a THC- rich product which might actually increase seizures."ⁱⁱⁱ

➤ **FDA Cracking Down on CBD Producers Making Unsubstantiated Medical Claims**

The Food and Drug Administration (FDA) has sent warning letters to several CBD producers who make unsubstantiated medical claims for their products on the Internet where they sell them. The FDA tested the products and, like the Denver lab, found that most contained only trace amounts of CBD.ⁱⁱⁱ

Moving beyond the serious flaw of determining medicine by legislation rather than expanding legitimate clinical trials, there are other concerns with HB 63.

➤ **HB 63 allows for edible marijuana infused products.**

How many other medicines are commercially infused into candies, cookies, “soft” drinks, cereals, chocolate bars, pies, cakes, sausages, beef jerky, ice cream bars, mac & cheese, peanut butter cups, and so on?

The proliferation of marijuana-infused foods in medical marijuana states is sending children who accidentally eat them and overdose to hospital emergency rooms. An article published in Clinical Pediatrics June 7, 2015, finds that the rate of such marijuana exposures among children younger than six increased by 147.5% in the U.S. between 2000 and 2013. Of even more concern, the rate increased nearly 610% in medical marijuana states. More than three- fourths of the children exposed were younger than age 3. Almost half of the children were managed at a health care facility. Of those, 29 percent were treated and released, 12 percent were admitted to a noncritical care unit, and 7 percent were admitted to a critical care unit. Common clinical effects seen were drowsiness or lethargy, ataxia [failure of muscle coordination], agitation or irritability, and confusion. Serious effects included coma, respiratory depression, and single or multiple seizures. All of the coma cases occurred in children ages 3 or younger.^{iv}

HB 63 does not limit the number of cultivation, processing, and retail facilities that will be allowed to exist in the state and it preempts local government’s ability to restrict.

- Other medical marijuana states have allowed a commercial industry to grow, process, and sell medical marijuana. Before medical marijuana was commercialized, Colorado had some 6,000 registered medical marijuana patients. With the onset of commercial dispensaries, in just one year the number of patients increased to 41,000 and grew to 115,467 by the end of 2014.^v There are 321 local jurisdictions (cities, towns, and counties) in Colorado and of those, only 88 allow medical marijuana production. **This means nearly 75% of the state's local jurisdictions have banned the production and sale of medical marijuana in their communities.** Florida's county and city governments should not be stripped of the ability to make decisions related to the public health and safety of their constituents.

- While HB 63 requires the use of a uniform insignia for advertising marijuana products and services, the state cannot regulate marketing. With commercialization comes product invention and marketing to increase consumption in order to increase profits. The Colorado Healthy Kids Survey looked at the lifetime use rates for the year 2013 (one year after Colorado legalized recreational marijuana but one year before the law was implemented). 40,000 students were surveyed and data were presented for school systems in each of 21 state regions. Nine of those divisions had a total of 168 medical marijuana dispensaries by the end of 2013 and high school students' lifetime marijuana use in those divisions ranged from a low of 21.3% to a high of 36.4%. The remaining divisions had a total of 327 medical dispensaries (almost double the amount). High school student marijuana use in those divisions ranged from 39.5% to 52.1%, demonstrating once again that availability drives use.^{vi}

Questions the Florida Legislature Should Consider.

1. Current and proposed law limits THC to .08%. How will Florida law enforcement officers be able to eradicate marijuana plants without having to test the THC content of each plant to determine which ones are legal under the new or proposed law? Is the state prepared to bear the cost of such testing?
2. What kind of security system will the state require to prevent the diversion of marijuana into the black market? Will it be a seed to sale tracking system and who will cover the cost? What state agency should administer the system?
3. What process will the state establish to require that all marijuana grown in Florida and products extracted from it will be tested for purity and potency? What will the process cost?
4. Will the state monitor labelling of low-THC products to ensure the labels accurately reflect purity and potency? What state agency will monitor product labels and at what cost?
5. Will the state repeal SB 1030 and potentially HB 63 when/if FDA approves Epidiolex or some other pharmaceutical-grade CBD or low-THC-based medication which doctors will be able to prescribe and pharmacies will be able to sell?
6. Who will be liable for potential FDA crackdowns on low-THC or CBD drugs the state produces or allows to be produced?
7. Who will be liable for paying the cost of treating the potential severe side effects of low-THC or CBD products? Will the state establish a fund to pay for such treatment?
8. Will the state provide adequate funding to public and private nonprofit agencies to deliver marijuana prevention services to prevent use from increasing?

Recommendations

We are deeply concerned about HB 63 and believe that current law should instead be amended in the following manner:

- **For children and adults with rare forms of epilepsy—replace low-THC marijuana with pharmaceutical-grade CBD (which contains less than 0.2 percent THC) and finance the expansion of Florida’s FDA expanded access program to serve these children who need CBD.**
- **For patients with the other diseases specified in the current law—replace low-THC marijuana with pharmaceutical-grade CBD and finance a research program to test whether it is safe and effective to treat any of those diseases. The Florida Surgeon General could oversee the program. Public and private research universities could implement the program with possible matching research funds from the National Institutes of Health.**
- **For patients who are terminally ill with one year or less to live—establish a committee of physicians who will timely review, on a case-by-case basis, whether to grant permission to doctors treating terminally ill patients to recommend pharmaceutical-grade CBD for them. Relief against lawsuits should be provided for the physicians in the approval process.**

ⁱ Letter from Amy Brooks-Kayal, MD President, American Epilepsy Society, Chief and Ponzio Family Chair, Children’s Hospital Colorado, Professor of Pediatrics and Neurology, University of Colorado School of Medicine, to Representative Matthew Baker, Chair, Pennsylvania House of Representatives Health Committee.
http://www.legis.state.pa.us/cfdocs/legis/TR/transcripts/2015_0040_0001_TSTMNY.pdf Accessed May 16, 2015.

ⁱⁱ Bill Briggs. “Colorado Marijuana Study Finds Legal Weed Contains Potent THC Levels.” NBC News, March 23, 20-15.
<http://www.nbcnews.com/storyline/legal-pot/legal-weed-surprisingly-strong-dirty-tests-find-n327811>
Accessed May 16, 2015.

ⁱⁱⁱ David Downs, FDA Warns Seven CBD and Hemp Oil Over Medical Claims, East Bay Express, March 6, 2015.
<http://www.eastbayexpress.com/LegalizationNation/archives/2015/03/06/fda-warns-seven-cbd-and-hemp-oil-companies-over-medical-claims>. Sample warning letter: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm436066.htm> Both websites accessed June 18, 2015.

^{iv} Bridget Onders, BS, Marcel J. Casavant, MD, Henry A. Spiller, MS, D.ABAT, Thiphalak Chounthirath, MS, and Gary A. Smith, MD, DrPH. Marijuana Exposure Among Children Younger Than Six Years in the United States. *Clinical Pediatrics*, June 7, 2015.
<http://cpj.sagepub.com/content/early/2015/06/03/0009922815589912.full>

^v The Legalization of Marijuana in Colorado, The Impact. Rocky Mountain High Intensity Drug Trafficking Area, pages 2-4.
<http://www.rmhidta.org/html/FINAL%20Legalization%20of%20MJ%20in%20Colorado%20The%20Impact.pdf>

^{vi} The More Medical Marijuana Dispensaries, the More Adolescent Users. The Marijuana Report Fact Sheets.
<http://themarijuanareport.org/fact-sheets/>