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Background Paper on Legalization of Marijuana for Medical Use Prepared for the Georgia Medical Cannabis Commission

As president and CEO of National Families in Action (NFIA), I attended the first hearing of the Georgia Medical Cannabis Commission. National Families in Action is a nonprofit drug prevention, education, and policy organization founded in Atlanta in 1977. A profile of NFIA is attached for your information.

[HB 1](#) charges you with developing recommendations for the regulation of a medical cannabis system in Georgia to include:

1. Reviewing the conditions, needs, issues, and problems of medical cannabis
2. Evaluating the best practices, experiences, and results of medical cannabis in other states
3. Recommending any proposed action or legislation you deem necessary, and determining which state department or departments should have oversight of such a system.

This Background Paper highlights key issues, poses questions based on other states' experiences, and offers several recommendations as the Commission works to achieve these charges.

1. Reviewing the conditions, needs, issues, and problems of medical cannabis

1a. No Randomized Controlled Clinical Trials

A physician's pledge is, "First, do no harm." Commissioners must understand that no randomized, controlled clinical trials have been conducted to show that cannabidiol (CBD) preparations and other forms of marijuana that states have legalized are safe or effective for the treatment of any disease. None have 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 Georgia children who 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 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 [full text of her letter is attached]:

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 antiseizure medications because they have put all their hope in CBD oils.¹

1b. 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. Colorado requires such testing for recreational but *not medical* marijuana (the legislature changed that recently but implementation has not yet begun). A few months ago, 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 cannabidiol 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). Said Andy LaFrate, president of the Denver lab which conducted the test, "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."² ("Legalized" CBD oils like Charlotte's Web, none of which have been approved as safe or effective by FDA, are what the children referred to in Dr. Brooks-Kayal's letter were taking).

1c. FDA Cracking Down on CBD Producers Making Unsubstantiated Medical Claims

FDA has sent warning letters to several CBD producers who make unsubstantiated medical claims for their products on the Internet where they sell them. FDA tested the products and, like the Denver lab, found that most *contained only trace amounts of CBD*.³

1d. Five percent THC Makes People High

Jesse Stanley of the Stanley Brothers, who make Charlotte's Web oil, misinformed members of the Georgia House Judiciary Non-Civil Committee at the hearing it held on HB 1 last winter. He described Charlotte's Web as being "low" in THC and "high" in CBD, explaining that five percent THC is so minimal it will not make people high.⁴ He is quite wrong. Americans were getting high on marijuana with less than five percent THC in the 1960s, 1970s, 1980s, and 1990s. Street marijuana did not reach five percent THC until 1997. In 1998, THC content dropped below that but rose to five percent again in 2001 and has steadily increased since then, according to the Marijuana Potency Monitoring Project.⁵

1e. Marijuana Edibles Are Hurting Children

At the first Commission meeting, Mike Liszewski of [Americans for Safe Access](#) claimed that marijuana must be infused into foods for patients to consume their "medicine." This raises an interesting question: how many other medicines must be 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 percent in the United States between 2000 and 2013. During that time, 1,969 children were so exposed. Of even more concern, *the rate increased nearly 610 percent in medical marijuana states*. More than three-fourths of the children exposed were younger than age 3 (average age 1^{1/2}). The data come from the National Poison Data System, a database maintained and continuously updated by poison control centers across the US. 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 the coma cases occurred in children ages 3 or younger.⁶

1f. Pharmaceutical CBD Products in FDA Clinical Trials vs Artisanal CBD

Two pharmaceutical companies, GW Pharmaceuticals in Great Britain and Insys Therapeutics in the US, have developed pharmaceutical-grade CBD products that are now being (GW) or are about to be (Insys) tested in FDA clinical trials. The Insys candidate is synthesized CBD and the GW candidate, Epidiolex, is CBD that the company extracts from marijuana and purifies. Epidiolex contains 98 percent CBD and only trace amounts of THC and other cannabinoids. This is important because THC can induce seizures, the very problem parents of children with epilepsy are seeking to reduce or end. THC also damages the developing brain in a number of other ways. Because Insys Therapeutics has not yet begun clinical trials, less is known about its CBD candidate. Thus, the choice for families and patients with other diseases permitted by HB1 boils down to the following:

Pharmaceutical CBD	Artisanal CBD
Pharmaceutical CBD (Epidiolex) ⁷ <ul style="list-style-type: none"> • 98 percent CBD • Trace amounts of THC • Tested in animals for five years 	Artisanal CBD that states have legalized (like Charlotte's Web Oil) <ul style="list-style-type: none"> • From 15 percent to 30 percent CBD • 5 percent THC • Never tested in animals
Pharmaceutical CBD (Insys Therapeutics CBD candidate) <ul style="list-style-type: none"> • Synthesized CBD • Not yet in clinical trials • Tested in animals 	

When a new drug has shown in animal testing that it is safe to test in humans, its maker can apply to FDA for an Investigational New Drug application (IND) to test it in humans. Once this step is taken, FDA can grant [expanded access](#) to the experimental drug for patients who are critically ill but for whom no other medications work while the drug is undergoing clinical trials. Last year, Governor Deal announced that Georgia Regent's University (GRU) would apply to FDA for a statewide expanded access program to provide Epidiolex to children with epilepsy.

Commissioner Yong D. Park is in charge of that program at GRU and can provide more information about it to the Commission.

1g. What is a medical marijuana doctor?

Advocates recommend that patients consult a “medical marijuana doctor” who is knowledgeable about “cannabis therapy.” We are unaware of any US medical school that offers training in “cannabis therapy” or any state that certifies “medical marijuana” physicians. Nonetheless, a group titled [MDHerb](#) announced this month that it is available to Georgians to:

provide educational content about cannabis to the everyday general consumer. Our content comes directly from the top RN's and MD's in the industry, and we strive to help provide you with resources to help you find the proper medication for your ailments. We here at MDHerb have created an organization that we believe fulfills the promise of medical cannabis information on the Internet.

MDHerb's chief medical liaison is a chiropractor, and the organization provides information from [Leafly](#) about which marijuana strains allegedly cure what illnesses. Leafly promotes itself as the world's largest cannabis strain resource. It ranks more than 1,000 marijuana strains for their alleged effects based on user reviews rather than scientific studies. It also publishes maps showing the locations of thousands of dispensaries in medical marijuana states.

Another Internet organization, [MD-Marijuana Doctors](#) invites Georgians to “Find a Marijuana Doctor on the #1 Medical Marijuana Portal. GEORGIA Patients: Complete the form at right to find a certified physician near you.” As we write this, an email press release announces yet a third group of medical marijuana doctors: “First Medical Cannabis Clinic in Georgia Receives Patients From Marijuana Doctor Network.” The clinic, [Aerete Integrative Medicine of Atlanta](#), is located in Cobb County. For \$225 and access to their medical records, Aerete's staff of “Board Certified physicians” will help qualifying patients obtain a Low THC Registry Card from the Georgia Department of Public Health, something patients are perfectly capable of doing themselves on the Internet for a fee of \$25. Aerete is a member of MD-Marijuana Doctors. At the bottom of its webpage is a list of “Our Marijuana Partners.” One is “Medical Marijuana Dispensaries.” The other partner is “Marijuana Legalization Petition.”

1h. Is marijuana about medicine or money?

HB1's sponsor, Representative Allen Peake, told the committee hearing his bill that two Colorado CBD producers stood ready to ship the product directly to Georgia patients if HB1 passed. He later identified one supplier as the Stanley Brothers, who produce Charlotte's Web Oil. The Stanley Brothers recently created a new company and website, [CW Botanicals](#), to market their products. Their nonprofit organization, [Realm of Caring](#), provides information and discounts on Charlotte's Web products for registered patients. [Novus Acquisition & Development Corp. \(OTC PINK: NDEV\)](#), through its “wholly-owned subsidiary, Novus Medical Group,” announced recently that it has signed an agreement with Realm of Caring to provide a 64 percent discount on Charlotte's Web advanced products and a 30 percent discount on Charlotte's Web consumer products. To qualify for a discount, patients join Novus Medical Group for \$20 a month. CW Botanicals' pricing structure has fluctuated quite a bit. Initially, it listed the retail price of its advanced products at \$995.00 per 3.34 ounce bottle. A few months later, the company announced a sale price for these products of \$695.00. The sale price has now become the retail price.

The CW Botanicals website also lists several partners in Colorado and other states where patients may purchase Charlotte's Web Oil products. The street addresses of some of the partners are difficult to find on Google Maps. They appear to be virtual shops with phantom addresses that operate exclusively as Internet websites. All of this virtual marketing activity for unnecessary and perhaps fraudulent medical services as well as virtual sales of Charlotte's Web Oil are being generated for a drug that FDA has not approved and is illegal under the federal Controlled Substances Act.

2. Evaluating the Best Practices, Experiences, and Results of Medical Cannabis in Other States

2a. Advocacy vs Reality

Despite the fact that states have legalized marijuana to treat a total of more than 250 different diseases and/or conditions, in practice very few patients actually obtain marijuana to treat most of them. In the medical marijuana states that collect data, only one to two percent on average obtain marijuana for HIV/AIDS, chemotherapy-related nausea, glaucoma, and other serious diseases and conditions. Most patients are in their 30s and 40s, the majority are males, and in most states 90 percent or more obtain marijuana for chronic pain. Colorado is typical. As of year-end 2014, 115,467 patients possessed valid medical marijuana cards. Some 65 percent were males, average age 41. The percent of patients who obtained marijuana for various diseases are: (note, does not add up to 100 percent because some patients listed more than one debilitating condition.)⁸

- Cachexia, 1 percent
- Cancer, 3 percent
- Glaucoma, 1 percent
- HIV/AIDS, 1 percent
- Muscle Spasms, 15 percent
- Seizures, 2 percent
- Severe pain, 93 percent
- Severe Nausea, 10 percent

Other states report similar statistics: 90 percent or more patients obtain medical marijuana for severe or chronic pain.

2b. A Commercial Medical Marijuana Industry Increases Marijuana Use among Children

Like Colorado, other medical marijuana states have allowed a commercial industry to grow, process, and sell medical marijuana. With commercialization comes product invention and marketing to increase consumption in order to increase profits. Again, Colorado is a good example. That state legalized marijuana for medical use in 2000. Patients could designate a "caregiver" to grow up to six plants for his or her use and each caregiver could grow marijuana for up to five or six patients. However, most caregivers grew considerably more than their allotted amounts, which created a huge black market. To remedy that, the legislature legalized commercial growing, processing, and sales in 2008. 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 patients by the end of 2014.⁹ (A total of 283,587 new patient applications have been received by the state since 2001 when the registry began.)

The Colorado Department of Revenue is responsible for all marijuana regulation. There are 321 local jurisdictions (cities, towns, and counties) in Colorado. Of these, 67 allow both medical and recreational production and sales; 21 more allow medical only. This means nearly 75 percent—233—of the state’s local jurisdictions have banned the production and sale of medical marijuana in their communities. The Department’s 2014 year-end report finds there were 1,416 medical marijuana businesses licensed in the 88 jurisdictions that allow marijuana. These licensees sold 109,578 pounds of medical marijuana flowers and 1,964,917 units of medical marijuana edible products (“medibles”) in 2014.¹⁰

2c. Availability Drives Use among Children

National Families in Action analyzed Colorado’s first survey of high school students, which the state conducted in 2013—one year after Colorado legalized recreational marijuana but one year before full legalization was implemented. The survey is an offshoot of the Centers for Disease Control’s Youth Behavior Risk Survey (YRBS). Some 40,000 students were surveyed, and data was presented for school systems in each of 21 state divisions. 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 percent to a high of 36.4 percent. The remaining divisions had a total of 327 medical dispensaries. High school student marijuana use in those divisions ranged from 39.5 percent to 52.1 percent demonstrating once again that availability drives use.¹¹ (Chart attached).

2d. Doctors and Scientists Are Dismayed at States’ Legalizing Marijuana for Medical Use

Just a few weeks ago, the *Journal of the American Medical Association* (JAMA) published a systematic review and meta-analysis of 79 studies,¹² as well as an editorial,¹³ suggesting that states legalizing marijuana for medical use have the cart before the horse. The meta-analysis finds that there is little to no evidence to support medical marijuana use for most of the diseases and conditions states are permitting. Furthermore, adverse effects, both short-term and long-term, can be significant.

The editorial discusses why state action is premature and concludes:

If the goal is to make marijuana available for medical purposes, then it is unclear why the approval process should be different from that used for other medications. Evidence justifying marijuana use for various medical conditions will require the conduct of adequately powered, double-blind, randomized, placebo/active controlled clinical trials to test its short- and long-term efficacy and safety. The federal government and states should support medical marijuana research. Since medical marijuana is not a life-saving intervention, it may be prudent to wait before widely adopting its use until high-quality evidence is available to guide the development of a rational approval process. Perhaps it is time to place the horse back in front of the cart.

A research letter in the same issue reports that of 75 edible medical marijuana products (47 different brands), only 17 percent were accurately labeled. Some overstated, others understated THC content, while four products were over labeled and nine were under labeled for CBD.¹⁴

It is notable that as a result of the findings published in this issue of JAMA, *The Denver Post* editorial board recommended that Colorado should consider repealing its medical marijuana law.¹⁵

The American Medical Association (AMA) has opposed legalizing marijuana for medical use for many years due to the lack of evidence to support such action. In addition to AMA, the following medical associations also oppose legalizing marijuana or any of its components for medical use before FDA-quality evidence is available:

American Epilepsy Society

“The recent anecdotal reports of positive effects of the marijuana derivative cannabidiol for some individuals with treatment-resistant epilepsy give reason for hope. However, we must remember that these are only anecdotal reports, and robust scientific evidence for the use of marijuana is lacking. The lack of information does not mean that marijuana is ineffective for epilepsy. It merely means that we do not know if marijuana is a safe and effective treatment for epilepsy, which is why it should be studied using the well-founded research methods that all other effective treatments for epilepsy have undergone. Such safety concerns coupled with a lack of evidence of efficacy in controlled studies result in a risk/benefit ratio that does not support use of marijuana for treatment of seizures at this time.”¹⁶

American Society of Addiction Medicine

“ASAM asserts that cannabis, cannabis-based products and cannabis delivery devices should be subject to the same standards that are applicable to other prescription medications and medical devices, and that these products should not be distributed or otherwise provided to patients unless and until such products or devices have received marketing approval from the Food and Drug Administration. ASAM rejects smoking as a means of drug delivery since it is not safe. ASAM rejects a process whereby State and local ballot initiatives approve medicines because these initiatives are being decided by individuals not qualified to make such decisions.”

American Cancer Society

“The ACS is supportive of more research into the benefits of cannabinoids. Better and more effective treatments are needed to overcome the side effects of cancer and its treatment. The ACS does not advocate the use of inhaled marijuana or the legalization of marijuana.”

American Glaucoma Foundation

“Marijuana, or its components administered systemically, cannot be recommended without a long term trial which evaluates the health of the optic nerve. Although marijuana can lower IOP, its 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.”

National Multiple Sclerosis Society

“Although it is clear that cannabinoids have potential both for the management of MS symptoms, such as pain and spasticity, as well as for neuroprotection, the Society cannot at this time recommend that medical marijuana be made widely available to people with MS for symptom management. This decision was not only based on existing legal barriers to its use but, even more importantly, because studies to date do not demonstrate a clear benefit compared to existing symptomatic therapies and because issues of side effects, systemic effects, and long-term effects are not yet clear.”

The American Academy of Pediatrics (AAP)

believes that “[a]ny change in the legal status of marijuana, even if limited to adults, could affect the prevalence of use among adolescents.” While it supports scientific research on the possible medical use of cannabinoids as opposed to smoked marijuana, it opposes the legalization of marijuana.”¹⁷

National Eye Institute, National Institutes of Health

"In an effort to determine whether marijuana, or drugs derived from marijuana, might be effective as a glaucoma treatment, the National Eye Institute (NEI) supported research studies beginning in 1978... However, none of these studies demonstrated that marijuana -- or any of its components -- could lower IOP [intraocular pressure] as effectively as drugs already on the market. In addition, some potentially serious side effects were noted, including an increased heart rate and a decrease in blood pressure in studies using smoked marijuana. . . . The identification of side effects from smoked marijuana, coupled with the emergence of highly effective FDA-approved medications for glaucoma treatment, may have led to diminished interest in this research area.”¹⁸

American Psychiatric Association

Contribution of Marijuana to Psychiatric Illness--There is currently no scientific evidence to support the use of marijuana as an effective treatment for any psychiatric illness. Several studies have shown that cannabis use may in fact exacerbate or hasten the onset of psychiatric illnesses, as evidenced by both international trials and meta-analyses. This includes the contribution of marijuana to symptoms of mood disorders, anxiety and psychosis, particularly in young adulthood. Cannabis use is associated with the emergence of mood disorders, particularly symptoms of bipolar disorder, among those with a family history of mood disorder. Among those with major depressive disorder, co-morbid cannabis use is associated with increased rates of both suicidal ideation and attempts, raising grave safety concerns. Among those with a predisposition to psychotic disorders, cannabis may hasten the emergence of both positive and negative psychotic symptoms. The use of higher potency cannabis, for longer periods of time and with more frequency, is also associated with increased risk of psychosis. Several studies have demonstrated the link between marijuana use and mood, anxiety and psychotic disorders among adolescents. Cannabis use is associated with increased depression, suicidal ideation, use of other substances and risky behavior among adolescents. Regular adolescent cannabis use is also associated with increased incidence of anxiety disorders. Cannabis use significantly increases the risk of psychotic disorders among young adults. Additionally, younger age of cannabis use is associated with an earlier onset of psychosis among those at risk. Adolescents with a history of cannabis use tend to have higher severity of illness, lower psychosocial functioning, less insight, and longer courses of untreated psychosis compared to those without a history of cannabis use. These findings are of particular concern as symptoms often persist into adulthood, and therefore cannabis use may increase the risk of lifelong symptoms and disability due to mental illness.

Serious Adverse Effects of Marijuana Use: Cognitive and Functional--Marijuana use is associated with serious cognitive problems such as short-term memory deficits, poor concentration, attention, and information processing. These impairments might be

caused by neurotoxic effects of cannabis on the developing brain, the effects of which can lead to long-term cognitive problems well into adulthood. Adolescents with daily cannabis use show deficits in learning up to six weeks after stopping marijuana use. This may contribute to significantly decreased academic achievement, including increased rates of school dropout, failure to enter higher education or attain higher degrees. Among both adolescents and adults, cannabis significantly impairs driving, particularly as the drug affects automatic driving functions in a highly dose-dependent fashion. Cannabis use, particularly in combination with alcohol, greatly increases the risk of motor vehicle crashes due to effects on cognition and coordination.

Addiction and burden of psychiatric illness--Cannabis use is associated with an increased risk of developing a cannabis use disorder. Studies indicate that 9% of users become dependent on cannabis, and this number increases to 25-50% among daily users and to 1 in 6 among adolescents. Adolescents remain at particular risk for cannabis use disorder, and can experience significant withdrawal symptoms including appetite changes, restlessness, irritability, depression, twitches and shakes, perspiration, and thoughts/cravings of cannabis. Marijuana use is also associated with poorer outcomes among those with mental illness. Among individuals with schizophrenia, cannabis use is associated with poorer long-term clinical outcomes. Individuals with psychotic illness may be more sensitive to both the psychosis-inducing and mood-altering effects of cannabis. This may explain why even among those taking medications for psychotic disorders, cannabis use is associated with an increased risk of relapse into psychotic symptoms. Legalization of medical marijuana may reduce the perceived risks of use, the perception of societal disapproval, or the barriers to access, and potentially increase the incidence of the adverse events noted above.

Summary--Given the gravity of concerns regarding marijuana as medicine, professionals in both neurology and psychiatry have emphasized the importance of prospective studies to understand the mechanisms by which cannabis functions, and its impact on mental health and behavior before instituting changes in practice and policy.¹⁹

We quote most of the APA statement because it clearly delineates the harms of marijuana, especially to children. Desperately ill children, such as those suffering from devastating forms of epilepsy, are even more vulnerable to those harms, as the American Epilepsy Society's president, Dr. Brooks-Kayal, so eloquently describes in her letter (attached). We believe that the Commission has a responsibility to protect such children by ensuring that they are given purified pharmaceutical CBD that has been tested in animals to ensure it is safe to administer to humans and is in FDA clinical trials to further test its safety and efficacy.

2e. Questions Georgia Medical Marijuana Commission Members Might Want to Consider

Here are some questions for Commissioners to consider. The questions are based on experiences of current medical marijuana states:

1. How will the state prevent marijuana grown in Georgia from entering the black market as it has in other medical marijuana states?
2. The Colorado producers of Charlotte's Web Oil have rebranded their products as hemp extracts. Congress legally defined hemp in Section 7606 of the farm bill last year as

marijuana that contains no more than 0.3% THC. Georgia might decide to legalize hemp to produce the oil rather than marijuana. If so, how will Georgia law enforcement officers be able to eradicate a field of marijuana plants without having to test the THC content of each plant to determine which ones are marijuana and which ones are hemp? Is the state prepared to bear the cost of doing such testing?

3. What kind of security system will the state establish to prevent the diversion of marijuana into the black market? What will such a system cost? Will the state provide adequate funding for such a system? What state agency should administer such a system?
4. What process will the state establish to require that all marijuana/hemp grown in Georgia and all products extracted from it will be tested for purity and potency according to FDA protocols? What will such a process cost? Will the state cover such costs?
5. Will the state monitor labeling of CBD products to ensure the labels accurately reflect purity and potency? What state agency will monitor product labels?
6. Will the state add more illnesses in the future to those specified in HB1 that qualify for CBD use? If yes, on what basis?
7. Will the state allow more medical marijuana products than CBD products alone to be produced? (Such products include medical marijuana strains, vaping products, edible products, THC concentrates, butane hash oils, and others). If so, what restrictions should be placed on allowable THC levels in such products?
8. Will the state allow CBD and perhaps other marijuana products to be advertised? If so, will any restrictions on advertising be made, similar to restrictions on alcohol and tobacco advertising to protect children?
9. Will the state repeal HB1 when/if FDA approves Epidiolex or some other pharmaceutical-grade CBD oil which doctors will be able to prescribe and pharmacies will be able to sell?
10. Who will be liable for potential FDA crackdowns on CBD drugs the state produces or allows to be produced?
11. HB1 allows patients and their families to possess up to 20 ounces of oil containing a minimum of five percent CBD and up to five percent THC. Because THC can *cause* seizures, will the state reduce allowable THC levels to only trace amounts for children with intractable seizures?
12. Who will be liable for paying the cost of treating the severe side effects of CBD oils such as those described by Dr. Brooks-Kayal? Will the state establish a fund to pay for such treatment?
13. Will the state mandate that the only doctors who can recommend medical marijuana to patients suffering from the diseases specified in HB1 must be trained as specialists to treat those diseases?

14. Will the state prevent THC poisonings among young children by banning CBD/marijuana edibles?
15. Will the state require data collection, including the number of patients who hold Low THC Registry Cards and the diseases for which they seek medical marijuana? Will that and other data be publicly accessible as it is in most other medical marijuana states?
16. Will state agencies produce CBD oil and make it available to patients at cost in order to prevent the emergence of a commercial medical marijuana industry?
17. Will the state provide adequate funding to public and private nonprofit agencies to deliver marijuana prevention services to prevent use from increasing and marijuana treatment services to those who become addicted?

3. Recommending Any Proposed Action or Legislation You Deem Necessary Determining Which State Department or Departments Should Have Oversight of Such a System

There is evidence that artisanal CBD products which states have legalized but FDA has not approved are harming severely ill children.

There is ample evidence that medical marijuana products are harming healthy children when a commercial marijuana industry emerges to target children in order to increase consumption, as the tobacco and alcohol industries do.

There is incontrovertible evidence that children's marijuana use has doubled as their perception that marijuana is harmful has been cut in half since 1991 when advocates first began pushing for marijuana to be legalized for medical use.²⁰

We believe the Commission must consider the needs of *all* of Georgia's children to protect the health of those who are severely ill as well as the health of those who are not.

The medical community nearly universally condemns legalizing marijuana for medical use until there is evidence to justify such action.

An experimental CBD drug, Epidiolex, is in FDA clinical trials. It is available to Georgia children who are participating in clinical trials, as well as to those who don't qualify for clinical trials, through Governor Deal's statewide FDA expanded access program being implemented by Georgia Regents University.

3a. Recommendations

For all of these reasons, because you are empowered to "recommend any legislation you deem necessary," we believe the Commission should recommend that HB1 be modified in the following manner:

- ***For children and adults with rare forms of epilepsy—replace artisanal CBD (which can contain 5 percent THC according to HB1) with pharmaceutical-grade CBD***

(which contains less than 0.2 percent THC) and finance the expansion of Georgia’s FDA expanded access program to serve all children who need CBD. Georgia Regional University to oversee.

- ***For patients with the seven other diseases specified in HB1—replace artisanal CBD with pharmaceutical-grade CBD and finance a research program to test whether it is safe and effective to treat any of those diseases. Georgia Composite Medical Board to oversee, public and private research universities to implement 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 would be provided for the physicians in the approval process.***

4. Addendum

One source for further information is a website National Families in Action produces called [The Marijuana Report.Org](http://TheMarijuanaReport.Org). The Treatment Research Institute and Smart Approaches to Marijuana are partners in this effort. The website tracks the marijuana story that is unfolding across the nation. From 20 to 30 stories in the print, broadcast, and electronic media are summarized and posted to the website daily. The summaries include a link to the full text of each article. Summaries are filed under more than 50 categories; clicking on any category brings up all stories filed under that category. Medical marijuana stories are filed by state. The website can help Commissioners track what is going on in medical marijuana states. We also publish a weekly newsletter that is e-mailed to some 9,000 subscribers. Commissioners who wish to subscribe can do so [here](#). Both resources will keep you up to date on the pros and cons of medical and recreational marijuana legalization.

5. References

¹ 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.

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³ 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.

⁴ Georgia House of Representatives, Judiciary Non-Civil Committee Hearing on HB 1, February 3, 2015. <http://www.house.ga.gov/Committees/en-US/CommitteeArchives146.aspx> Accessed June 10, 2015

⁵ White House Office of National Drug Control Policy, Marijuana Facts, page 2. https://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/marijuana_fact_sheet_jw_10-5-10.pdf. Accessed May 10, 2105.

⁶ 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>

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- ²⁰ The annual [Monitoring the Future Survey](#) shows that past-month marijuana use increased from 3.2 percent in 1991 to 6.5 percent in 2014 among 8th grade students, from 8.7 percent to 16.6 percent among 10th grade students, and from 13.8 percent to 21.2 percent among 12th grade students. At the same time, the perception that regular marijuana use is harmful decreased among 8th grade students from 83.8 percent in 1991 to 58.9 percent in 2014, among 10th grade students from 82.1 percent to 45.4 percent, and among 12th grade students from 78.6 percent to 36.1 percent.